State Operations Manual

Appendix PP - Guidance to Surveyors for Long Term Care Facilities

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(Rev. 15, 11-25-05)

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(Rev. 5, Issued 11-19-04, Effective: 11-19-04, Implementation: 11-19-2004)

§483.5 Definitions

(a) Facility defined. For purposes of this subpart "facility" means, a skilled nursing facility (SNF) or a nursing facility (NF) which meets the requirements of §§1819 or 1919(a), (b), (c), and (d) of the Social Security Act, the Act. "Facility" may include a distinct part of an institution specified in §440.40 of this chapter, but does not include an institution for the mentally retarded or persons with related conditions described in §440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the "facility" is always the entity which participates in the program, whether that entity is comprised of all of, or a distinct part of a larger institution. For Medicare, a SNF (see §1819(a)(1)), and for Medicaid, a NF (see §1919(a)(1)) may not be an institution for mental diseases as defined in §435.1009.

Interpretive Guidelines §483.5

The following are the statutory definitions at §§1819(a) and 1919(a) of the Act for a SNF and a NF:

"Skilled nursing facility" is defined as an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases; has in effect a transfer agreement (meeting the requirements of §1861(1)) with one or more hospitals having agreements in effect under §1866; and meets the requirements for a SNF described in subsections (b), (c), and (d) of this section.

"Nursing facility" is defined as an institution (or a distinct part of an institution) which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, rehabilitation services for the rehabilitation of injured, disabled, or sick persons, or on a regular basis, health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, and is not primarily for the care and treatment of mental diseases; has in effect a transfer agreement (meeting the requirements of §1861(1)) with one or more hospitals having agreements in effect under §1866; and meets the requirements for a NF described in subsections (b), (c), and (d) of this section.

If a provider does not meet one of these definitions, it cannot be certified for participation in the Medicare and/or Medicaid programs.

NOTE: If the survey team finds substandard care in §§483.13, 483.15, or 483.25, follow the instructions for partial extended or extended surveys.

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§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights

Interpretive Guidelines §483.10

All residents in long term care facilities have rights guaranteed to them under Federal and State law. Requirements concerning resident rights are specified in §§483.10, 483.12, 483.13, and 483.15. Section 483.10 is intended to lay the foundation for the remaining resident's rights requirements which cover more specific areas. These rights include the resident's right to:

- Exercise his or her rights (§483.10(a));
- Be informed about what rights and responsibilities he or she has (§483.10(b));
- If he or she wishes, have the facility manage his personal funds (§483.10(c));
- Choose a physician and treatment and participate in decisions and care planning (§483.10(d));
- Privacy and confidentiality (§483.10(e));

- Voice grievances and have the facility respond to those grievances (§483.10(f));
- Examine survey results (§483.10(g));
- Work or not work (§483.10(h));
- Privacy in sending and receiving mail (§483.10(i));
- Visit and be visited by others from outside the facility (§483.10(j));
- Use a telephone in privacy (§483.10(k));
- Retain and use personal possessions (§483.10(1)) to the maximum extent that space and safety permit;
- Share a room with a spouse, if that is mutually agreeable (§483.10(m));
- Self-administer medication, if the interdisciplinary care planning team determines it is safe (§483.10(n)); and
- Refuse a transfer from a distinct part, within the institution (§483.10(o)).

A facility must promote the exercise of rights for each resident, including any who face barriers (such as communication problems, hearing problems and cognition limits) in the exercise of these rights. A resident, even though determined to be incompetent, should be able to assert these rights based on his or her degree of capability.

F151

§483.10(a) Exercise of Rights

§483.10(a)(1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

§483.10(a)(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

Interpretive Guidelines §483.10(a)(1)

Exercising rights means that residents have autonomy and choice, to the maximum extent possible, about how they wish to live their everyday lives and receive care, subject to the facility's rules, as long as those rules do not violate a regulatory requirement.

Intent §483.10(a)(2)

This regulation is intended to protect each resident in the exercise of his or her rights.

Interpretive Guidelines §483.10(a)(2)

The facility must not hamper, compel, treat differentially, or retaliate against a resident for exercising his/her rights. Facility behaviors designed to support and encourage resident participation in meeting care planning goals as documented in the resident assessment and care plan are not interference or coercion.

Examples of facility practices that may limit autonomy or choice in exercising rights include reducing the group activity time of a resident trying to organize a residents' group; requiring residents to seek prior approval to distribute information about the facility; discouraging a resident from hanging a religious ornament above his or her bed; singling out residents for prejudicial treatment such as isolating residents in activities; or purposefully assigning inexperienced aides to a resident with heavy care needs because the resident and/or his/her representative, exercised his/her rights.

Procedures §483.10(a)(2)

Pay close attention to resident or staff remarks and staff behavior that may represent deliberate actions to promote or to limit a resident's autonomy or choice, particularly in ways that affect independent functioning. Because reprisals may indicate abuse, if the team determines that a facility has violated this requirement through reprisals taken against residents, then further determine if the facility has an effective system to prevent the neglect and abuse of residents. (§483.13(c), F224-F225.)

F152

§483.10(a)(3) -- In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

§483.10(a)(4) -- In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

Interpretive Guidelines §483.10(a)(3) and (4)

When reference is made to "resident" in the Guidelines, it also refers to any person who may, under State law, act on the resident's behalf when the resident is unable to act for himself or herself. That person is referred to as the resident's surrogate or representative. If the resident has been formally declared incompetent by a court, the surrogate or representative is whoever was appointed by the court - a guardian, conservator, or

committee. The facility should verify that a surrogate or representative has the necessary authority. For example, a court-appointed conservator might have the power to make financial decisions, but not health care decisions.

A resident may wish to delegate decision-making to specific persons, or the resident and family may have agreed among themselves on a decision-making process. To the degree permitted by State law, and to the maximum extent practicable, the facility must respect the resident's wishes and follow that process.

The rights of the resident that may be exercised by the surrogate or representative include the right to make health care decisions. However, the facility may seek a health care decision (or any other decision or authorization) from a surrogate or representative only when the resident is unable to make the decision. If there is a question as to whether the resident is able to make a health care decision, staff should discuss the matter with the resident at a suitable time and judge how well the resident understands the information. In the case of a resident who has been formally declared incompetent by a court, lack of capacity is presumed. Notwithstanding the above, if such a resident can understand the situation and express a preference, the resident should be informed and his/her wishes respected to the degree practicable. Any violations with respect to the resident's exercise of rights should be cited under the applicable tag number.

The involvement of a surrogate or representative does not automatically relieve a facility of its duty to protect and promote the resident's interests. For example, a surrogate or representative does not have the right to insist that a treatment be performed that is not medically appropriate, and the right of a surrogate or representative to reject treatment may be subject to State law limits.

Procedures §483.10(a)(3) and (4)

Determine as appropriate if the rights of a resident who has been adjudged incompetent or who has a representative acting on his/her behalf to help exercise his/her rights are exercised by the legally appointed individual.

F153

§483.10(b)(2) -- The resident or his or her legal representative has the right--

> **(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and**
>
> **(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.**

Interpretive Guidelines §483.10(b)(2)

An oral request is sufficient to produce the current record for review.

In addition to clinical records, the term "records" includes all records pertaining to the resident, such as trust fund ledgers pertinent to the resident and contracts between the resident and the facility.

"Purchase" is defined as a charge to the resident for photocopying. If State statute has defined the "community standard" rate, facilities should follow that rate. In the absence of State statute, the "cost not to exceed the community standard" is that rate charged per copy by organizations such as the public library, the Post Office or a commercial copy center, which would be selected by a prudent buyer in addition to the cost of the clerical time needed to photocopy the records. Additional fees for locating the records or typing forms/envelopes may not be assessed.

F154

(Rev. 5, Issued 11-19-04, Effective: 11-19-04, Implementation: 11-19-2004)

§483.10(b)(3) -- The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

Interpretive Guidelines §483.10(b)(3)

"Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand. This includes minimizing use of technical jargon in communicating with the resident, having the ability to communicate in a foreign language and the use of sign language or other aids, as necessary. (See §483.10(d)(3), F175, for the right of the resident to plan care and treatment.)

Procedures §483.10(b)(3)

Look, particularly during observations and record reviews, for on-going efforts on the part of facility staff to keep residents informed. Look for evidence that information is communicated in a manner that is understandable to residents and communicated at times it could be most useful to residents, such as when they are expressing concerns, or raising questions, as well as on an on-going basis.

§483.10(d)(2) – The resident has the right to be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being;

Interpretive Guidelines §483.10(d)(2)

"Informed in advance" means that the resident receives information necessary to make a health care decision, including information about his/her medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives.

F155

§483.10(b)(4) -- The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

Interpretive Guidelines §483.10(b)(4)

"Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

"Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy, that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

"Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law relating to the provision of health care when the individual is incapacitated.

As provided under State law, a resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

A facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are met. (See §483.12(a)(1) and (2).)

If the resident is unable to make a health care decision, a decision by the resident's surrogate or representative to forego treatment may, subject to State law, be equally binding on the facility. The facility should determine exactly what the resident is refusing and why. To the extent the facility is able, it should address the resident's concern. For example, a resident requires physical therapy to learn to walk again after sustaining a fractured hip. The resident refuses therapy. The facility is expected to assess the reasons for this resident's refusal, clarify and educate the resident as to the

consequences of refusal, offer alternative treatments, and continue to provide all other services.

If a resident's refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident's refusal of treatment does not absolve a facility from providing a resident with care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being in the context of making that refusal.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining residents' permission.

Procedures §483.10(b)(4)

If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? In this regard, §483.75(c), Relationship to Other HHS Regulations applies (i.e., the facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research).

See §483.10(b)(8), F156 with respect to the advance directive requirement.

F156

(Rev. 5, Issued 11-19-04, Effective: 11-19-04, Implementation: 11-19-2004)

§483.10(b)(1) -- The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under §1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

Intent §483.10(b)(1)

This requirement is intended to assure that each resident know his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, as appropriate during the resident's stay, and when the facility's rules change.

Interpretive Guidelines §483.10(b)(1)

"In a language that the resident understands" is defined as communication of information concerning rights and responsibilities that is clear and understandable to each resident, to the extent possible considering impediments which may be created by the resident's health and mental status. If the resident's knowledge of English or the predominant language of the facility is inadequate for comprehension, a means to communicate the information concerning rights and responsibilities in a language familiar to the resident must be available and implemented. For foreign languages commonly encountered in the facility locale, the facility should have written translations of its statements of rights and responsibilities, and should make the services of an interpreter available. In the case of less commonly encountered foreign languages, however, a representative of the resident may sign that he or she has explained the statement of rights to the resident prior to his/her acknowledgement of receipt. For hearing impaired residents who communicate by signing, the facility is expected to provide an interpreter. Large print texts of the facility's statement of resident rights and responsibilities should also be available.

"Both orally and in writing" means if a resident can read and understand written materials without assistance, an oral summary, along with the written document, is acceptable.

Any time State or Federal laws relating to resident rights or facility rules change during the resident's stay in the facility, he/she must promptly be informed of these changes.

"All rules and regulations" relates to facility policies governing resident conduct. A facility cannot reasonably expect a resident to abide by rules he or she has never been told about. Whatever rules the facility has formalized, and by which it expects residents to abide, should be included in the statement of rights and responsibilities.

§483.10(b)(5) -- The facility must--

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of--

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

§483.10(b)(6) -- The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the

facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

Interpretive Guidelines §483.10(b)(5) and (6)

Residents should be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes.

"Periodically" means that whenever changes are being introduced that will affect the residents liability and whenever there are changes in services.

A Medicare beneficiary who requires services upon admission that are not covered under Medicare may be required to submit a deposit provided the notice provisions of §483.10(b)(6), if applicable, are met.

Procedures §483.10(b)(5) and (6)

See §483.10(c)(8) for those items and services that must be included in payment under skilled nursing and nursing facility benefits.

§483.10(b)(7) -- The facility must furnish a written description of legal rights which includes--

> **(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;**
>
> **(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple's non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels;**
>
> **(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and**
>
> **(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, and misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.**

Interpretive Guidelines §483.10(b)(7)

"The protection and advocacy network" refers to the system established to protect and advocate the rights of individuals with developmental disabilities specified in the Developmental Disabilities Assistance and Bill of Rights Act, and the protection and advocacy system established under the Protection and Advocacy for Mentally Ill Individuals Act.

Procedures §483.10(b)(7)

At the Entrance Conference, request a copy of the written information that is provided to residents regarding their rights and review it to determine if it addresses the specified requirements. Additional requirements that address the implementation of these rights are cross-referenced below.

§483.10(b)(8) -- The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law

Interpretive Guidelines §483.10(b)(8)

This provision applies to residents admitted on or after December 1, 1991. 42 CFR 489.102 specifies that at the time of admission of an adult resident, the facility must:

- Provide written information concerning his/her rights under State law (whether or not statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives;

- Document in the resident's medical record whether or not the individual has executed an advance directive;

- Not condition the provision of care or discriminate against an individual based on whether or not the individual has executed an advance directive;

- Ensure compliance with requirements of State law regarding advance directives;

- Provide for educating staff regarding the facility's policies and procedures on advance directives; and

- Provide for community education regarding the right under State law (whether or not recognized by the courts of the State) to formulate an advance directive and the facility's written policies and procedures regarding the implementation of these rights, including any limitations the facility may have with respect to implementing this right on the basis of conscience.

The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows the provider to conscientiously object. (See §483.10(b)(4), F155.)

The sum total of the community education efforts must include a summary of the State law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audio tapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.

Procedures §483.10(b)(8)

During Resident Review, review the records of two selected sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements.

- Determine to what extent the facility educates its staff regarding advance directives.

- Determine to what extent the facility provides education for the community regarding one's rights under State law to formulate advance directives.

§483.10(b)(9) -- The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

Interpretive Guidelines §483.10(b)(9)

"Physician responsible for his or her care" is defined as the attending or primary physician or clinic, whichever is responsible for managing the resident's medical care, and excludes other physicians whom the resident may see from time to time. When a resident has selected an attending physician, it is appropriate for the facility to confirm that choice when complying with this requirement. When a resident has no attending physician, it is appropriate for the facility to assist residents to obtain one in consultation with the resident and subject to the resident's right to choose. (See §483.10(d)(1), F163.)

If a facility uses the services of a clinic or similar arrangement, it may be sufficient for residents to have the name and contact information for the primary physician and/or a central number for the clinic itself.

§483.10(b)(10) -- The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

Interpretive Guidelines §483.10(b)(10)

To fulfill this requirement, the facility may use written materials issued by the State Medicaid agency and the Federal government relating to these benefits. Facilities may fulfill their obligation to orally inform residents or applicants for admission about how to apply for Medicaid or Medicare by assisting them in contacting the local Social Security Office or the local unit of the State Medicaid agency. Nursing facilities are not responsible for orally providing detailed information about Medicare and Medicaid eligibility rules.

"Refunds for previous payments" refers to refunds due as a result of Medicaid and Medicare payments when eligibility has been determined retroactively.

As part of determining Medicaid eligibility, at the time of admission, a married couple has the right to request and have the appropriate State agency assess the couple's resources.

F157

§483.10(b)(11) -- Notification of changes.

(i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is--

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in <u>§483.12(a)</u>.

(ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is--

(A) A change in room or roommate assignment as specified in §483.15(e)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

Interpretive Guidelines §483.10(b)(11)

For purposes of §483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

In the case of a competent individual, the facility must still contact the resident's physician and notify interested family members, if known. That is, a family that wishes to be informed would designate a member to receive calls. Even when a resident is mentally competent, such a designated family member should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident.

The requirements at §483.10(b)(1) require the facility to inform the resident of his/her rights upon admission and during the resident's stay. This includes the resident's right to privacy (§483.10(e), F164). If, after being informed of the right to privacy, a resident specifies that he/she wishes to exercise this right and not notify family members in the event of a significant change as specified at this requirement, the facility should respect this request, which would obviate the need to notify the resident's interested family member or legal representative, if known. If a resident specifies that he/she does not wish to exercise the right to privacy, then the facility is required to comply with the notice of change requirements.

In the case of a resident who is incapable of making decisions, the representative would make any decisions that have to be made, but the resident should still be told what is happening to him or her.

In the case of the death of a resident, the resident's physician is to be notified immediately in accordance with State law.

The failure to provide notice of room changes could result in an avoidable decline in physical, mental, or psychosocial well-being.

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§483.10(c) Protection of Resident Funds

F158

§483.10(c)(1) Protection of Resident Funds

The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

F159

§483.10(c)(2) Management of Personal Funds

Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)-(8) of this section.

§483.10(c)(3) Deposit of Funds

(i) Funds in excess of $50. The facility must deposit any residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(ii) Funds less than $50. The facility must maintain a resident's personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

NOTE: The Social Security Amendments of 1994 amended §1819(c)(6)(B)(i) to raise the limit from $50.00 to $100.00 for the minimum amount of resident funds that facilities must entrust to an interest bearing account. This increase applies only to Medicare SNF residents. While a facility may continue to follow a minimum of $50.00, the regulations do not require it.

Interpretive Guidelines §483.10(c)(1) through (3)

This requirement is intended to assure that residents who have authorized the facility in writing to manage any personal funds have ready and reasonable access to those funds. If residents choose to have the facility manage their funds, the facility may not refuse to handle these funds, but is not responsible for knowing about assets not on deposit with it.

Placement of residents' personal funds of less than $50.00 ($100.00 for Medicare residents) in an interest bearing account **is** permitted. Thus, a facility may place the total amount of a resident's funds, including funds of $50.00 ($100.00 for Medicare residents) or less, into an interest-bearing account. The law and regulations are intended to assure that residents have access to $50.00 ($100.00 for Medicare residents) in cash within a reasonable period of time, when requested. Requests for less than $50.00 ($100.00 for Medicare residents) should be honored within the same day. Requests for $50.00 ($100.00 for Medicare residents) or more should be honored within three banking days. Although the facility need not maintain $50.00 ($100.00 for Medicare residents) per resident on its premises, it is expected to maintain amounts of petty cash on hand that may be required by residents.

If pooled accounts are used, interest must be prorated per individual on the basis of actual earnings or end-of quarter balance.

Residents should have access to petty cash on an ongoing basis and be able to arrange for access to larger funds.

"Hold, safeguard, manage and account for" means that the facility must act as fiduciary of the resident's funds and report at least quarterly on the status of these funds in a clear and understandable manner. Managing the resident's financial affairs includes money that an individual gives to the facility for the sake of providing a resident with a noncovered service (such as a permanent wave). It is expected that in these instances, the facility will provide a receipt to the gift giver and retain a copy.

"Interest bearing" means a rate of return equal to or above the passbook savings rate at local banking institutions in the area.

Although the requirements are silent about oral requests by residents to have a facility hold personal funds, under the provisions regarding personal property (§483.10(l)), and misappropriation of property (§483.13(c)), residents may make oral requests that the facility temporarily place their funds in a safe place, without authorizing the facility to manage those funds. The facility has the responsibility to implement written procedures to prevent the misappropriation of these funds.

If you determine potential problems with funds through interviews, follow-up using the following procedures as appropriate:

If the facility does not have written authorization to handle resident's funds, but is holding funds for more than a few days, determine if the facility is managing these funds without written authorization. There must be written authorization for the facility to be in compliance with this requirement.

To assure that facilities are not using oral requests by residents as a way to avoid obtaining written authorization to hold, manage, safeguard and account for resident's funds, make sure that:

- There is a written declaration by the resident that the funds are being held for no more than a few days by the facility at the resident's request;

- These funds are not held for more than a few days; and

- The facility provides the resident a receipt for these funds and retains a copy for its records.

Review the administrative or business file and the bookkeeping accounts of residents selected for a comprehensive review who have authorized the facility to handle their personal funds.

- Are residents' funds over $50.00 ($100.00 for Medicare residents) or, at the facility's option, all resident funds, in an interest bearing account(s)?

- What procedure was followed when residents requested their funds?

- How long does it take for residents to receive: (a) petty cash allotments; (b) funds needing to be withdrawn from bank accounts?

- Were limits placed on amounts that could be withdrawn? If yes, was the reason based on resident care needs or facility convenience?

- Are funds records treated with privacy as required at F164?

NOTE: Banks may charge the resident a fee for handling their funds. Facilities may not charge residents for managing residents' funds because the services are covered by Medicare or Medicaid.

If problems are identified, review also §483.10(b)(7), Tag F156.

Monies due residents should be credited to their respective bank accounts within a few business days.

§483.10(c)(4) Accounting and Records

The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements and on request to the resident or his or her legal representative.

Interpretive Guidelines §483.10(c)(4)

This requirement constitutes the overall response of the facility to the resident's right to have the facility manage the resident's funds.

"Generally accepted accounting principles" means that the facility employs proper bookkeeping techniques, by which it can determine, upon request, the amount of individual resident funds and, in the case of an interest bearing account, how much interest these funds have earned for each resident, as last reported by the banking institution to the facility.

Proper bookkeeping techniques would include an individual ledger card, ledger sheet or equivalent established for each resident on which only those transactions involving his or her personal funds are recorded and maintained. The record should have information on when transactions occurred, what they were, as well as maintain the ongoing balance for every resident.

Anytime there is a transaction the resident should be given a receipt and the facility retains a copy.

Monies due residents should be credited to their respective bank accounts within a few business days.

"Quarterly statements" are to be provided in writing to the resident or the resident's representative within 30 days after the end of the quarter.

§483.10(c)(5) Notice of Certain Balances

The facility must notify each resident that receives Medicaid benefits--

> **(i) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section <u>1611(a)(3)(B)</u> of the Act; and**
>
> **(ii) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.**

Interpretive Guidelines §483.10(c)(5)

The Social Security District Office can provide you with information concerning current SSI resource limits.

Procedures §483.10(c)(5)

If problems are identified for sampled residents who are Medicaid recipients, review financial records to determine if their accounts are within $200.00 of the SSI limit. If there are sampled residents in this situation, ask them or their representatives if they have received notice.

F160

483.10(c)(6) Conveyance upon death

Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

Procedures §483.10(c)(6)

As part of closed records review, determine if within 30 days of death, the facility conveyed the deceased resident's personal funds and a final accounting to the individual or probate jurisdiction administering the individual's estate as provided by State law.

F161

483.10(c)(7) Assurance of Financial Security

The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

Interpretive Guidelines §483.10(c)(7)

A surety bond is an agreement between the principal (the facility), the surety (the insurance company), and the obligee (depending on State law, either the resident or the State acting on behalf of the resident), wherein the facility and the insurance company agree to compensate the resident (or the State on behalf of the resident) for any loss of residents' funds that the facility holds, safeguards, manages, and accounts for.

The purpose of the surety bond is to guarantee that the facility will pay the resident (or the State on behalf of the resident) for losses occurring from any failure by the facility to hold, safeguard, manage, and account for the residents' funds, i.e., losses occurring as a result of acts or errors of negligence, incompetence or dishonesty.

Unlike other types of insurance, the surety bond protects the obligee (the resident or the State), not the principal (the facility), from loss. The surety bond differs from a fidelity bond, which covers no acts or errors of negligence, incompetence or dishonesty.

The surety bond is the commitment of the facility in an objective manner to meet the standard of conduct specified in §483.10(c)(2), that the facility will hold, safeguard, manage and account for the funds residents have entrusted to the facility. The facility assumes the responsibility to compensate the obligee for the amount of the loss up to the entire amount of the surety bond.

Reasonable alternatives to a surety bond must:

- Designate the obligee (depending on State law, the resident individually or in aggregate, or the State on behalf of each resident) who can collect in case of a loss;

- Specify that the obligee may collect due to any failure by the facility, whether by commission, bankruptcy, or omission, to hold, safeguard, manage, and account for the residents' funds; and

- Be managed by a third party unrelated in any way to the facility or its management.

The facility cannot be named as a beneficiary.

Self-insurance is not an acceptable alternative to a surety bond. Likewise, funds deposited in bank accounts protected by the Federal Deposit Insurance Corporation, or similar entity, also are not acceptable alternatives.

Procedures §483.10(c)(7)

As part of Phase 2, if your team has any concerns about residents' funds, check the amount of the surety bond to make sure it is at least equal to the total amount of residents' funds, as of the most recent quarter.

If the State survey agency determines that individual circumstances associated with a facility's surety bond or its alternative are such that the survey agency cannot determine whether or not the facility is in compliance with the requirements at §483.10(c)(7), then it would be appropriate to make the referral to the State's fiscal department.

If a corporation has a surety bond that covers all of its facilities, there should be a separate review of the corporation's surety bond by the appropriate State agency, such as the State's fiscal department, to ensure that all the residents in the corporation's facilities within the State are covered against any losses due to acts or errors by the corporation or any of its facilities. The focus of the review should be to ensure that if the corporation

were to go bankrupt or otherwise cease to operate, the funds of the residents in the corporation's facilities would be protected.

F162

§483.10(c)(8) Limitation on Charges to Personal Funds

The facility may not impose a charge against the personal funds of a resident for any item or services for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts).

The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services:

(A) Nursing services as required at §483.30 of this subpart.

(B) Dietary services as required at §483.35 of this subpart.

(C) An activities program as required at §483.15(f) of this subpart.

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing, and basic personal laundry.

(F) Medically-related social services as required at §483.15(g) of this subpart.

(ii) Items and services that may be charged to residents' funds. Listed below are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone;

(B) Television/radio for personal use;

(C) Personal comfort items, including smoking materials, notions and novelties, and confections;

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare;

(E) Personal clothing;

(F) Personal reading matter;

(G) Gifts purchased on behalf of a resident;

(H) Flowers and plants; and

(I) Social events and entertainment offered outside the scope of the activities program, provided under §483.15(f) of this subpart.

(J) Noncovered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Specially prepared or alternative food requested instead of the food generally prepared by the facility, as required by §483.35 of this subpart.

Intent §483.10(c)(8)

The intent of this requirement is to specify that facilities not charge residents for items and services for which payment is made under Medicare or Medicaid.

Interpretive Guidelines §483.10(c)(8)

The facility may charge the resident the difference for requested services that are more expensive than or in excess of covered services in accordance with §489.32 of this

chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See §447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or co-payment required by the plan to be paid by the individual.) If a State plan does not cover an item or service, such as eyeglasses, the resident may purchase that item or service out of his/her funds. See §483.15(g), F250 for the facility's responsibility to assist the resident in obtaining those services.

Procedures §483.10(c)(8)

As appropriate during Phase 2 of the survey, review the written information given to Medicare/Medicaid eligible residents and family members on admission that notifies them of the items and services that are covered under Medicare or the State plan. Review a sample of residents' monthly statements to ensure that personal funds are not used to pay for covered services. If charges found on monthly statements indicate that residents may have paid for covered items or services, determine if these items or services are over and above what is paid by Medicare or Medicaid.

If, through observations or interviews of residents selected for comprehensive or focused review, the team determines that families or residents hire sitters, and/or that a large number of residents or families are paying for outside food, determine if these practices reflect inadequate staffing and/or food.

Interpretive Guidelines §483.10(c)(8)(i)(E)

Prescription drugs are part of the pharmaceutical services that facilities are required to provide. (See §483.25(l) and (m), and §483.60.) However, at times, a resident needs a medical service that is recognized by State law, but not covered by the State plan. Such a medical service includes a prescription drug that is not on the State's formulary or that exceeds the number of medications covered by Medicaid. It may also include prescription eyeglasses or dentures. If a resident needs a recognized medical service over what is allowed by the State plan, the resident has the right under the Medicaid statute to spend his/her income on that service. If the service is more than what Medicaid pays, the resident may deduct the actual cost of the service from the Medicaid share of the cost. The facility must assist the resident in exercising his or her right to the uncovered medical expense deduction and may not charge the resident for such services.

"Hair hygiene supplies" refers to comb, brush, shampoos, trims and simple hair cuts provided by facility staff as part of routine grooming care. Hair cuts, permanent waves, hair coloring, and relaxing performed by barbers and beauticians not employed by a facility are chargeable.

"Nail hygiene services" refers to routine trimming, cleaning, filing, but not polishing of undamaged nails, and on an individual basis, care for ingrown or damaged nails.

"Basic personal laundry" does not include dry cleaning, mending, washing by hand, or other specialty services that need not be provided. A resident may be charged for these specialty services if he or she requests and receives them.

Interpretive Guidelines §483.10(c)(8)(ii)(I) Social Events

Facilities are required by §483.15(f) to provide an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and physical, mental, and psychosocial well-being of each resident, and cannot charge residents for these services, whether they occur at the facility or off-site. Resident funds should not be charged for universal items such as bookmobile services or local newspaper subscriptions intended for use by more than one resident. However, if a resident requests and attends a social event or entertainment that is not part of the activities assessment and care plan for that resident, a facility may charge that resident's account only for actual expenses. Further, because of expenses associated with transportation, escorts and other related costs, a resident may be charged for actual expenses for an event or entertainment he or she requests and attends that may be free to the public.

Interpretive Guidelines §483.10(c)(8)(ii)(L) Specially Prepared Foods

A resident may refuse food usually prepared and food substitutions of similar nutritive value because of personal, religious, cultural, or ethnic preference. If the resident requests and receives food that is either not commonly purchased by the facility or easily prepared, then the facility may charge the resident. For example, the facility may charge the resident's account for specially prepared food if the facility has a restricted diet policy and notified the resident on admission of the fact, in accordance with §483.10(b). The facility may not charge the resident's account for specially prepared foods that are required by the physician's order of a therapeutic diet. If a facility changes its menu so that the menu no longer reflects the food preferences of residents, see F165, F242, and F243 to determine compliance with these requirements.

(iii) Requests for items and services.

(A) The facility must not charge a resident (or his or her representative) for any item or service not requested by the resident.

(B) The facility must not require a resident (or his or her representative) to request any item or service as a condition of admission or continued stay.

(C) The facility must inform the resident (or his or her representative) requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

Interpretive Guidelines §483.10(c)(8)(iii) Requests for Items and Services

A facility may not charge a resident or the resident's representative for items and services that are not requested by the resident or representative, whether or not the item or services is requested by a physician. The item or service ordered by the physician should fit in with the resident's care plan.

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§483.10(d) Free Choice

The resident has the right to--

F163

§483.10(d)(1) -- Choose a personal attending physician

Interpretive Guidelines §483.10(d)(1)

The right to choose a personal physician does not mean that the physician must or will serve the resident, or that a resident must designate a personal physician. If a physician of the resident's choosing fails to fulfill a given requirement, such as §483.25(l)(1), Unnecessary drugs; §483.25(l)(2), Antipsychotic drugs; or §483.40, frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physicians. For example, if a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his or her choice in finding another physician.

Before consulting an alternate physician, one mechanism to alleviate a possible problem could involve the facility's utilization of a peer review process for cases which cannot be satisfactorily resolved by discussion between the medical director and the attending physician. Only after a failed attempt to work with the attending physician or mediate differences in delivery of care should the facility request an alternate physician when requested to do so by the resident or when the physician will not adhere to the regulations.

If it is a condition for admission to a continuing care retirement center, the requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges at the retirement center.

A resident in a distinct part of a general acute care hospital can choose his/her own physician, unless the hospital requires that physicians with residents in the distinct part have hospital admitting privileges. If this is so, the resident can choose his/her own physician, but cannot have a physician who does not have hospital admitting privileges.

If residents appear to have problems in choosing physicians, determine how the facility makes physician services available to residents.

F164

(Rev. 5, Issued 11-19-04, Effective: 11-19-04, Implementation: 11-19-2004)

§483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when--

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law

Interpretive Guidelines §483.10(e)

"**Right to privacy**" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include full visual, and, to the extent desired, for visits or other activities, auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes.

For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that

private space is provided for those requesting it without infringement on the rights of other residents.

With the exception of the explicit requirement for privacy curtains in all initially certified facilities (see §483.70(d)(1)(v)), the facility is free to innovate to provide privacy for its residents, as exemplified in the preceding paragraph. This may, but need not, be through the provision of a private room.

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Personal and clinical records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated or other.

Additional guidelines on mail, visitation rights and telephone communication are addressed in §483.10(i), (j) and (k). See §483.70(d)(1)(iv) for full visual privacy around beds.

Procedures §483.10(e)(1) - (3)

Document **any** instances where you **observe** a resident's privacy being violated. Completely document how the resident's privacy was violated (e.g., Resident #12 left without gown or bed covers and unattended), and where and when this occurred (e.g., 2B Corridor, 3:30 pm, February 25). If possible, identify the responsible party.

§483.75(l)(4) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by--

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract; or

(iv) The resident.

Interpretive Guidelines §483.75(l)(4)

"Keep confidential" is defined as safeguarding the content of information including video, audio, or other computer stored information from unauthorized disclosure without the consent of the individual and/or the individual's surrogate or representative.

If there is information considered too confidential to place in the record used by all staff, such as the family's financial assets or sensitive medical data, it may be retained in a secure place in the facility, such as a locked cabinet in the administrator's office. The record should show the location of this confidential information.

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§483.10(f) Grievances

A resident has the right to--

F165

A resident has the right to –

§483.10(f)(1) --Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and

(SEE TAG 166 FOR GUIDANCE)

F166

A resident has the right to--

§483.10(f)(2) -- Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

Intent §483.10(f)

The intent of the regulation is to support each resident's right to voice grievances (e.g., those about treatment, care, management of funds, lost clothing, or violation of rights) and to assure that after receiving a complaint/grievance, the facility actively seeks a resolution and keeps the resident appropriately apprised of its progress toward resolution

Interpretive Guidelines §483.10(f)

"Voice grievances" is not limited to a formal, written grievance process but may include a resident's verbalized complaint to facility staff.

“Prompt efforts...to resolve” include facility acknowledgment of complaint/grievances and actively working toward resolution of that complaint/grievance.

If residents’ responses indicate problems in voicing grievances and getting grievances resolved, determine how the facility deals with and makes prompt efforts to resolve resident complaints and grievances.

- With permission, review resident council minutes.
- Interview staff about how grievances are handled.
- Interview staff about communication (to resident) of progress toward resolution of complaint/grievance.

If problems are identified, also investigate compliance with §483.10(b)(7)(iii).

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§483.10(g) Examination of Survey Results

F167

A resident has the right to--

(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to residents and must post a notice of their availability; and

SEE GUIDANCE UNDER TAG 168

F168

A resident has the right to:

§483.10(g)(2) -- Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

Interpretive Guidelines §483.10(g)(1)-(2)

“Results of the most recent survey” means the Statement of Deficiencies (Form CMS-2567) and the Statement of Isolated Deficiencies generated by the most recent standard survey and any subsequent extended surveys, and any deficiencies resulting from any subsequent complaint investigation(s).

"Made available for examination" means that survey results and approved plan of correction, if applicable, are available in a readable form, such as a binder, large print, or are provided with a magnifying glass, have not been altered by the facility unless authorized by the State agency, and are available to residents without having to ask a staff person.

"Place readily accessible to residents" is a place (such as a lobby or other area frequented by most residents) where individuals wishing to examine survey results do not have to ask to see them.

F169

§483.10(h) Work

The resident has the right to--

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when--

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care

Interpretive Guidelines §483.10(h)(1)-(2)

"Prevailing rate" is the wage paid to workers in the community surrounding the facility for essentially the same type, quality, and quantity of work requiring comparable skills.

All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to discussion of medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated.

Procedures §483.10(h)(1)-(2)

Are residents engaged in what may be paid or volunteer work (e.g., doing housekeeping, doing laundry, preparing meals)? Pay special attention to the possible work activities of residents with mental retardation or mental illness. If you observe such a situation,

determine if the resident is in fact performing work and, if so, is this work, whether voluntary or paid, described in the plan of care?

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§483.10(i) Mail

The resident has the right to privacy in written communications, including the right to--

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F170

§483.10(i)(1) Send and promptly receive mail that is unopened; and

SEE GUIDANCE UNDER TAG 171

F171

§483.10(i)(2) Have access to stationery, postage, and writing implements at the resident's own expense.

Interpretive Guidelines §483.10(i)(1)-(2)

"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours, except when there is no regularly scheduled postal delivery and pick-up service.

F172

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.10(j) Access and Visitation Rights

§483.10(j)(1) The resident has the right and the facility must provide immediate access to any resident by the following:

(i) Any representative of the Secretary;

(ii) Any representative of the State;

(iii) The resident's individual physician;

(iv) The State long term care ombudsman (established under section 307 (a)(12) of the Older Americans Act of 1965);

(v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);

(vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);

(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

§483.10(j)(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

Interpretive Guidelines: §483.10(j)(1) and (2)

The facility must provide immediate access to any representative of the Secretary of the Department of Health and Human Services, the State, the resident's individual physician, the State long term care ombudsman, or the agencies responsible for the protection and advocacy of developmentally disabled or mentally ill individuals. The facility cannot refuse to permit residents to talk with surveyors. Representatives of the Department of Health and Human Services, the State, the State ombudsman system, and protection and advocacy agencies for mentally ill and mentally retarded individuals are not subject to visiting hour limitations.

Immediate family or other relatives are not subject to visiting hour limitations or other restrictions not imposed by the resident. However, the facility may try to change the location of visits to assist care giving or protect the privacy of other residents, if these visitation rights infringe upon the rights of other residents in the facility. For example, a resident's family visits in the late evening, which prevents the resident's roommate from sleeping.

Non-family visitors must also be granted "immediate access" to the resident. The facility may place reasonable restrictions upon the exercise of this right such as reasonable visitation hours to facilitate care giving for the resident or to protect the privacy of other residents, such as requiring that visits not take place in the resident's room if the roommate is asleep or receiving care.

An individual or representative of an agency that provides health, social, legal, or other services to the resident has the right of "reasonable access" to the resident, which means

that the facility may establish guidelines regarding the timing or other circumstances of the visit, such as location. These guidelines must allow for ready access of residents to these services.

Procedures §483.10(j)(1) and (2)

If you identify problems during interviews, determine how the facility ensures access to:

- Representatives of the State;
- Representatives of the U.S. Department of Health and Human Services;
- The resident's individual physician;
- Representatives of the State long-term care ombudsman;
- Representatives of agencies responsible for protecting and advocating rights of persons with mental illness or developmental disabilities;
- Family or relatives; and
- Other visitors.

F173

§483.10(j)(3) -- The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.

Procedures §483.10(j)(3)

Ask the ombudsman if the facility allows him/her to examine residents' clinical records with the permission of the resident, and to the extent allowed by State law.

F174

§483.10(k) Telephone

The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

Interpretive Guidelines §483.10(k)

Telephones in staff offices or at nurses' stations do not meet the provisions of this requirement. Examples of facility accommodations to provide reasonable access to the use of a telephone without being overheard include providing cordless telephones or having telephone jacks in residents' rooms.

"Reasonable access" includes placing telephones at a height accessible to residents who use wheelchairs and adapting telephones for use by the residents with impaired hearing.

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.10(l) Personal Property

The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

Intent §483.10(l)

The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits.

Interpretive Guidelines §483.10(l)

All residents' possessions, regardless of their apparent value to others, must be treated with respect, for what they are and for what they may represent to the resident. The right to retain and use personal possessions assures that the residents' environment be as homelike as possible and that residents retain as much control over their lives as possible. The facility has the right to limit the resident's exercise of this right on grounds of space and health or safety.

Procedures §483.10(l)

If residents' rooms have few personal possessions, ask residents, families and the local ombudsman if:

- Residents are encouraged to have and to use them;
- The facility informs residents not to bring in certain items and for what reason; and
- Personal property is safe in the facility.

Ask staff if the facility sets limits on the value of the property that residents may have in their possession or requires that residents put personal property in the facility's safe.

F175

§483.10(m) Married Couples

The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

Interpretive Guidelines §483.10(m)

The right of residents who are married to each other to share a room does not give a resident the right, or the facility the responsibility, to compel another resident to relocate to accommodate a spouse. The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose. If a married resident's spouse is admitted to the facility later and the couple want to share a room, the facility must provide a shared room as quickly as possible. However, a couple is not able to share a room if one of the spouses has a different payment source for which the facility is not certified (if the room is in a distinct part, unless one of the spouses elects to pay for his or her care).

F176

§483.10(n) Self-Administration of Drugs

An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.

Interpretive Guidelines §483.10(n)

If a resident requests to self-administer drugs, it is the responsibility of the interdisciplinary team to determine that it is safe for the resident to self-administer drugs before the resident may exercise that right. The interdisciplinary team must also determine who will be responsible (the resident or the nursing staff) for storage and documentation of the administration of drugs, as well as the location of the drug administration (e.g., resident's room, nurses' station, or activities room). Appropriate notation of these determinations should be placed in the resident's care plan.

The decision that a resident has the ability to self-administer medication(s) is subject to periodic re-evaluation based on change in the resident's status. The facility may require that drugs be administered by the nurse or medication aide, if allowed by State law, until the care planning team has the opportunity to obtain information necessary to make an assessment of the resident's ability to safely self-administer medications. If the resident

chooses to self-administer drugs, this decision should be made at least by the time the care plan is completed within seven days after completion of the comprehensive assessment.

Medication errors occurring with residents who self-administer drugs should not be counted in the facility's medication error rate (see Guidelines for §483.25(m)), but should call into question the judgment made by the facility in allowing self-administration for those residents.

Probes: §483.10(n)

For residents selected for a comprehensive review or a focused review, as appropriate:

- Does resident self-administer drugs? Which ones? How much? How often?
- Does the care plan reflect self-administration?

F177

§483.10(o) Refusal of Certain Transfers

(1) An individual has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate--

(i) A resident of a SNF, from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) A resident of a NF, from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(2) A resident's exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the individual's eligibility or entitlement to Medicare or Medicaid benefits.

Interpretive Guidelines §483.10(o)

This requirement applies to transfer within a physical plant.

These provisions allow a resident to refuse transfer from a room in one distinct part of an institution to a room in another distinct part of the institution for purposes of obtaining Medicare or Medicaid eligibility. If a resident refuses to transfer from a portion of the institution that is not Medicare certified, the resident forgoes the possibility of Medicare coverage for the care received there. If that portion of the institution is Medicaid certified and the resident is Medicaid-eligible, then Medicaid covered services would be paid by Medicaid. If the resident is Medicaid-eligible, but that portion of the institution

is not Medicaid certified, then the resident would assume responsibility for payment for the services. If the resident is unable to pay for those services, then the facility may, after giving the resident a 30-day notice, transfer the resident under the provisions of §483.12(a).

When a resident occupies a bed in a distinct part NF that participates in Medicaid and not in Medicare, he or she may not be moved involuntarily to another part of the institution by the facility (or required to be moved by the State) solely for the purpose of assuring Medicare eligibility for payment. Such moves are only appropriate when they occur at the request of a resident (for example, when a privately paying Medicare beneficiary believes that admission to a bed in a Medicare-participating distinct part of the institution may result in Medicare payment).

See Guidelines, §483.12 for further discussion regarding transfers.

For transfers of residents between Medicare or Medicaid approved distinct parts:

- Is there a documented medical reason for the transfer?
- Was the resident transferred because of a change in payment source?
- If a Medicare or Medicaid resident is notified that he/she is no longer eligible, does the facility transfer the resident? Did the facility give the resident the opportunity to refuse the transfer? How? What happened?
- Ask the local ombudsman about facility compliance with transfer requirements. See also §483.12, Criteria for Transfer.

§483.12 Admission, Transfer, and Discharge Rights

§483.12(a) Transfer, and Discharge

(1) Definition

Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

Guidelines §483.12

This requirement applies to transfers or discharges that are initiated by the facility, not by the resident. Whether or not a resident agrees to the facility's decision, these requirements apply whenever a facility initiates the transfer or discharge. "Transfer" is moving the resident from the facility to another legally responsible institutional setting,

while “discharge” is moving the resident to a non-institutional setting when the releasing facility ceases to be responsible for the resident’s care.

If a resident is living in an institution participating in both Medicare and Medicaid (SNF/NF) under separate provider agreements, a move from either the SNF or NF would constitute a transfer.

Transfer and discharge provisions significantly restrict a facility’s ability to transfer or discharge a resident once that resident has been admitted to the facility. The facility may not transfer or discharge the resident unless:

1. The transfer or discharge is necessary to meet the resident’s welfare and the resident’s welfare cannot be met in the facility;

2. The transfer or discharge is appropriate because the resident’s health has improved sufficiently so the resident no longer needs the services provided by the facility;

3. The safety of individuals in the facility is endangered;

4. The health of individuals in the facility would otherwise be endangered;

5. The resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility; or

6. The facility ceases to operate.

To demonstrate that any of the events specified in 1 - 5 have occurred, the law requires documentation in the resident’s clinical record. To demonstrate situations 1 and 2, the **resident’s** physician must provide the documentation. In situation 4, the documentation must be provided by **any** physician. (See §483.12(a)(2).)

Moreover, before the transfer or discharge occurs, the law requires that the facility notify the resident and, if known, the family member, surrogate, or representative of the transfer and the reasons for the transfer, and record the reasons in the clinical record. The facility’s notice must include an explanation of the right to appeal the transfer to the State as well as the name, address, and phone number of the State long-term care ombudsman. In the case of a developmentally disabled individual, the notice must include the name, address and phone number of the agency responsible for advocating for the developmentally disabled, and in the case of a mentally ill individual, the name, address and phone number of the agency responsible for advocating for mentally ill individuals. (See §483.12(a)(3) and (5).)

Generally, this notice must be provided at least 30 days prior to the transfer. Exceptions to the 30-day requirement apply when the transfer is effected because of:

- Endangerment to the health or safety of others in the facility;
- When a resident's health has improved to allow a more immediate transfer or discharge;
- When a resident's urgent medical needs require more immediate transfer; and
- When a resident has not resided in the facility for 30 days.

In these cases, the notice must be provided as soon as practicable before the discharge. (See §483.12(a)(4).)

Finally, the facility is required to provide sufficient preparation and orientation to residents to ensure safe and orderly discharge from the facility. (See §483.12(a)(6).)

Under Medicaid, a participating facility is also required to provide notice to its residents of the facility's bed-hold policies and readmission policies prior to transfer of a resident for hospitalization or therapeutic leave. Upon such transfer, the facility must provide written notice to the resident and an immediate family member, surrogate or representative of the duration of any bed-hold. With respect to readmission in a Medicaid participating facility, the facility must develop policies that permit residents eligible for Medicaid, who were transferred for hospitalization or therapeutic leave, and whose absence exceeds the bed-hold period as defined by the State plan, to return to the facility in the first available bed. (See §483.12(b).)

A resident cannot be transferred for non-payment if he or she has submitted to a third party payor all the paperwork necessary for the bill to be paid. Non-payment would occur if a third party payor, including Medicare or Medicaid, denies the claim and the resident refused to pay for his or her stay.

§483.10(o), Tag F177, addresses the right of residents to refuse certain transfers within an institution on the basis of payment status.

F201

§483.12(a)(2) Transfer and Discharge Requirements

The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless--

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv)The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a nursing facility, the nursing facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

SEE GUIDANCE UNDER TAG 202

F202

§483.12(a)(3) Documentation

When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by--

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

Interpretive Guidelines §483.12(a)(2) and (3)

If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct the appropriate assessment to determine if a new care plan would allow the facility to meet the resident's needs. (See §483.20(b)(4)(iv), F274, for information concerning assessment upon significant change.)

Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment.

Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others.

Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.

Procedures §483.12(a)(2) and (3)

During closed record review, determine the reasons for transfer/discharge.

- Do records document accurate assessments and attempts through care planning to address resident's needs through multi-disciplinary interventions, accommodation of individual needs and attention to the resident's customary routines?

- Did the resident's physician document the record if:

    - The resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization)? or

    - The resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility.

- Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered?

- Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? Did the survey team observe residents with similar safety concerns in the facility? If so, determine differences between these residents and those who were transferred or discharged.

- Look for changes in source of payment coinciding with transfer. If you find such transfer, determine if the transfers were triggered by one of the criteria specified in §483.12(a)(2).

- Ask the ombudsman if there were any complaints regarding transfer and/or discharge. If there were, what was the result of the ombudsman's investigation?

- If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

F203

§483.12(a)(4) Notice Before Transfer

Before a facility transfers or discharges a resident, the facility must--

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

§483.12(a)(5) Timing of the notice.

(i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when--

(A) The safety of the individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

§483.12(a)(6) Contents of the notice

The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

Procedures §483.12(a)(4)-(6)

If the team determines that there are concerns about the facility's transfer and discharge actions, during closed record review, look at notices to determine if the notice requirements are met, including:

- Advance notice (either 30 days or, as soon as practicable, depending on the reason for transfer/discharge);
- Reason for transfer/discharge;
- The effective date of the transfer or discharge;
- The location to which the resident was transferred or discharged;
- Right of appeal;
- How to notify the ombudsman (name, address, and telephone number); and
- How to notify the appropriate protection and advocacy agency for residents with mental illness or mental retardation (mailing address and telephone numbers).
- Determine whether the facility notified a family member or legal representative of the proposed transfer or discharge.

F204

§483.12(a)(7) Orientation for Transfer or Discharge

A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

Interpretive Guidelines §483.12(a)(7)

"Sufficient preparation" means the facility informs the resident where he or she is going and takes steps under its control to assure safe transportation. The facility should actively involve, to the extent possible, the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits, if possible, by the resident to a new location; working with family to ask their assistance in assuring the resident that valued possessions are not left behind or lost; orienting staff in the receiving facility to resident's daily patterns; and reviewing with staff routines for handling transfers and discharges in a manner that minimizes unnecessary and avoidable anxiety or depression and recognizes characteristic resident reactions identified by the resident assessment and care plan.

Procedures §483.12(a)(7)

During Resident Review, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.

F205

§483.12(b) Notice of Bed-Hold Policy and Readmission

§483.12(b)(1) Notice before transfer. Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies--

> **(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and**
>
> **(ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.**

§483.12(b)(2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the

resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

Interpretive Guidelines §483.12(b)(1) and (2)

The nursing facility's bed-hold policies apply to all residents.

These sections require two notices related to the facility's bed-hold policies to be issued. The first notice of bed-hold policies could be given well in advance of any transfer. However, reissuance of the first notice would be required if the bed-hold policy under the State plan or the facility's policy were to change. The second notice, which specifies the duration of the bed-hold policy, must be issued at the time of transfer

In cases of emergency transfer, notice "at the time of transfer" means that the family, surrogate, or representative are provided with written notification within 24 hours of the transfer. The requirement is met if the resident's copy of the notice is sent with other papers accompanying the resident to the hospital.

Bed-hold for days of absence in excess of the State's bed-hold limit are considered non-covered services which means that the resident could use his/her own income to pay for the bed-hold. However, if such a resident does not elect to pay to hold the bed, readmission rights to the next available bed are specified at §483.12(b)(3). Non-Medicaid residents may be requested to pay for all days of bed-hold.

If residents (or their representatives in the case of residents who are unable to understand their rights) are unsure or unclear about their bed-hold rights, **review** facility bed-hold policies.

- Do policies specify the duration of the bed-hold?
- Is this time period consistent with that specified in the State plan?
- During closed record review, look at records of residents transferred to a hospital or on therapeutic leave to determine if bed-hold requirements were followed. Was notice given before and at the time of transfer?
- During closed record review, look at records of residents transferred to a hospital or on therapeutic leave to determine if bed-hold requirements were followed. Was notice given before and at the time of transfer?

F206

§483.12(b)(3) Permitting Resident to Return to Facility

A nursing facility must establish and follow a written policy under which a resident whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident--

(i) Requires the services provided by the facility; and

(ii) Is eligible for Medicaid nursing facility services.

Interpretive Guidelines §483.12(b)(3)

"First available bed in a semi-private room" means a bed in a room shared with another resident of the same sex. (see §483.10(m) for the right of spouses to share a room.)

Medicaid-eligible residents who are on therapeutic leave or are hospitalized beyond the State's bed-hold policy must be readmitted to the first available bed even if the residents have outstanding Medicaid balances. Once readmitted, however, these residents may be transferred if the facility can demonstrate that non-payment of charges exists and documentation and notice requirements are followed. The right to readmission is applicable to individuals seeking to return from a transfer or discharge as long as all of the specific qualifications set out in §483.12(b)(3) are met.

Procedures §483.12(b)(3)

For Medicaid recipients whose hospitalization or therapeutic leave exceeds the bed-hold period, do facility policies specify readmission rights?

Refer to the Minimum Data Set (MDS), section A.10, Discharge Planned; MDS 2.0, section Q, Discharge Potential and Overall Status.

Review the facility's written bed-hold policy to determine if it specifies legal readmission rights. Ask the local ombudsman if there are any problems with residents being readmitted to the facility following hospitalization. In closed record review, determine why the resident did not return to the facility.

Ask the social worker or other appropriate staff what he/she tells Medicaid-eligible residents about the facility's bed-hold policies and the right to return and how Medicaid-eligible residents are assisted in returning to the facility.

If potential problems are identified, talk to discharge planners at the hospital to which residents are transferred to determine their experience with residents returning to the facility.

F207

§483.12(c) Equal Access to Quality Care

§483.12(c)(1) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment;

§483.12(c)(2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement in §483.10(b)(5)(i) and (b)(6) describing the charges; and

§483.12(c)(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

Interpretive Guidelines §483.12(c)

Facilities must treat all residents alike when making transfer and discharge decisions. "Identical policies and practices" concerning services means that facilities must not distinguish between residents based on their source of payment when providing services that are required to be provided under the law. All nursing services, specialized rehabilitative services, social services, dietary services, pharmaceutical services, or activities that are mandated by the law must be provided to residents according to residents' individual needs, as determined by assessments and care plans.

Procedures §483.12(c)

Determine if residents are grouped in separate wings or floors for reasons other than care needs.

F208

§483.12(d) Admissions Policy

(1) The facility must--

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Interpretive Guidelines §483.12(d)(1)

This provision prohibits both direct and indirect request for waiver of rights to Medicare or Medicaid. A direct request for waiver, for example, requires residents to sign admissions documents explicitly promising or agreeing not to apply for Medicare or Medicaid. An indirect request for waiver includes requiring the resident to pay private rates for a specified period of time, such as two years ("private pay duration of stay contract") before Medicaid will be accepted as a payment source for the resident. Facilities must not seek or receive any kind of assurances that residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

Procedures §483.12(d)(1)

If concerns regarding admissions procedures arise during interviews, review admissions packages and contracts to determine if they contain prohibited requirements (e.g., "side agreements" for the resident to be private pay or to supplement the Medicaid rate).

Ask staff what factors lead to decisions to place residents in different wings or floors. Note if factors other than medical and nursing needs affect these decisions. Do staff know the source of payment for the residents they take care of?

Ask the ombudsman if the facility treats residents differently in transfer, discharge and covered services based on source of payment.

With respect to transfer and discharge, if the facility appears to be sending residents to hospitals at the time (or shortly before) their payment source changes from private-pay or Medicare to Medicaid, call the hospitals and ask their discharge planners if they have detected any pattern of dumping. Also, ask discharge planners if the facility readmits Medicaid recipients who are ready to return to the facility. During the tour, observe possible differences in services

- Observe if there are separate dining rooms. If so, are different foods served in these dining rooms? For what reasons? Are residents excluded from some dining rooms because of source of payment?

- Observe the placement of residents in rooms in the facility. If residents are segregated on floors or wings by source of payment, determine if the facility is providing different services based on source of payment. Be particularly alert to differences in treatment and services. For example, determine whether less experienced aides and nursing staff are assigned to Medicaid portions of the facility. Notice the condition of the rooms (e.g., carpeted in private-pay wings, tile in Medicaid wings, proximity to the nurses' station, quality of food served as evening snacks).

As part of closed record review, determine if residents have been treated differently in transfers or discharges because of payment status. For example, determine if the facility is sending residents to acute care hospitals shortly before they become eligible for Medicaid as a way of getting rid of Medicaid recipients.

Ask social services staff to describe the facility's policy and practice on providing services, such as rehabilitative services. Determine if services are provided based on source of payment, rather than on need for services to attain or maintain functioning.

§483.12(d)(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

Interpretive Guidelines §483.12(d)(2)

The facility may not require a third person to accept personal responsibility for paying the facility bill out of his or her own funds. However, he or she may use the resident's money to pay for care. A third party guarantee is not the same as a third party payor, e.g., an insurance company; and this provision does not preclude the facility from obtaining information about Medicare or Medicaid eligibility or the availability of private insurance. The prohibition against third-party guarantees applies to all residents and prospective residents in all certified long term care facilities, regardless of payment source.

§483.12(d)(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,--

> **(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and**
>
> **(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.**

Interpretive Guidelines §483.12(d)(3)

This requirement applies only to Medicaid certified nursing facilities.

Facilities may not charge for any service that is included in the definition of "nursing facility services" and, therefore, required to be provided as part of the daily rate. Facilities may not accept additional payment from residents or their families as a prerequisite to admission or to continued stay in the facility. Additional payment includes deposits from Medicaid-eligible residents or their families, or any promise to pay private rates for a specified period of time.

A nursing facility may charge a Medicaid beneficiary for a service the beneficiary has requested and received, **only** if:

- That service is not defined in the State plan as a "nursing facility" service;
- The facility informs the resident and the resident's representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and
- The resident's admission or continued stay is not conditioned on the resident's requesting and receiving that service.

Procedures §483.12(d)(3)

Review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services.

Determine if the facility requires deposits from residents. If you identify potential problems with discrimination, review the files of one or more residents selected for a focused or comprehensive review to determine if the facility requires residents to submit deposits as a precondition of admission besides what may be paid under the State plan.

If interviews with residents suggest that the facility may have required deposits from Medicaid recipients at admission, except those admitted when Medicaid eligibility is pending, corroborate by, for example, reviewing the facility's admissions documents or interviewing family members.

§483.12(d)(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

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§483.13 Resident Behavior and Facility Practices

F221

Use Tag F221 for deficiencies concerning **physical** restraints.

USE GUIDANCE UNDER TAG F222

F222

Use Tag F222 for deficiencies concerning **chemical** restraints.

§483.13(a) Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

Intent §483.13(a)

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Interpretive Guidelines §483.13(a)

Definitions of Terms

"Physical Restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

"Chemical Restraints" is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

"Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

"Convenience" is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest.

“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.

“Convenience” is defined as any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and not in the resident’s best interest.

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident’s right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.

Physical Restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body.

“Physical restraints” include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily. Also included as restraints are facility practices that meet the definition of a restraint, such as:

- Using side rails that keep a resident from voluntarily getting out of bed;
- Tucking in or using velcro to hold a sheet, fabric, or clothing tightly so that a resident’s movement is restricted;
- Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident can not remove easily, that prevent the resident from rising;
- Placing a resident in a chair that prevents a resident from rising; and
- Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed.

Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident’s medical symptoms. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death.

The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom.

The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident.

An enclosed framed wheeled walker, with or without a posterior seat, would not meet the definition of a restraint if the resident could easily open the front gate and exit the device. If the resident cannot open the front gate (due to cognitive or physical limitations that prevent him or her from exiting the device or because the device has been altered to prevent the resident from exiting the device), the enclosed framed wheeled walker would meet the definition of a restraint since the device would restrict the resident's freedom of movement (e.g. transferring to another chair, to the commode, or into the bed). The decision on whether framed wheeled walkers are a restraint must be made on an individual basis.

"Medical Symptom" is defined as an indication or characteristic of a physical or psychological condition.

The resident's medical symptoms should not be viewed in isolation, rather the symptoms should be viewed in the context of the resident's condition, circumstances and environment. Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of the medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. Before a resident is restrained, the facility must determine the presence of a specific medical symptom that would require the use of restraints, and how the use of restraints would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being.

Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. While there must be a physician's order reflecting the presence of a medical symptom, CMS will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents

whose care plans indicate the need for restraints, that the facility engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting.

Consideration of Treatment Plan

In order for the resident to be fully informed, the facility must explain, in the context of the individual resident's condition and circumstances, the potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use. Whenever restraint use is considered, the facility must explain to the resident how the use of restraints would treat the resident's medical symptoms and assist the resident in attaining or maintaining his/her highest practicable level of physical or psychological well-being. In addition, the facility must also explain the potential negative outcomes of restraint use which include, but are not limited to, declines in the resident's physical functioning (e.g., ability to ambulate) and muscle condition, contractures, increased incidence of infections and development of pressure sores/ulcers, delirium, agitation, and incontinence. Moreover, restraint use may constitute an accident hazard. Restraints have been found in some cases to increase the incidence of falls or head trauma due to falls and other accidents (e.g., strangulation, entrapment). Finally, residents who are restrained may face a loss of autonomy, dignity and self respect, and may show symptoms of withdrawal, depression, or reduced social contact. In effect, restraint use can reduce independence, functional capacity, and quality of life. Alternatives to restraint use should be considered and discussed with the resident. Alternatives to restraint use might include modifying the resident's environment and/or routine.

In the case of a resident who is incapable of making a decision, the legal surrogate or representative may exercise this right based on the same information that would have been provided to the resident. (See §483.10(a)(3) and (4).) However, the legal surrogate or representative cannot give permission to use restraints for the sake of discipline or staff convenience or when the restraint is not necessary to treat the resident's medical symptoms. That is, the facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval.

Assessment and Care Planning for Restraint Use

There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis.

Before using a device for mobility or transfer, assessment should include a review of the resident's:

- Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and

- Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?).

The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom.

- Interventions that the facility might incorporate in care planning include:

    - Providing restorative care to enhance abilities to stand, transfer, and walk safely;

    - Providing a device such as a trapeze to increase a resident's mobility in bed;

    - Placing the bed lower to the floor and surrounding the bed with a soft mat;

    - Equipping the resident with a device that monitors his/her attempts to arise;

    - Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom;

    - Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or

    - Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use.

Procedures: §483.13(a)

Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being.

Probes: §483.13(a)

This systematic approach should answer these questions:

1. What are the medical symptoms that led to the consideration of the use of restraints?

2. Are these symptoms caused by failure to:

    a. Meet individual needs in accordance with the resident assessments including, but not limited to, section III of the MDS, Customary Daily Routines (MDS Version 2.0, section AC), in the context of relevant information in sections I and II of the MDS (MDS Version 2.0, sections AA and AB)?

    b. Use rehabilitative/restorative care?

    c. Provide meaningful activities?

    d. Manipulate the resident's environment, including seating?

3. Can the cause(s) of the medical symptoms be eliminated or reduced?

4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use? (See Physical Restraints Resident Assessment Protocol (RAP), paragraph I).

5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives?

6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained?

7. Does the facility use the Physical Restraints RAP to evaluate the appropriateness of restraint use?

8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

F223

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Intent §483.13(b)

Each resident has the right to be free from abuse, corporal punishment, and involuntary seclusion. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals.

Interpretive Guidelines §483.13(b) and (c)

"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." (42 CFR §488.301)

This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"Verbal abuse" is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again.

"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment.

"Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.

“Involuntary seclusion” is defined as separation of a resident from other residents or from her/his room or confinement to her/his room (with or without roommates) against the resident’s will, or the will of the resident’s legal representative. Emergency or short term monitored separation from other Residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident’s needs.

Investigation of possible involuntary seclusion, may involve one of two types of situations: that in which residents are living in an area of the facility that restricts their freedom of movement throughout the facility, or that in which a resident is temporarily separated from other residents.

- If the stated purpose of a unit which prevents residents from free movement throughout the facility is to provide specialized care for residents who are cognitively impaired, then placement in the unit is not considered involuntary seclusion, as long as care and services are provided in accordance with each resident’s individual needs and preferences rather than for staff convenience, and as long as the resident, surrogate, or representative (if any) participates in the placement decision, and is involved in continuing care planning to assure placement continues to meet resident needs and preferences.

- If a resident is receiving emergency short-term monitored separation due to temporary behavioral symptoms (such as brief catastrophic reactions or combative or aggressive behaviors which pose a threat to the resident, other residents, staff or others in the facility), this is not considered involuntary seclusion as long as this is the least restrictive approach for the minimum amount of time, and is being done according to resident needs and not for staff convenience.

If a resident is being temporarily separated from other residents, i.e., for less than 24 hours, as an emergency short-term intervention, answer these questions:

1. What are the symptoms that led to the consideration of the separation?

2. Are these symptoms caused by failure to:

    a. Meet individual needs?

    b. Provide meaningful activities?

    c. Manipulate the resident’s environment?

3. Can the cause(s) be removed?

4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?

5. If these alternatives have been tried and found ineffective, does the facility use separation for the least amount of time?

6. To what extent has the resident, surrogate or representative (if any) participated in care planning and made an informed choice about separation?

7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?

If, during the course of the survey, you identify the possibility of abuse according to the definitions above, investigate through interviews, observations, and record review. (For investigative options, refer to the Guidelines for Complaint Investigation which outlines the steps of investigations for various types of suspected abuse and misappropriation of property.)

Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse and where and when it occurred. Ensure that the facility addresses the incident immediately.

Properly trained staff should be able to respond appropriately to resident behavior. The CMS does not consider striking a combative resident an appropriate response in any situation. Retaliation by staff is abuse and should be cited as such.

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§483.13(c) Staff Treatment of Residents (F224* and F226**)

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

§483.13(c)(1)(i) Staff Treatment of Residents

(1) The facility must--

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

F224 *

*** Intent §483.13(c) (F224)**

Each resident has the right to be free from mistreatment, neglect and misappropriation of property. This includes the facility's identification of residents whose personal histories render them at risk for abusing other residents, and development of intervention strategies to prevent occurrences, monitoring for changes that would trigger abusive behavior, and reassessment of the interventions on a regular basis.

* Use tag F224 for deficiencies concerning mistreatment, neglect, or misappropriation of resident property.

*** Guidelines §483.13(c) (F224)**

"Neglect" means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (42 CFR 488.301)

"Misappropriation of resident property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent. (42 CFR 488.301)

F226 **

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

**** Intent §483.13(c), F226**

The facility must develop and operationalize policies and procedures for screening and training employees, protection of residents and for the prevention, identification, investigation, and reporting of abuse, neglect, mistreatment, and misappropriation of property. The purpose is to assure that the facility is doing all that is within its control to prevent occurrences.

** Use tag F226 for deficiencies concerning the facility's development and implementation of policies and procedures.

**** Guidelines §483.13(c), F226**

The facility must develop and implement policies and procedures that include the seven components: screening, training, prevention, identification, investigation, protection and reporting/response. The items under each component listed below are examples of ways in which the facility could operationalize each component.

I. Screening (483.13(c)(1)(ii)(A)&(B): Have procedures to:

- Screen potential employees for a history of abuse, neglect or mistreating residents as defined by the applicable requirements at 483.13(c)(1)(ii)(A) and (B). This includes attempting to obtain information from previous employers and/or current employers, and checking with the appropriate licensing boards and registries.

II. Training (42 CFR 483.74(e)): Have procedures to:

- Train employees, through orientation and on-going sessions on issues related to abuse prohibition practices such as:
    - Appropriate interventions to deal with aggressive and/or catastrophic reactions of residents;
    - How staff should report their knowledge related to allegations without fear of reprisal;
    - How to recognize signs of burnout, frustration and stress that may lead to abuse; and
    - What constitutes abuse, neglect and misappropriation of resident property.

III. Prevention (483.13(b) and 483.13(c)): Have procedures to:

- Provide residents, families and staff information on how and to whom they may report concerns, incidents and grievances without the fear of retribution; and provide feedback regarding the concerns that have been expressed. (See 483.10(f) for further information regarding grievances.)
- Identify, correct and intervene in situations in which abuse, neglect and/or misappropriation of resident property is more likely to occur.
- This includes an analysis of:
    - Features of the physical environment that may make abuse and/or neglect more likely to occur, such as secluded areas of the facility;
    - The deployment of staff on each shift in sufficient numbers to meet the needs of the residents, and assure that the staff assigned have knowledge of the individual residents' care needs;
    - The supervision of staff to identify inappropriate behaviors, such as using derogatory language, rough handling, ignoring residents while

giving care, directing residents who need toileting assistance to urinate or defecate in their beds; and

- The assessment, care planning, and monitoring of residents with needs and behaviors which might lead to conflict or neglect, such as residents with a history of aggressive behaviors, residents who have behaviors such as entering other residents' rooms, residents with self-injurious behaviors, residents with communication disorders, those that require heavy nursing care and/or are totally dependent on staff.

IV. Identification (483.13(c)(2)): Have procedures to:

- Identify events, such as suspicious bruising of residents, occurrences, patterns, and trends that may constitute abuse; and to determine the direction of the investigation.

V. Investigation (483.13(c)(3)): Have procedures to:

- Investigate different types of incidents; and

- Identify the staff member responsible for the initial reporting, investigation of alleged violations and reporting of results to the proper authorities. (See §483.13 (c)(2), (3), and (4).)

VI. Protection (483.13(c)(3): Have procedures to:

- Protect residents from harm during an investigation.

VII. Reporting/Response (483.13(c)(1)(iii), 483.13(c)(2) and 483.13(c)(4)): Have procedures to:

- Report all alleged violations and all substantiated incidents to the state agency and to all other agencies as required, and take all necessary corrective actions depending on the results of the investigation;

- Report to the State nurse aide registry or licensing authorities any knowledge it has of any actions by a court of law which would indicate an employee is unfit for service; and

- Analyze the occurrences to determine what changes are needed, if any, to policies and procedures to prevent further occurrences.

F225

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

The facility must—

§483.13(c)(1)(ii) Not employ individuals who have been--

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities

§483.13(c)(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

§483.13(c)(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

§483.13(c)(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

Intent §483.13(c)(1)(ii) and (iii)

The facility must not hire a potential employee with a history of abuse, if that information is known to the facility. The facility must report knowledge of actions by a court of law against an employee that indicates the employee is unfit for duty. The facility must report alleged violations, conduct an investigation of all alleged violations, report the results to proper authorities, and take necessary corrective actions.

Interpretive Guidelines §483.13(c)(1)(ii) and (iii)

Facilities must be thorough in their investigations of the past histories of individuals they are considering hiring. In addition to inquiry of the State nurse aide registry or licensing authorities, the facility should check information from previous and/or current employers and make reasonable efforts to uncover information about any past criminal prosecutions.

"**Found guilty** … **by a court of law**" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere.

"**Finding**" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents, or misappropriation of their property.

A certified nurse aide found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have her/his name entered into the nurse aide registry. A licensed staff member found guilty of the above must be reported to their licensing board. Further, if a facility determines that actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home (e.g., felony conviction of child abuse, sexual assault, or assault with a deadly weapon), then the facility must report that individual to the nurse aide registry (if a nurse aide) or to the State licensing authorities (if a licensed staff member). Such a determination by the facility is not limited to mistreatment, neglect and abuse of residents and misappropriation of their property, but to any treatment of residents or others inside or outside the facility which the facility determines to be such that the individual should not work in a nursing home environment.

A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

Interpretive Guidelines §483.13(c)(2) and (4)

The facility's reporting requirements under 483.13(c)(2) and (4) include reporting both alleged violations and the results of investigations to the State survey agency.

"Injuries of unknown source" – An injury should be classified as an "injury of unknown source" when both of the following conditions are met:

- The source of the injury was not observed by any person **or** the source of the injury could not be explained by the resident; **and**

- The injury is suspicious because of the extent of the injury **or** the location of the injury (e.g., the injury is located in an area not generally vulnerable to trauma) **or** the number of injuries observed at one particular point in time **or** the incidence of injuries over time.

"Immediately" means as soon as possible, but ought not exceed 24 hours after discovery of the incident, in the absence of a shorter State time frame requirement. Conformance with this definition requires that each State has a means to collect reports, even on off-duty hours (e.g., answering machine, voice mail, fax).

The phrase **"in accordance with State law"** modifies the word "officials" only. As such, State law may stipulate that alleged violations and the results of the investigations be reported to additional State officials beyond those specified in Federal regulations. This phrase does not modify what **types** of alleged violations must be reported or the time frames in which the reports are to be made. As such, States may not eliminate the obligation for any of the alleged violations (i.e., mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident property) to be reported, not can the State extablish longer time frames for reporting than mandated in the regulations at §§483.13(c)(2) and (4). No State can override the obligation of the nursing home to fulfill the requirements under §483.13(c), so long as the Medicare/Medicaid certification is in place.

F240

§483.15 Quality of Life

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

Interpretive Guidelines §483.15

The intention of the quality of life requirements is to specify the facility's responsibilities toward creating and sustaining an environment that humanizes and individualizes each resident. Compliance decisions here are driven by the quality of life each resident experiences.

F241

§483.15(a) Dignity

The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

Interpretive Guidelines §483.15(a)

"Dignity" means that in their interactions with residents, staff carries out activities that assist the resident to maintain and enhance his/her self-esteem and self-worth. For example:

- Grooming residents as they wish to be groomed (e.g., hair combed and styled, beards shaved/trimmed, nails clean and clipped);

- Assisting residents to dress in their own clothes appropriate to the time of day and individual preferences;

- Assisting residents to attend activities of their own choosing;

- Labeling each resident's clothing in a way that respects his or her dignity;

- Promoting resident independence and dignity in dining (such as avoidance of day-to-day use of plastic cutlery and paper/plastic dishware, bibs instead of napkins, dining room conducive to pleasant dining, aides not yelling);

- Respecting resident's private space and property (e.g., not changing radio or television station without resident's permission, knocking on doors and requesting permission to enter, closing doors as requested by the resident, not moving or inspecting resident's personal possessions without permission);

- Respecting resident's social status, speaking respectfully, listening carefully, treating residents with respect (e.g., addressing the resident with a name of the resident's choice, not excluding residents from conversations or discussing residents in community setting); and

- Focusing on residents as individuals when they talk to them and addressing residents as individuals when providing care and services.

Procedures §483.15(a)

For sampled residents, use the Resident Assessment Instrument (RAI) and comprehensive care plan to consider the resident's former life style and personal choices made while in the facility to obtain a picture of characteristic resident behaviors. As part of the team's information gathering and decision-making, look at the actions and omissions of staff and the uniqueness of the individual sampled resident and on the needs and preferences of the resident, not on the actions and omissions themselves.

Throughout the survey, observe: Do staff show respect for residents? When staff interact with a resident, do staff pay attention to the resident as an individual? Do staff respond in a timely manner to the resident's requests for assistance? In group activities, do staff focus attention on the group of residents? Or, do staff appear distracted when they interact with residents? For example, do staff continue to talk with each other while doing a "task" for a resident(s) as if she/he were not present?

If the survey team identifies potential compliance issues regarding the privacy of residents during treatment, refer to §483.10(e), F164.

F242

§483.15(b) Self-Determination and Participation

The resident has the right to--

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

Procedures §483.15(b)

Observe how well staff know each resident and what aspects of life are important to him/her. Determine if staff make adjustments to allow residents to exercise choice and self-determination.

Review MDS Background Information III (MDS version 2.0 section AC) for customary routines. For sampled residents, review MDS to determine level of participation in assessment and care planning by resident and family members. Review MDS, section G (MDS version 2.0 section F) for Psychosocial Well-Being and Care Planning.

If the facility has failed to reasonably accommodate the preferences of the resident consistent with interests, assessments and plan of care, see §483.15(e), F246.

Interpretive Guidelines §483.15(b)(3)

The intent of this requirement is to specify that the facility must create an environment that is respectful of the right of each resident to exercise his or her autonomy regarding what the resident considers to be important facets of his or her life. For example, if a facility changes its policy and prohibits smoking, it must allow current residents who smoke to continue smoking in an area that maintains the quality of life for these residents. Weather permitting, this may be an outside area. Residents admitted after the facility changes its policy must be informed of this policy at admission. (See §483.10(b)(1)). Or, if a resident mentions that her therapy is scheduled at the time of her favorite television program, the facility should accommodate the resident to the extent that it can.

F243

§483.15(c) Participation in Resident and Family Groups

(1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result form group meetings;

SEE INTEPRETIVE GUIDANCE FOR §483.15(c) AT TAG F244

F244

§483.15(c)(6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

Interpretive Guidelines §483.15(c)

This requirement does not require that residents' organize a residents or family group. However, whenever residents or their families wish to organize, facilities must allow them to do so without interference. The facility must provide the group with space, privacy for meetings, and staff support. Normally, the designated staff person responsible for assistance and liaison between the group and the facility's administration and any other staff members attend the meeting only if requested.

- "A resident's or family group" is defined as a group that meets regularly to:
    - Discuss and offer suggestions about facility policies and procedures affecting residents' care, treatment, and quality of life;
    - Support each other;
    - Plan resident and family activities;

- Participate in educational activities; or
- For any other purpose.

The facility is required to listen to resident and family group recommendations and grievances. Acting upon these issues does not mean that the facility must accede to all group recommendations, but the facility must seriously consider the group's recommendations and must attempt to accommodate those recommendations, to the extent practicable, in developing and changing facility policies affecting resident care and life in the facility. The facility should communicate its decisions to the resident and/or family group.

Procedures §483.15(c)

If no organized group exists, determine if residents have attempted to form one and have been unsuccessful, and, if so, why.

F245

§483.15(d) Participation in Other Activities

A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

Interpretive Guidelines §483.15(d)

The facility, to the extent possible, should accommodate an individual's needs and choices for how he/she spends time, both inside and outside the facility.

Ask the social worker or other appropriate staff how they help residents pursue activities outside the facility.

F246

(Rev. 5, Issued 11-19-04, Effective: 11-19-04, Implementation: 11-19-2004)

§483.15(e) Accommodation of Needs

A resident has a right to --

§483.15(e)(1) Reside and receive services in the facility with reasonable accommodations of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

ALSO SEE INTERPRETIVE GUIDANCE AT TAG F247

F247

A resident has a right to—

§483.15(e)(2) Receive notice before the resident's room or roommate in the facility is changed.

Interpretive Guidelines §483.15(e)

"Reasonable accommodations of individual needs and preferences," is defined as the facility's efforts to individualize the resident's environment. The facility's physical environment and staff behaviors should be directed toward assisting the resident in maintaining and/or achieving independent functioning, dignity, and well-being to the extent possible in accordance with the resident's own preferences, assessment and care plans. The facility should attempt to adapt such things as schedules, call systems, and room arrangements to accommodate residents' preferences, desires, and unique needs.

This requirement applies to areas and environment in accordance with needs and preferences NOT addresses at: §§483.10(k), Telephone; 483.10(1), Personal Property; 483.10(m), Married Couples; 483.15(b), Self-Determination and Participation; 483.15(f)(1), Activities; 483.15(g)(1), Social Services; 483.15(h)(1), Homelike Environment; 483.25(a)(2) and (3), Activities of Daily Living;483.25(f)(1), Psychosocial functioning; 483.25(h)(2), Accidents, Prevention-Assistive devices; 483.35(d)(3), Food prepared in a form designed to meet individual needs.

The facility must demonstrate that it accommodates residents' needs. For example, if the resident refuses a bath because he or she prefers a shower, prefers it at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the staff should make the necessary adjustments realizing the resident is not refusing to be clean but refusing the bath under the circumstance provided. The facility staff should meet with the resident to make adjustments in the care plan to accommodate his or her needs.

This includes learning the residents preferences and taking them into account when discussing changes of rooms or roommates and the timing of such changes. In addition, this also includes making necessary adjustments to ensure that residents are able to reach call cords, buttons or other communication mechanisms, as well as accommodating food activities or room choices.

Procedures §483.15(e)

Observe resident-staff interaction and determine to what extent staff attempt to accommodate residents' preferences. For those areas not addressed in other regulations, determine what happens when a resident states a preference in the form of a refusal. How does the staff attempt to learn what the resident is refusing, and why, and make adjustments to an extent practicable to meet the resident's needs?

Probes: §483.15(e)

- Are rooms arranged such that residents in wheel chairs can easily access personal items and transfer in and out of bed?
- Does the facility respond to residents' stated needs and preferences?
- If the resident is unable to express needs and preferences that would individualize care, has the family expressed the resident's routine and has the facility responded?

Interpretive Guidelines §483.15(e)(1)

Review the extent to which the facility adapts the physical environment to enable residents to maintain unassisted functioning. These adaptations include, but are not limited to:

1. Furniture and adaptive equipment that enable residents to:

    a. Stand independently;

    b. Transfer without assistance (e.g., arm supports, correct chair height, firm support);

    c. Maintain body symmetry; and

    d. Participate in resident-preferred activities.

2. Measures that:

    a. Enable residents with dementia to walk freely;

    b. Reorient and remotivate residents with restorative potential (e.g., displaying easily readable calendars and clocks, wall hangings evocative of the lives of residents);

    c. Promote conversation and socialization (pictures and decorations that speak to the resident's age cohort); and

d. Promote mobility and independence for disabled residents in going to the bathroom (e.g., grab bars, elevated toilet seats).

Determine if staff use appropriate measures to facilitate communication with residents who have difficulty communicating. For example, if necessary, does staff get at eye level, allow them to remove a resident from noisy surroundings?

Determine if staff communicate effectively with residents with cognitive impairments, such as referring in a non-contradictory way to what residents are saying, and addressing what residents are trying to express to the agenda behind their behavior.

Probes: §483.15(e)(1)(2)

How have residents' needs been accommodated? Do environmental adaptations enhance residents' independence, self-control, and highest practicable well-being? Is the fit between residents' needs and environment positive?

F248

§483.15(f) Activities

§483.15(f)(1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

Interpretive Guidelines §483.15(f)(1)

Because the activities program should occur within the context of each resident's comprehensive assessment and care plan, it should be multi-faceted and reflect each individual resident's needs. Therefore, the activities program should provide stimulation or solace; promote physical, cognitive and/or emotional health; enhance, to the extent practicable, each resident's physical and mental status; and promote each resident's self-respect by providing, for example, activities that support self-expression and choice.

Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers and visitors.

Probes: §483.15(f)(1)

Observe individual, group and bedside activities.

1. Are residents who are confined or choose to remain in their rooms provided with in room activities in keeping with life-long interests (e.g., music, reading, visits with individuals who share their interests or reasonable attempts to connect the

resident with such individuals) and in-room projects they can work on independently? Do any facility staff members assist the resident with activities he or she can pursue independently?

2. If residents sit for long periods of time with no apparently meaningful activities, is the cause:

    a. Resident choice;

    b. Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities;

    c. Lack of assistance with ambulation;

    d. Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs.

    e. Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?

For residents selected for a comprehensive review, or a focused review, as appropriate, determine to what extent the activities reflect the individual resident's assessment. (See especially MDS version 2.0 sections AC, B, C, D, and N.)

Review the activity calendar for the month prior to the survey to determine if the formal activity program:

- Reflects the schedules, choices and rights of the residents;
- Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends);
- Reflects the cultural and religious interests of the resident population; and
- Would appeal to both men and women and all age groups living in the facility.

Review clinical records and activity attendance records of residents receiving a comprehensive review, or a focused review, as appropriate, to determine if:

- Activities reflect individual resident history indicated by the comprehensive assessment;
- Care plans address activities that are appropriate for each resident based on the comprehensive assessment;
- Activities occur as planned; and

Outcomes/responses to activities interventions are identified in the progress notes of each resident.

_____

_____

F249

§483.15(f)(2) The activities program must be directed by a qualified professional who--

(i) Is a qualified therapeutic recreation specialist or an activities professional who--

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

Interpretive Guidelines §483.15(f)(2)

A “recognized accrediting body” refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists.

Procedures §483.15(f)(2)

If there are problems with provision of activities, determine if these services are provided by qualified staff.

§483.15(g) Social Services

F250

§483.15(g)(1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Intent §483.15(g)

To assure that sufficient and appropriate social service are provided to meet the resident's needs.

Interpretive Guidelines §483.15(g)(1)

Regardless of size, all facilities are required to provide for the medically related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. It is not required that a qualified social worker necessarily provide all of these services. Rather, it is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate disciplines.

"Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example:

- Making arrangements for obtaining needed adaptive equipment, clothing, and personal items;
- Maintaining contact with facility (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning;
- Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications;
- Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation);
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements);

- Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities);

- Providing or arranging provision of needed counseling services;

- Through the assessment and care planning process, identifying and seeking ways to support residents' individual needs;

- Promoting actions by staff that maintain or enhance each resident's dignity in full recognition of each resident's individuality;

- Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions;

- Finding options that most meet the physical and emotional needs of each resident;

- Providing alternatives to drug therapy or restraints by understanding and communicating to staff why residents act as they do, what they are attempting to communicate, and what needs the staff must meet;

- Meeting the needs of residents who are grieving; and

- Finding options which most meet their physical and emotional needs

Factors with a potentially negative effect on physical, mental, and psychosocial well being include an unmet need for:

- Dental /denture care;

- Podiatric care;

- Eye Care;

- Hearing services

- Equipment for mobility or assistive eating devices; and

- Need for home-like environment, control, dignity, privacy

Where needed services are not covered by the Medicaid State plan, nursing facilities are still required to attempt to obtain these services. For example, if a resident requires transportation services that are not covered under a Medicaid state plan, the facility is

required to arrange these services. This could be achieved, for example, through obtaining volunteer assistance.

Types of conditions to which the facility should respond with social services by staff or referral include:

- Lack of an effective family/support system;
- Behavioral symptoms;
- If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior. For example, a resident may be re-enacting an activity he or she used to perform at the same time everyday. If that resident senses that another is in the way of his re-enactment, the resident may strike out at the resident impeding his or her progress. The facility is responsible for the safety of any potential resident victims while it assesses the circumstances of the residents behavior);
- Presence of a chronic disabling medical or psychological condition (e.g., multiple sclerosis, chronic obstructive pulmonary disease, Alzheimer's disease, schizophrenia);
- Depression
- Chronic or acute pain;
- Difficulty with personal interaction and socialization skills;
- Presence of legal or financial problems
- Abuse of alcohol or other drugs;
- Inability to cope with loss of function;
- Need for emotional support;
- Changes in family relationships, living arrangements, and/or resident's condition or functioning; and
- A physical or chemical restraint.
- For residents with or who develop mental disorders as defined by the "Diagnostic and Statistical Manual for Mental Disorders (DSM-IV)," see §483.45, F406.

Probes: §483.15(g)(1)

For residents selected for a comprehensive or focused review as appropriate:

- How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
- How do staff responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly?
- How does the care plan link goals to psychosocial functioning/well-being?
- Have the staff responsible for social work established and maintained relationships with the resident's family or legal representative?
- [NFs] What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan?

Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

For sampled residents, review MDS, section H.

F251

§483.15(g)(2) and (3)

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) Qualifications of a social worker. A qualified social worker is an individual with-

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals

Procedures §483.15(g)(2) and (3)

If there are problems with the provision of social services in a facility with over 120 beds, determine if a qualified social worker is employed on a full time basis. See also F250.

F252

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.15(h) Environment

The facility must provide--

§483.15(h)(1) A safe, clean, comfortable and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

Interpretive Guidelines §483.15(h)(1)

For "safe" environment, also see Guidelines for §§483.25(h), Accidents, and 483.70(a), Life Safety Code."

For Comfortable Environment, see Guidelines for 483.15(h)(5), Adequate and Comfortable Lighting Levels; 483.15(h)(6), Comfortable and Safe Temperature Levels; and 483.15(h)(7), Comfortable Sound Levels.

A determination of "comfortable and homelike" should include, whenever possible, the resident's or representative of the resident's opinion of the living environment.

The absence of a personalized, homelike environment in a resident's room, is not meaningful unless the survey team determines that the absence of personal belongings is a result of facility practices, rather than the result of resident choice or circumstances (e.g., lack of resident funds, lack of family support system, resident's reason for being in the facility, such as short-term rehabilitation).

A "homelike environment" is one that de-emphasizes the institutional character of the setting, to the extent possible, and allows the resident to use those personal belongings that support a homelike environment. A personalized, homelike environment recognizes the individuality and autonomy of the resident, provides an opportunity for self-expression and encourages links with the past and family members. Use this Tag when the facility fails to allow the resident to personalize his or her individual environment to the extent possible. Use Tag F224, 483.15(c), if the facility fails to have a system in place to prevent the misappropriation of resident's property.

For purposes of this requirement, “environment” refers to any environment in the facility that is frequented by residents, including the residents’ rooms, bathrooms, hallways, activity areas, and therapy areas.

If the survey team observes that the rooms of residents with dementia do not appear to be homelike, determine if this decision was made in the context of assessment and care planning; i.e., that this environment assists these residents to maintain their highest practicable functioning levels.

If the team observes non-homelike environments for residents with dementia, determine if each of these residents have the same plan of care and the reason why each of these residents have the same plan of care.

By observing the residents’ surroundings, what can the survey team learn about their everyday life and interests? Their life prior to residing in the facility? Observe for family photographs, books and magazines, bedspreads, knickknacks, mementos, and furniture that belong to the residents. For residents who have no relatives or friends, and have few assets, determine the extent to which the facility has assisted these residents to make their rooms homelike, if they so desire.

F253

§483.15(h)(2)

§483.15(h)(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

Intent §483.15(h)(2)

The intent of this requirement is to focus on the facility’s responsibility to provide effective housekeeping and maintenance services.

Interpretive Guidelines §483.15(h)(2)

“Sanitary” includes, but is not limited to, preventing the spread of disease-causing organisms by keeping resident care equipment clean and properly stored. Resident care equipment includes toothbrushes, dentures, denture cups, glasses and water pitchers, emesis basins, hair brushes and combs, bed pans, urinals, feeding tubes, leg bags and catheter bags, pads and positioning devices.

For kitchen sanitation, see §483.70(h), Other Environmental Conditions.

For facility-wide sanitary practices affecting the quality of care, see §483.65, Infection Control.

"Orderly" is defined as an uncluttered physical environment that is neat and well-kept.

Procedures §483.15(h)(2)

Balance the resident's need for a homelike environment and the requirements of having a "sanitary" environment in a congregate living situation. For example, a resident may prefer a cluttered room, but does this clutter result in unsanitary or unsafe conditions?

Probes: §483.15(h)(2)

Is resident care equipment sanitary?

Is the area orderly?

Is the area uncluttered and in good repair?

Can residents and staff function unimpeded?

F254

§483.15(h)(3)

§483.15(h)(3) Clean bed and bath linens that are in good condition;

Probes: §483.15(h)(3)

Are bed linens clean and in good condition? Are there clean towels and wash cloths in good condition available for the resident?

F255

§483.15(h)(4)

§483.15(h)(4) Private closet space in each resident room, as specified in §483.70(d)(2)(iv) of this part;

Interpretive Guidelines §483.15(h)(4)

§483.70(d)(2)(iv) states: "The facility must provide each resident with individual closet space in his/her bedroom with clothes racks and shelves accessible to the resident."

Probes: §483.15(h)(4)

Are there individual closet spaces with accessible shelves?

Also see F470.

F256

§483.15(h)(5)

§483.15(h)(5) Adequate and comfortable lighting levels in all areas;

Interpretive Guidelines §483.15(h)(5)

"Adequate lighting" is defined as levels of illumination suitable to tasks the resident chooses to perform or the facility staff must perform. For some residents (e.g., those with glaucoma), lower levels of lighting would be more suitable.

"Comfortable" lighting is defined as lighting which minimizes glare and provides maximum resident control, where feasible, over the intensity, location, and direction of illumination so that visually impaired residents can maintain or enhance independent functioning.

Procedures §483.15(h)(5)

Are there adequate and comfortable lighting levels for individual resident and staff work needs?

Consider the illumination available from any source, natural or artificial. For hallways, observe the illumination that is normally present. For resident rooms or for other spaces where residents can control the lighting, turn on the lights and make the rating under these conditions.

F257

§483.15(h)(6)

§483.15(h)(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71 - 81° F; and

Procedures §483.15(h)(6)

"Comfortable and safe temperature levels" means that the ambient temperature should be in a relatively narrow range that minimizes residents' susceptibility to loss of body heat and risk of hypothermia or susceptibility to respiratory ailments and colds. Although there are no explicit temperatures standards for facilities certified on or before October 1, 1990, these facilities still must maintain safe and comfortable temperature levels.

For facilities certified after October 1, 1990, temperatures may exceed the upper range of 81° F for facilities in geographic areas of the country (primarily at the northernmost latitudes) where that temperature is exceeded only during rare, brief unseasonably hot weather. This interpretation would apply in cases where it does not adversely affect resident health and safety, and would enable facilities in areas of the country with relatively cold climates to avoid the expense of installing air conditioning equipment that would only be needed infrequently. Conversely, the temperatures may fall below 71° F for facilities in areas of the country where that temperature is exceeded only during brief episodes of unseasonably cold weather (minimum temperature must still be maintained at a sufficient level to minimize risk of hypothermia and susceptibility to loss of body heat, respiratory ailments and colds.)

Measure the air temperature above floor level in resident rooms, dining areas, and common areas. If the temperature is out of the 71-81 degree range, then ask staff what actions they take when residents complain of heat or cold, e.g., provide extra fluids during heat waves and extra blankets and sweaters in cold.

F258

§483.15(h)(7)

§483.15(h)(7) For the maintenance of comfortable sound levels.

Interpretive Guidelines §483.15(h)(7)

"Comfortable" sound levels do not interfere with resident's hearing and enhance privacy when privacy is desired, and encourage interaction when social participation is desired. Of particular concern to comfortable sound levels is the resident's control over unwanted noise.

Procedures §483.15(h)(7)

Determine if the sound levels are comfortable to residents. Do residents and staff have to raise their voices to communicate over background sounds? Are sound levels suitable for the activities occurring in that space during observation?

Consider whether residents have difficulty hearing or making themselves heard because of background sounds (e.g., overuse or excessive volume of intercom, shouting, loud TV, cleaning equipment). Consider if it is difficult for residents to concentrate because of distractions or background noises such as traffic, music, equipment, or staff behavior. Consider the comfort of sound levels based on the needs of the residents participating in a particular activity, e.g., the sound levels may have to be turned up for hard of hearing individuals watching TV or listening to the radio. Consider the effect of noise on the comfort of residents with dementia.

During resident reviews, ask residents if during evenings and at nighttime, sounds are at comfortable levels? (If yes) Have you told staff about it and how have they responded?

F271

§483.20(a) Admission Orders

At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

Intent §483.20(a)

To ensure the resident receives necessary care and services.

Interpretive Guidelines §483.20(a)

"Physician orders for immediate care" are those written orders facility staff need to provide essential care to the resident, consistent with the resident's mental and physical status upon admission. These orders should, at a minimum, include dietary, drugs (if necessary) and routine care to maintain or improve the resident's functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.

F272

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident's functional capacity.

Intent §483.20

To provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, family members, or outside consultants and review of the resident's record.

§483.20(b) Comprehensive Assessments

§483.20(b)(1) Resident Assessment Instrument. A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State. The assessment must include at least the following:

- **(i) Indentification and demographic information**
- **(ii) Customary routine.**
- **(iii) Cognitive patterns.**
- **(iv) Communication.**
- **(v) Vision.**
- **(vi) Mood and behavior patterns.**
- **(vii) Psychological well-being.**
- **(viii) Physical functioning and structural problems.**
- **(ix) Continence.**
- **(x) Disease diagnosis and health conditions.**
- **(xi) Dental and nutritional status.**
- **(xii) Skin Conditions.**
- **(xiii) Activity pursuit.**
- **(xiv) Medications.**
- **(xv) Special treatments and procedures.**
- **(xvi) Discharge potential.**
- **(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.**
- **(xviii) Documentation of participation in assessment.**

§483.20(b) Intent

To ensure that the RAI is used in conducting comprehensive assessments as part of an ongoing process through which the facility identifies the resident's functional capacity and health status.

§483.20(b) Guidelines

The information required in §483.20(b)(i-xvi) is incorporated into the MDS, which forms the core of each State's approved RAI. Additional assessment information is also gathered using triggered RAPs.

Each facility must use its State-specified RAI (which includes both the MDS and utilization guidelines which include the RAPs) to assess newly admitted residents, conduct an annual reassessment and assess those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or RAPs. The scope of

the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. Furthermore:

(i) Identification and demographic information

"Identification and demographic information" corresponds to MDS v 2.0 sections AA, BB and A, and refers to information that uniquely identifies each resident and the facility in which he/she resides, date of entry into the facility and residential history.

(ii) Customary routine

"Customary routine" corresponds to MDS v 2.0 section AC, and refers to information regarding the resident's usual community lifestyle and daily routine in the year prior to the date of entry to the nursing home.

(iii) Cognitive patterns

"Cognitive patterns" (iii) corresponds to MDS v. 2.0 section B. "Cognitive patterns" is defined as the resident's ability to problem solve, decide, remember, and be aware of and respond to safety hazards.

(iv) Communication

"Communication" (iv) corresponds to MDS v. 2.0 section C, and refers to the resident's ability to hear, understand others, make him or herself understood (with assistive devices if they are used).

(v) Vision

"Vision" (v) corresponds to MDS v. 2.0 section D, and I.1.jj, kk, ll and mm, and refers to the resident's visual acuity, limitations and difficulties, and appliances used to enhance vision.

(vi) Mood and behavior patterns

"Mood and behavior patterns" (vi) corresponds to MDS v. 2.0 section E, and refers to the resident's patterns of mood and behavioral symptoms

(vii) Psychosocial well-being

"Psychosocial well-being" (vii) corresponds to MDS v. 2.0 sections E1o and p, and F and refers to the resident's positive or negative feelings about him or herself or his/her social relationships.

(viii) Physical functioning and structural problems

"Physical functioning and structural problems" (viii) corresponds to MDS v. 2.0 section G, and refers to the resident's physical functional status, ability to perform activities of daily living, and the resident's need for staff assistance and assistive devices or equipment to maintain or improve functional abilities.

(ix) Continence

"Continence" (ix) corresponds to MDS v. 2.0, section H, and refers to the resident's patterns of bladder and bowel continence (control), pattern of elimination, and appliances used.

(x) Disease diagnosis and health conditions

"Disease diagnoses and health conditions" (x) corresponds to MDS v. 2.0, sections AB.9 and 10, I.1 and 2, and J.

(xi) Dental and nutritional status

"Dental and nutritional status" (xi) corresponds to MDS v. 2.0, sections K1 and L.

"Dental condition status" refers to the condition of the teeth, gums, and other structures of the oral cavity that may affect a resident's nutritional status, communication abilities, or quality of life. The assessment should include the need for, and use of, dentures or other dental appliances.

"Nutritional status" corresponds to MDS v. 2.0, section K2-6.

Nutritional status refers to weight, height, hematologic and biochemical assessments, clinical observations of nutrition, nutritional intake, resident's eating habits and preferences, dietary restrictions, supplements, and use of appliances.

(xii) Skin conditions

"Skin conditions" (xii) corresponds to MDS v. 2.0 sections M, G1a, G6a, H1a, H1b, and P4c, and refers to the resident's development, or risk of development of a pressure sore.

(xiii) Activity pursuit

"Activity pursuit" (xiii) corresponds to MDS v. 2.0 sections N and AC.

"Activity pursuit" refers to the resident's ability and desire to take part in activities which maintain or improve, physical, mental, and psychosocial well-being. Activity pursuits refer to any activity outside of activities of daily living

(ADLs) which a person pursues in order to obtain a sense of well-being. Also, includes activities which provide benefits in self-esteem, pleasure, comfort, health education, creativity, success, and financial or emotional independence. The assessment should consider the resident's normal everyday routines and lifetime preferences.

(xiv) Medications

"Medications" (xiv) corresponds to MDS v. 2.0, section O, and section U, if completed.

"Medications" refers to all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information need not appear in the assessment. However, it must be in the resident's clinical record and included in the care plan.

(xv) Special treatments and procedures

"Special treatments and procedures" (xv) corresponds to MDS v. 2.0 sections K5, M5, and P1, and section T, if completed.

"Special treatments and procedures" refers to treatments and procedures that are not part of basic services provided. For example, treatment for pressure sores, naso-gastric feedings, specialized rehabilitation services, respiratory care, or devices and restraints.

(xvi) Discharge potential

"Discharge potential" (xvi) corresponds to MDS v. 2.0 section Q.

"Discharge potential" refers to the facility's expectation of discharging the resident from the facility within The next 3 months.

(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols

"Documentation of summary information (xvii) regarding the additional assessment performed through the resident assessment protocols (RAPs)" corresponds to MDS v. 2.0 section V, and refers to documentation concerning which RAPs have been triggered, documentation of assessment information in support of clinical decision making relevant to the RAP, documentation regarding where, in the clinical record, information related to the RAP can be found, and for each triggered RAP, whether the identified problem was included in the care plan.

(xviii) Documentation of participation in assessment

"Documentation of participation in the assessment" corresponds to MDS v. 2.0 section R, and refers to documentation of who participated in the assessment process. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

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§483.20(b)(2)

§483.20(b)(2) When required, a facility must conduct a comprehensive assessment of a resident as follows:

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, "readmission" means a return to the facility following a temporary absence for hospitalization for therapeutic leave.)

Intent §483.20(b)(2)

To assess residents in a timely manner.

F274

§483.20(b)(2)(ii)

(ii) Within 14 days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purpose of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

§483.20(b)(2)(ii) Guidelines

The following are the criteria for significant changes:

A significant change reassessment is generally indicated if decline or improvement is consistently noted in 2 or more areas of decline or 2 or more areas of improvement:

Decline:

- Any decline in activities of daily living (ADL) physical functioning where a resident is newly coded as 3, 4 or 8 Extensive Assistance, Total Dependency, activity did not occur (note that even if coding in both columns A and B of an ADL category changes, this is considered 1 ADL change);
- Increase in the number of areas where Behavioral Symptoms are coded as "not easily altered" (e.g., an increase in the use of code 1's for E4B);
- Resident's decision-making changes from 0 or 1, to 2 or 3;
- Resident's incontinence pattern changes from 0 or 1 to 2, 3 or 4, or placement of an indwelling catheter;
- Emergence of sad or anxious mood as a problem that is not easily altered;
- Emergence of an unplanned weight loss problem (5% change in 30 days or 10% change in 180 days);
- Begin to use trunk restraint or a chair that prevents rising for a resident when it was not used before;
- Emergence of a condition/disease in which a resident is judged to be unstable;
- Emergence of a pressure ulcer at Stage II or higher, when no ulcers were previously present at Stage II or higher; or
- Overall deterioration of resident's condition; resident receives more support (e.g., in ADLs or decision making).

Improvement:

- Any improvement in ADL physical functioning where a resident is newly coded as 0, 1, or 2 when previously scored as a 3, 4, or 8;
- Decrease in the number of areas where Behavioral Symptoms or Sad or Anxious Mood are coded as "not easily altered";
- Resident's decision making changes from 2 or 3, to 0 or 1;
- Resident's incontinence pattern changes from 2, 3, or 4 to 0 or 1; or
- Overall improvement of resident's condition; resident receives fewer supports.

- If the resident experiences a significant change in status, the next annual assessment is not due until 366 days after the significant change reassessment has been completed.

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§483.20(b)(2)(iii)

(iii) Not less than once every 12 months.

Interpretive Guidelines §483.20(b)(2)(iii):

The annual resident assessment must be completed within 366 days after final completion of the most recent comprehensive resident assessment.

Probes§483.20(b)(2):

- Has each resident in the sample been comprehensively assessed using the State-specified RAI within the regulatory timeframes (i.e., within 14 days after admission, on significant change in status, and at least annually)?

- Has the facility identified, in a timely manner, those residents who have experienced a change?

- Has the facility reassessed residents using the State-specific RAI who had a significant change in status within 14 days after determining the change was significant.

- Has the facility gathered supplemental assessment information based on triggered RAPs prior to establishing the care plan?

- Does information in the RAI correspond with information obtained during observations of and interviews with the resident, facility staff and resident's family?

F276

§483.20(c) Quality Review Assessment.

A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

Intent §483.20(c):

To assure that the resident's assessment is updated on at least a quarterly basis.

Interpretive Guidelines §483.20(c):

At least each quarter, the facility shall review each resident with respect to those MDS items specified under the State's quarterly review requirement. At a minimum, this would include all items contained in CMS' standard quarterly review form. A Quarterly review assessment must be completed within 92 days of the date at MDS Item R2b of the most recent, clinical assessment (AA8a=1,2,3,4,5 or 10). If the resident has experienced a significant change in status, the next quarterly review is due no later than 3 months after the significant change reassessment.

Probes §483.20(c):

Is the facility assessing and acting, no less than once every 3 months, on the results of resident's functional and cognitive status examinations?

Is the quarterly review of the resident's condition consistent with information in the progress notes, the plan of care and your resident observations and interviews?

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§483.20(d) Use

A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record.

Intent §483.20(d):

Facilities are required to maintain 15 months of assessment data in the resident's active clinical record.

Interpretive Guidelines §483.20(d):

The requirement to maintain 15 months of data in the resident's active clinical record applies regardless of form of storage to all MDS forms, RAP Summary forms, Quarterly Assessment forms, Face Sheet Information and Discharge and Reentry Tracking Forms and MDS Correction Request Forms (including signed attestation). MDS assessments must be kept in the resident's active clinical record for 15 months following the final completion date, tracking forms for discharge and reentry must be kept for 15 months following the date of the event, Correction Request Forms must be kept for 15 months following the final completion date of the MDS Correction Request form.

The information must be kept in a centralized location, accessible to all professional staff members (including consultants) who need to review the information in order to provide care to the resident.

After the 15-month period, RAI information may be thinned from the clinical record and stored in the medical records department, provided that it is easily retrievable if requested by clinical staff, the State agency, or CMS.

Whether or not the facility's clinical record system is entirely electronic, a hard copy of all MDS forms, including the signatures of the facility staff attesting to the accuracy and completion of the records, must be maintained in the resident's clinical record.

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§483.20(f) Automated Data Processing Requirement

§483.20(f)(1) Encoding Data. Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.

(ii) Annual assessment updates.

(iii) Significant change in status assessments.

(iv) Quarterly review assessments.

(v) A subset of items upon a resident's transfer, reentry, discharge, and death.

(vi) Background (face-sheet) information, if there is no admission assessment.

§483.20(f)(2) Transmitting data. Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

§483.20(f)(3) Monthly transmittal requirements. A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:

(i) Admission assessment.

(ii) Annual assessment.

(iii) Significant change in status assessment.

(iv) Significant correction of prior full assessment.

(v) Significant correction of prior quarterly assessment.

(vi) Quarterly review.

(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

§483.20(f)(4) Data format. The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

Intent §483.20(f)(1-4):

The intent is to enable a facility to better monitor a resident's decline and progress over time. Computer-aided data analysis facilitates a more efficient, comprehensive and sophisticated review of health data. The primary purpose of maintaining the assessment data is so a facility can monitor resident progress over time. The information should be readily available at all times.

Interpretive Guidelines §483.20(f)(1-4):

"Encoding" means entering MDS information into a computer.

"Transmitting data" refers to electronically sending encoded MDS information, from the facility to the State database, using a modem and communications software.

"Capable of transmitting" means that the facility has encoded and edited according to CMS specifications, the record accurately reflects the resident's overall clinical status as of the assessment reference date, and the record is ready for transmission.

"Passing standard edits" means that the encoded responses to MDS items are consistent and within range, in accordance with CMS specified standards. In general, inconsistent responses are either not plausible or ignore a skip pattern on the MDS. An example of inconsistency would be if one or more MDS items on a list were checked as present, and the "None of the Above" response was also checked for the same list. Out of range responses are invalid responses, such as using a response code of 2 for an MDS item for which the valid responses are zero or 1.

"Monthly Transmittal" means electronically transmitting to the State, an MDS record that passes CMS' standard edits, within 31 days of the final completion date of the record.

“Accurate” means that the encoded MDS data matches the MDS form in the clinical record. Also refer to guidance regarding accuracy at §483.20(g), and the information accurately reflects the resident’s status as of the Assessment Reference Date at MDS Item A3a.

“Complete” means that all items required according to the record type, and in accordance with CMS’ record specifications and State required edits are in effect at the time the record is completed.

In accordance with the final rule, facilities will be responsible to edit the encoded MDS data to ensure that it meets the standard edit specifications.

We encourage facilities to use software that has a programmed capability to automatically edit MDS records according to CMS’ edit specifications.

For §483.20(f)(1)(v), the subset of items required upon a resident’s transfer, discharge, and death are contained in the Discharge Tracking form and the items required for reentry are contained in the Reentry Tracking form. Refer to Appendix R for further information about the Discharge Tracking and Reentry Tracking forms.

All nursing homes must computerize MDS information. The facility must edit MDS information using standard CMS-specified edits, revise the information to conform to the edits and to be accurate, and be capable of transmitting that data to the State system within 7 days of:

- Completing a comprehensive assessment (the date at MDS item VB4);
- Completing an assessment that is not comprehensive (the date at MDS item R2b);
- A discharge event (the date at MDS item R4);
- A reentry event (the date at MDS item A4a); or
- Completing a correction request form (the date at MDS item AT6).

Submission must be according to State and Federal time frames. Therefore the facility must:

- Encode the MDS and RAP Summary (where applicable) in machine readable format;
- Edit the MDS and RAP Summary (where applicable) according to edits specified by CMS. Within the 7 day time period specified above for editing, the facility must revise any information on the encoded MDS and RAP Summary (if applicable) that does not pass CMS-specified edits, revise any

otherwise inaccurate information, and make the information ready for submission. The MDS Vendor software used at the facility should have an automated editing process that alerts the user to entries in an MDS record that do not conform with the CMS-specified edits and that prompts the facility to complete revisions within the 7-day editing and revision period. After editing and revision, MDS information and RAP summary information (if applicable) must always accurately reflect the resident's overall clinical status as of the original Assessment Reference date for an assessment or the original event date for a discharge or reentry;

- Print the edited and revised MDS and RAP summary form (where applicable). Discharge or Reentry Tracking form or Correction Request form, and place it in the resident's record. The hard copy of the MDS record must match the record that the facility transmits to the State, and it must accurately reflect the resident's status as of the Assessment Reference date or event date. If a hard copy exists prior to data entry, the facility must correct the hard copy to reflect the changes associated with the editing and revision process.

Electronically submit MDS information to the State MDS database within 31 days of:

- The date the Care Planning Decision process was complete (the date at MDS Item VB4) for comprehensive assessments;

- The date the RN Coordinator certified that the MDS was complete (the date at MDS Item R2b) for assessments that are not comprehensive;

- The date of death or discharge (the date at MDS Item R4) for Discharge Tracking forms;

- The date of reentry (the date at MDS Item A4a) for Reentry Tracking forms; and

- The date of completion of a correction request (the date at MDS Item AT6)

For a discussion of the process that a facility should follow in the event an error is discovered in an MDS record after editing and revision but before it is transmitted to the State, refer to "Correction Policy for MDS Records" in the State Operations Manual, Appendix R, Part IV.

The facility must maintain RAI assessments and Discharge and Reentry Tracking forms, as well as correction information, including Correction Request forms as a part of the resident's clinical record. Whether or not the facility's system is entirely electronic, a hard copy of completed MDS forms, including the signature of the facility staff attesting to the accuracy and completion of the corrected record, must be maintained in the resident's clinical record.

A facility must complete and submit to the State a subset of items when the resident is discharged from the facility (discharge tracking form), or readmitted to the facility (reentry tracking form.

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§483.20(g) Accuracy of Assessment

The assessment must accurately reflect the resident's status.

Intent §483.20(g):

To assure that each resident receives an accurate assessment by staff that are qualified to assess relevant care areas and knowledgeable about the resident's status, needs, strengths, and areas of decline.

Interpretive Guidelines §483.20(g):

"The accuracy of the assessment" means that the appropriate, qualified health professional correctly documents the resident's medical, functional, and psychosocial problems and identifies resident strengths to maintain or improve medical status, functional abilities, and psychosocial status. The initial comprehensive assessment provides baseline data for ongoing assessment of resident progress.

§483.20(h) Coordination

A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

Intent §483.20(h):

The registered nurse will conduct and/or coordinate the assessment, as appropriate. Whether conducted or coordinated by the registered nurse, he or she is responsible for certifying that the assessment has been completed.

Interpretive Guidelines §483.20(h):

According to the Utilization Guidelines for each State's RAI, the physical, mental and psychosocial condition of the resident determines the appropriate level of involvement of physicians, nurses, rehabilitation therapists, activities professionals, medical social workers, dietitians, and other professionals, such as developmental disabilities specialists, in assessing the resident, and in correcting resident assessments. Involvement of other disciplines is dependent upon resident status and needs.

Probes §483.20(g)(h):

Have appropriate health professionals assessed the resident? For example, has the resident's nutritional status been assessed by someone who is knowledgeable in nutrition and capable of correctly assessing a resident?

If the resident's medical status, functional abilities, or psychosocial status declined and the decline was not clinically unavoidable, were the appropriate health professionals involved in assessing the resident?

Based on your total review of the resident, is each portion of the assessment accurate?

Are the appropriate certifications in place, including the RN Coordinator's certification of completion of an assessment or Correction Request form, and the certification of individual assessors of the accuracy and completion of the portion(s) of the assessment, tracking form or face sheet they completed or corrected. On an assessment or correction request, the RN Assessment Coordinator is responsible for certifying overall completion once all individual assessors have completed and signed their portion(s) of the MDS forms. When MDS forms are completed directly on the facility's computer, (e.g., no paper form has been manually completed), the RN Coordinator signs and dates the computer generated hard copy after reviewing it for completeness, including the signatures of all individual assessors. Backdating a completion date is not acceptable.

§483.20(i) Certification

(1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

Interpretive Guidelines §483.20(i):

Whether the MDS forms are manually completed, or computer generated following data entry, each individual assessor is responsible for certifying the accuracy of responses on the forms relative to the resident's condition and discharge or reentry status. Manually completed forms are signed and dated by each individual assessor the day they complete their portion(s) of the MDS record. When MDS forms are completed directly on the facility's computer (e.g., no paper form has been manually completed), then each individual assessor signs and dates a computer generated hard copy, after they review it for accuracy of the portion(s) they completed. Backdating completion dates is not acceptable.

§483.20(j) Penalty for Falsification

(1) Under Medicare and Medicaid, an individual who willfully and knowingly--

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty or not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

Interpretive Guidelines §483.20(j):

MDS information serves as the clinical basis for care planning and delivery. With the introduction of additional uses of MDS information such as for payment rate setting and quality monitoring, MDS information as it is reported impacts a nursing home's payment rate and standing in terms of the quality monitoring process. A pattern within a nursing home of clinical documentation or of MDS assessment or reporting practices that result in higher RUG scores, untriggering RAP(s), or unflagging QI(s), where the information does not accurately reflect the resident's status, may be indicative of payment fraud or avoidance of the quality monitoring process. Such practices may include but are not limited to a pattern or high prevalence of the following:

- Submitting MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Reentry Tracking forms, where the information does not accurately reflect the resident's status as of the Assessment Reference date, or the Discharge or Reentry date, as applicable;

- Submitting correction(s) to information in the State MDS database where the corrected information does not accurately reflect the resident's status as of the original Assessment Reference date, or the original Discharge or Reentry date, as applicable, or where the record it claims to correct does not appear to have been in error;

- Submitting Significant Correction Assessments where the assessment it claims to correct does not appear to have been in error;

- Submitting Significant Change in Status Assessments where the criteria for significant change in the resident's status do not appear to be met;

- Delaying or withholding MDS Assessments (including any reason(s) for assessment, routine or non-routine), Discharge or Reentry Tracking information, or correction(s) to information in the State MDS database.

When such patterns or practices are noticed, they should be reported by the State Agency to the proper authority.

F279

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.20(d) (A facility must..) use the results of the assessment to develop, review and revise the resident's comprehensive plan of care.

§483.20(k) Comprehensive Care Plans

(1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following:

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and

(ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

Interpretive Guidelines §483.20(k):

An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The interdisciplinary team should show evidence in the RAP summary or clinical record of the following:

- The resident's status in triggered RAP areas;
- The facility's rationale for deciding whether to proceed with care planning; and
- Evidence that the facility considered the development of care planning interventions for all RAPs triggered by the MDS.

The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to monitor resident progress. Facilities may, for some residents,

need to prioritize their care plan interventions. This should be noted in the clinical record or on the plan or care.

The requirements reflect the facility's responsibilities to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record (see guidelines at §483.10(b)(4) for additional guidance concerning refusal of treatment).

Probes§483.20(k)(1):

Does the care plan address the needs, strengths and preferences identified in the comprehensive resident assessment?

Is the care plan oriented toward preventing avoidable declines in functioning or functional levels? How does the care plan attempt to manage risk factors? Does the care plan build on resident strengths?

Does the care plan reflect standards of current professional practice?

Do treatment objectives have measurable outcomes?

Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents, especially those identified as refusing treatment.

Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment.

If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?

For implementation of care plan, see §483.20(k)(3).

F280

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.10(d)(3) – The resident has the right to -- unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

Interpretive Guidelines §483.10(d)(3)

"**Participates in planning care and treatment**" means that the resident is afforded the opportunity to select from alternative treatments. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident's right to participate in care planning and to refuse treatment are covered in §§483.20(d)(2) and 483.10(b)(4).

A resident whose ability to make decisions about care and treatment is impaired, or a resident who has been formally declared incompetent by a court, should, to the extent practicable, be kept informed and be consulted on personal preferences.

Whenever there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate.

Procedures §483.10(d)(3)

Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes (e.g., ask residents or their representatives during interviews).

§483.20(k)(2)

§483.20(k)(2) A comprehensive care plan must be--

(i) Developed within 7 days after the completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

Interpretive Guidelines §483.20(k)(2):

As used in this requirement, "Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care

plan (e.g., a face-to-face meeting, teleconference, written communication) is at the discretion of the facility.

The physician must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-on-one discussions and conference calls.

The resident's right to participate in choosing treatment options, decisions in care planning and the right to refuse treatment are addressed at §483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse treatment. The facility has a responsibility to assist residents to participate, e.g., helping residents, and families, legal surrogates or representatives understand the assessment and care planning process; when feasible, holding care planning meetings at the time of day when a resident is functioning best; planning enough time for information exchange and decision making; encouraging a resident's advocate to attend (e.g. family member, friend) if desired by a resident.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. (See §483.20(k)(2)(ii) and 483.10(b)(4).) The facility should encourage residents, legal surrogates and representatives to participate in care planning, including attending care planning conferences if they so desire.

While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, legal surrogate or representative to demand that the facility use specific medical intervention or treatment that the facility deems inappropriate. Statutory requirements hold the facility ultimately accountable for the resident's care and safety, including clinical decisions.

Probes §483.20(k)(2):

1. Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities?

    a. For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability?

    b. Do the dietitian and speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident?

    c. Is there evidence of physician involvement in development of the care plan (e.g., presence at care plan meetings, conversations with team members concerning the care plan, conference calls)?

2. In what ways do staff involve residents and families, surrogates, and/or representatives in care planning?

3. Do staff make an effort to schedule care plan meetings at the best time of the day for residents and their families?

4. Ask the ombudsman if he/she has been involved in a care planning meeting as a resident advocate. If yes, ask how the process worked.

5. Do facility staff attempt to make the process understandable to the resident/family?

6. Ask residents whether they have brought questions or concerns about their care to the attention of facility's staff. If so, what happened as a result?

Interpretive Guidelines §483.20(k)(2)(iii):

See §483.75(g)(2)(iii) for "Qualified Person,"

Probes §483.20(k)(2)(iii):

Is the care plan evaluated and revised as the resident's status changes?

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§483.20(k)(3)

(3) The services provided or arranged by the facility must--

(i) Meet professional standards of quality and;

Intent §483.20(k)(3)(i):

The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

Interpretive Guidelines §483.20(k)(3)(i):

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.

- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.

- Clinical practice guidelines published by the Agency of Health Care Policy and Research.

- Current professional journal articles.

If a negative resident outcome is determined to be related to the facility's failure to meet professional standards, and the team determines a deficiency has occurred, it should be cited under the appropriate quality of care or other relevant requirement.

Probes §483.20(k)(3):

Question only those practices which have a negative outcome or have a potential negative outcome. Ask the facility to produce references upon which the practice is based.

- Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems?

- Are residents with acute conditions who require intensive monitoring and hospital-level treatments that the facility is unable to provide, promptly hospitalized?

- Are there errors in the techniques of medication administration? (Cite actual medication errors at §483.25(m).)

- Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and comprehensive care plan?

- Are physicians' orders carried out, unless otherwise indicated by an advanced directive?

F282

§483.20(k)(3)(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

Interpretive Guidelines §483.20(k)(3)(ii):

If you find problems with quality of care, quality of life, or resident rights, are these problems attributable to the qualifications of the facility staff, or lack of, inadequate or incorrect implementation of the care plan?

Probes §483.20(k)(3)(ii):

- Can direct care-giving staff describe the care, services, and expected outcomes of the care they provide; have a general knowledge of the care and services being provided by other therapists; have an understanding of the expected outcomes of this care, and understand the relationship of these expected outcomes to the care they provide?

F283

§483.20(l) Discharge Summary

When the facility anticipates discharge a resident must have a discharge summary that includes:

(1) A recapitulation of the resident's stay;
(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

Intent §483.20(l):

To ensure appropriate discharge planning and communication of necessary information to the continuing care provider.

Interpretive Guidelines §483.20(l):

"Anticipates" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition) or due to the resident's death.

"Adjust to his or her living environment" means that the post-discharge plan, as appropriate, should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple caregivers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/caregiver education needs and ability to meet care needs after discharge.

F284

§483.20(l)(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

Interpretive Guidelines §483.20(l)(3):

A post-discharge plan of care for an anticipated discharge applies to a resident whom the facility discharges to a private residence, to another NF or SNF, or to another type of residential facility such as a board and care home or an intermediate care facility for individuals with mental retardation. Resident protection concerning transfer and discharge are found at §483.12. A "post-discharge plan of care" means the discharge planning process which includes: assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community.

Probes §483.20(l):

- Does the discharge summary have information pertinent to continuing care for the resident?
- Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)?
- Do discharge plans address necessary post-discharge care?
- Has the facility aided the resident and his/her family in locating and coordinating post-discharge services?
- What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

F285

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.20(e) Coordination

A facility must coordinate assessments with the pre-admission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.

Interpretive Guidelines §483.20(e)

With respect to the responsibilities under the Pre-Admission Screening and Resident Review (PASRR) program, the State is responsible for conducting the screens, preparing the PASRR report, and providing or arranging the specialized services that are needed as a result of conducting the screens. The State is required to provide a copy of the PASRR report to the facility. This report must list the specialized services that the individual requires and that are the responsibility of the State to provide. All other needed services are the responsibility of the facility to provide.

§483.20(m) Preadmission Screening for Mentally Ill Individuals and Individuals With Mental Retardation.

§483.20(m)(1) A nursing facility must not admit, on or after January 1, 1989, any new residents with:

(i) Mental illness as defined in paragraph (m)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission;

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and
(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

(ii) Mental retardation, as defined in paragraph (m)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission--

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and
(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

§483.20(m)(2) Definitions. For purposes of this section:

(i) An individual is considered to have "mental illness" if the individual has a serious mental illness defined at 483.102(b)(1).

(ii) An individual is considered to be "mentally retarded" if the individual is mentally retarded as defined in 483.102(b)(3) or is a person with a related condition as described in 42 CFR 1009.

Intent §483.20(m):

To ensure that individuals with mental illness and mental retardation receive the care and services they need in the most appropriate setting.

"Specialized services" are those services the State is required to provide or arrange for that raise the intensity of services to the level needed by the resident. That is, specialized services are an "add-on" to NF services--they are of a higher intensity and frequency than specialized rehabilitation services, which are provided by the NF.

The statute mandates preadmission screening for all individuals with mental illness (MI) or mental retardation (MR) who apply to NFs, regardless of the applicant's source of payment, except as provided below. (See §1919(b)(3)(F).) Residents readmitted and individuals who initially apply to a nursing facility directly following a discharge from an acute care stay are exempt if:

- They are certified by a physician prior to admission to require a nursing facility stay of less than 30 days; and

- They require care at the nursing facility for the same condition for which they were hospitalized.

The State is responsible for providing specialized services to residents with MI/MR residing in Medicaid-certified facilities. The facility is required to provide all other care and services appropriate to the resident's condition. Therefore, if a facility has residents with MI/MR, do not survey for specialized services, but survey for all other requirements, including resident rights, quality of life, and quality of care.

If the resident's PAS report indicates that he or she needs specialized services but the resident is not receiving them, notify the Medicaid agency. NF services ordinarily are not of the intensity to meet the needs of residents with MI or MR.

Probes §483.20(m):

If sampled residents have MI or MR, did the State Mental Health or Mental Retardation Authority determine:

- Whether the residents needed the services of a NF?

- Whether the residents need specialized services for their MR or MI?

F309

(Rev. 4, Issued 11-12-04, Effective: 11-12-04, Implementation: 11-12-2004)

§483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Use F309 for quality of care deficiencies not covered by §483.25(a)-(m).

Intent: §483.25

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

Definitions: §483.25

- "Highest practicable" is defined as the highest level of functioning and well-being possible, limited only by the individual's presenting functional status and potential for improvement or reduced rate of functional decline. Highest practicable is determined through the comprehensive resident assessment by competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

- "Skin Ulcer/Wound"

  NOTE: Skin ulcer definitions are included to clarify clinical terms related to skin ulcers. At the time of the assessment and diagnosis, the clinician is expected to document the clinical basis (e.g., underlying condition contributing to the ulceration, ulcer edges and wound bed, location, shape, condition of surrounding tissues) which permit differentiating the ulcer type, especially if the ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

  - "Arterial Ulcer" is ulceration that occurs as the result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis.

Inadequate blood supply to the extremity may initially present as intermittent claudication. Arterial/Ischemic ulcers may be present in individuals with moderate to severe peripheral vascular disease, generalized arteriosclerosis, inflammatory or autoimmune disorders (such as arteritis), or significant vascular disease elsewhere (e.g., stroke or heart attack). The arterial ulcer is characteristically painful, usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot (e.g., top of the foot or toe, outside edge of the foot). The wound bed is frequently dry and pale with minimal or no exudate. The affected foot may exhibit: diminished or absent pedal pulse, coolness to touch, decreased pain when hanging down (dependent) or increased pain when elevated, blanching upon elevation, delayed capillary fill time, hair loss on top of the foot and toes, toenail thickening.

- "Diabetic neuropathic ulcer" requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy. The diabetic ulcer characteristically occurs on the foot, e.g., at mid-foot, at the ball of the foot over the metatarsal heads, or on the top of toes with Charcot deformity.

- "Pressure ulcer". See Guidance at 42 CFR 483.25(c)-F314.

- "Venous insufficiency ulcer" (previously known as "stasis ulcer") is an open lesion of the skin and subcutaneous tissue of the lower leg, usually occurring in the pretibial area of the lower leg or above the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected. The resident may experience pain which may be increased when the foot is in a dependent position, such as when a resident is seated with her or his feet on the floor. Recent literature implicates venous hypertension as a causative factor. Earlier, the ulceration was believed to be due to the pooling of blood in the veins.

  Venous hypertension may be caused by one (or a combination of) factor(s) including: loss of (or compromised) valve function in the vein, partial or complete obstruction of the vein (e.g., deep vein thrombosis, obesity, malignancy), and/or failure of the calf muscle to pump the blood (e.g., paralysis, decreased activity). Venous insufficiency may result in edema and induration, dilated superficial veins, cellulitis in the lower third of the leg or dermatitis (typically characterized by change in skin pigmentation). The pigmentation may appear as darkening skin, tan or purple areas in light skinned residents and dark purple, black or dark brown in dark skinned residents.

Interpretive Guidelines §483.25

Use F309 when the survey team determines there are quality of care deficiencies not covered by §§483.25(a)-(m). "Highest practicable" is defined as the highest level of functioning and well-being possible, limited only by the individual's presenting functional status and potential for improvement or reduced rate of functional decline. Highest practicable is determined through the comprehensive resident assessment by competently and thoroughly addressing the physical, mental or psychosocial needs of the individual.

The facility must ensure that the resident obtains optimal improvement or does not deteriorate within the limits of a resident's right to refuse treatment, and within the limits of recognized pathology and the normal aging process.

In any instance in which there has been a lack of improvement or a decline, the survey team must determine if the occurrence was unavoidable or avoidable. A determination of unavoidable decline or failure to reach highest practicable well-being may be made only if all of the following are present:

- An accurate and complete assessment (see §483.20);
- A care plan which is implemented consistently and based on information from the assessment;
- Evaluation of the results of the interventions and revising the interventions as necessary.

Determine if the facility is providing the necessary care and services based on the findings of the RAI. If services and care are being provided, determine if the facility is evaluating the outcome to the resident and changing the interventions if needed. This should be done in accordance with the resident's customary daily routine. Use Tag F309 to cite quality of care deficiencies that are not explicit in the quality of care regulations.

Procedures §483.25

Assess a facility's compliance with these requirements by determining if the services noted in the plan of care, based on a comprehensive and accurate functional assessment of the resident's strengths, weaknesses, risk factors for deterioration and potential for improvement, is continually and aggressively implemented and updated by the facility staff. In looking at assessments, use both the MDS and RAPs information, any other pertinent assessments, and resulting care plans.

If the resident has been in the facility for less than 14 days (before completion of all the RAI is required), determine if the facility is conducting ongoing assessment and care planning, and, if appropriate, care and services are being provided.

If quality of care problems are noted in areas of nurse aide responsibility, review nurse aide competency requirements at §483.75(e).

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§483.25(a) Activities of Daily Living.

Based on the comprehensive assessment of a resident, the facility must ensure that

Intent §483.25(a)

The intent of this regulation is that the facility must ensure that a resident's abilities in ADLs do not deteriorate unless the deterioration was unavoidable.

F310

§483.25(a)(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to --

(i) Bathe, dress, and groom;
(ii) Transfer and ambulate;
(iii) Toilet;
(iv) Eat; and
(v) Use speech, language, or other functional communication systems.

Interpretive Guidelines §483.25(a)

The mere presence of a clinical diagnosis, in itself, justify a decline in a resident's ability to perform ADLs. Conditions which may demonstrate unavoidable diminution in ADLs include:

- The natural progression of the resident's disease;

- Deterioration of the resident's physical condition associated with the onset of a physical or mental disability while receiving care to restore or maintain functional abilities; and

- The resident's or his/her surrogate's or representative's refusal of care and treatment to restore or maintain functional abilities after aggressive efforts by the facility to counsel and/or offer alternatives to the resident, surrogate, or representative. Refusal of such care and treatment should be documented in the clinical record. Determine which interventions were identified on the care plan and/or could be in place to minimize or decrease complications. Note

also that depression is a potential cause of excess disability and, where appropriate, therapeutic interventions should be initiated.

Appropriate treatment and services includes all care provided to residents by employees, contractors, or volunteers of the facility to maximize the individual's functional abilities. This includes pain relief and control, especially when it is causing a decline or a decrease in the quality of life of the resident.

If the survey team identifies a pattern of deterioration in ADLs, i.e., a number of residents have deteriorated in more than one ADL or a number of residents have deteriorated in only one ADL (one in bathing, one in eating, one in toileting) and it is determined there is deficient practice, cite at F310.

For evaluating a resident's ADLs and determining whether a resident's abilities have declined, improved or stayed the same within the last twelve months, use the following definitions as specified in the State's RAI:

1. **Independent -** No help or staff oversight; or staff help/oversight provided only 1 or 2 times during prior 7 days.

2. **Supervision -** Oversight encouragement or cuing provided 3 or more times during the last 7 days, or supervision plus physical assistance provided only 1 or 2 times during the last 7 days.

3. **Limited Assistance -** Resident highly involved in activity, received physical help in guided maneuvering of limbs, and/or other non-weight bearing assistance 3 or more times; or more help provided only 1 or 2 times over 7-day period.

4. **Extensive Assistance -** While resident performed part of activity, over prior 7-day period, help of following type(s) was provided 3 or more times;

    a. Weight-bearing support; or

    b. Full staff performance during part (but not all) of week.

5. **Total Dependence -** Full staff performance of activity over entire 7-day period.

§483.25(a)(1)(i) Bathing, Dressing, Grooming

Interpretive Guidelines §483.25(a)(1)(i)

This corresponds to MDS section E; version 2.0, section G, when specified for use by the State.

"Bathing" means how resident takes full-body bath, sponge bath, and transfers in/out of tub/shower. Exclude washing of back and hair.

“Dressing” means how resident puts on, fastens, and takes off all items of clothing, including donning/removing prosthesis.

“Grooming” means how resident maintains personal hygiene, including preparatory activities, combing hair, brushing teeth, shaving, applying make-up, washing/drying face, hands and perineum. Exclude baths and showers.

BATHING, DRESSING, GROOMING
Procedures §483.25(a)(1)(i)

For each sampled resident selected for the comprehensive review or the focused review, as appropriate, determine:

1. Whether the resident’s ability to bathe, dress and/or groom has changed since admission, or over the past 12 months;

2. Whether the resident’s ability to bathe, dress and groom has improved, declined or stayed the same;

3. Whether any deterioration or lack of improvement was avoidable or unavoidable by:

4. Identifying if resident triggers RAPs for ADL functional/rehabilitation potential.

    b. What risk factors for decline of bathing, dressing, and/or grooming abilities did the facility identify?

    c. What care did the resident receive to address unique needs to maintain his/her bathing, dressing, and/or grooming abilities (e.g., resident needs a button hook to button his shirt; staff teaches the resident how to use it; staff provides resident with dementia with cues that allow him/her to dress him or herself)?

    d. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of bathing, dressing, and/or grooming abilities (e.g., resident now unable to button dress, even with encouragement; will ask family if we may use velcro in place of buttons so resident can continue to dress herself)?

Probes: §483.25(a)(1)(i)

If the resident’s abilities in bathing, dressing, and grooming have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Identify relevant sections of the MDS and consider whether assessment triggers the RAPs and the RAPs were followed.

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?

- Was the care plan driven by resident strengths identified in the comprehensive assessment?

- Was the care plan consistently implemented?

- What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress might have been possible?

TRANSFER AND AMBULATION
§483.25(a)(1)(ii)

Interpretive Guidelines §483.25(a)(1)(ii)

This corresponds to MDS section E; MDS 2.0 section G when specified for use by the State.

"Transfer" means how resident moves between surfaces - to/from: bed, chair, wheelchair, standing position. (Exclude to/from bath/toilet.)

"Ambulation" means how resident moves between locations in his/her room and adjacent corridor on same floor. If in wheelchair, self-sufficiency once in chair.

Procedures §483.25(a)(1)(ii)

Determine for each resident selected for a comprehensive review, or a focused review as appropriate, whether the resident's ability to transfer and ambulate has declined, improved or stayed the same and whether any deterioration or decline in function was avoidable or unavoidable.

Probes: §483.25(a)(1)(ii)

If the resident's transferring and ambulating abilities have declined, what evidence is there that the decline was unavoidable:

- What risk factors for decline of transferring or ambulating abilities did the facility identify (e.g., necrotic area of foot ulcer becoming larger, postural hypotension)?

- What care did the resident receive to address risk factors and unique needs to maintain transferring or ambulating abilities (e.g., a transfer board is provided to maintain ability to transfer from bed to wheelchair and staff teaches the resident how to use it)?

- What evidence is there that sufficient staff time and assistance are provided to maintain transferring and ambulating abilities?

- Has resident been involved in activities that enhance mobility skills?

- Were individual objectives of the plan of care periodically evaluated, and if goals were not met, were alternative approaches developed to encourage maintenance of transferring and ambulation abilities (e.g., resident remains unsteady when using a cane, returns to walker, with staff encouraging the walker's consistent use)?

- Identify if resident triggers RAPs for ADL functional/rehabilitation potential, psychosocial well-being, or mood state and the RAPs are followed.

If the resident's abilities in transferring and ambulating have been maintained, is there evidence that the resident could have improved if appropriate treatment and services were provided?

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?

- Was the care plan driven by resident strengths identified in the comprehensive assessment?

- Was the care plan consistently implemented? What changes were made in treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

TOILETING
§483.25(a)(1)(ii)

Interpretive Guidelines §483.25(a)(1)(iii)

This corresponds to MDS sections E; MDS 2.0 sections G and H when specified for use by the State.

"Toilet use" means how the resident uses the toilet room (or commode, bedpan, urinal); transfers on/off the toilet, cleanses self, changes pad, manages ostomy or catheter, adjusts clothes.

Procedures §483.25(a)(1)(iii)

Determine for each resident selected for a comprehensive review, or focused review as appropriate, whether the resident's ability to use the toilet has improved, declined or stayed the same and whether any deterioration or decline in improvement was avoidable or unavoidable.

Probes: §483.25(a)(1)(iii)

If the resident's toilet use abilities have declined, what evidence is there that the decline was unavoidable.

- What risk factors for the decline of toilet use abilities did the facility identify (e.g., severe arthritis in hands makes use of toilet paper difficult)?

- What care did resident receive to address risk factors and unique needs to maintain toilet use abilities (e.g., assistive devices to maintain ability to use the toilet such as using a removable elevated toilet seat or wall grab bar to facilitate rising from seated position to standing position)?

- Is there sufficient staff time and assistance provided to maintain toilet use abilities (e.g., allowing residents enough time to use the toilet independently or with limited assistance)?

- Were individual objectives of the plan of care periodically evaluated, and if objectives were not met, were alternative approaches developed to encourage maintaining toilet use abilities (e.g., if resident has not increased sitting stability, seek occupational therapy consult to determine the need for therapy to increase sitting balance, ability to transfer safely and manipulate clothing during the toileting process. For residents with dementia, remind periodically to use the toilet)?

- Identify if resident triggers RAPs for urinary incontinence, and ADL functional/rehabilitation potential and the RAPs were used to assess causal factors for decline or potential for decline or lack of improvement.

If the resident's toilet use abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided?

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?

- Was the care plan driven by resident strengths identified in the comprehensive assessment?

- Was the care plan consistently implemented? What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

- Identify if resident triggers RAPs for mood state and psychosocial well-being.

EATING
§483.25(a)(1)(iv)

Interpretive Guidelines §483.25(a)(1)(iv)

This corresponds to MDS sections E, L1 and MI; MDS 2.0, sections G and K when specified for use by the State.

"Eating" means how resident ingests and drinks (regardless of self-feeding skill).

Procedures §483.25(a)(1)(iv)

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, whether the resident's ability to eat or eating skills has improved, declined, or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.

If the resident's eating abilities have declined, is there any evidence that the decline was unavoidable?

1. What risk factors for decline of eating skills did the facility identify?

    a. A decrease in the ability to chew and swallow food

    b. Deficit in neurological and muscular status necessary for moving food onto a utensil and into the mouth

    c. Oral health status affecting eating ability

    d. Depression or confused mental state

2. What care did the resident receive to address risk factors and unique needs to maintain eating abilities?

    a. Assistive devices to improve resident's grasp or coordination;

    b. Seating arrangements to improve sociability;

    c. Seating in a calm, quiet setting for residents with dementia.

3. Is there sufficient staff time and assistance provided to maintain eating abilities (e.g., allowing residents enough time to eat independently or with limited assistance)?

4. Identify if resident triggers RAPs for ADL functional/rehabilitation potential, feeding tubes, and dehydration/fluid maintenance, and the RAPs were used to assess causal reasons for decline, potential for decline or lack of improvement.

5. Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintaining eating abilities?

Probes: §483.25(a)(1)(iv)

If the resident's eating abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?

- Was the care plan driven by resident strengths identified in the comprehensive assessment?

- Was the care plan consistently implemented? What changes are made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

Interpretive Guidelines §483.25(a)(1)(v)

This corresponds to MDS, section C; MDS 2.0 sections B and C when specified for use by the State.

"Speech, language or other functional communication systems" is defined as the ability to effectively communicate requests, needs, opinions, and urgent problems; to express emotion, to listen to others and to participate in social conversation whether in speech, writing, gesture or a combination of these (e.g., a communication board or electronic augmentative communication device).

USE OF SPEECH, LANGUAGE, OR OTHER FUNCTIONAL COMMUNCATION SYSTEMS
§483.25(a)(1)(v)

Procedures §483.25(a)(1)(v)

Determine for each resident selected for a comprehensive review, or focused review, as appropriate, if resident's ability to communicate has declined, improved or stayed the same and whether any deterioration or lack of improvement was avoidable or unavoidable.

Identify if resident triggers RAPs for communication, psychosocial well-being, mood state, and visual function, and if the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement.

Probes: §483.25(a)(1)(v)

If the resident's communication abilities have diminished, is there any evidence that the decline was unavoidable:

- What risk factors for decline of communication abilities did the facility identify and how did they address them (e.g., dysarthria, poor fitting dentures, few visitors, poor relationships with staff, Alzheimer's disease)?

- Has the resident received audiologic and vision evaluation? If not, did the resident refuse such services? (See also §483.10(b)(4).)

- What unique resident needs and risk factors did the facility identify (e.g., does the resident have specific difficulties in transmitting messages, comprehending messages, and/or using a variety of communication skills such as questions and commands; does the resident receive evaluation and training in the use of assistive devices to increase and/or maintain writing skills)?

- What care does the resident receive to improve communication abilities (e.g.,nurse aides communicate in writing with deaf residents or residents with severe hearing problems; practice exercises with residents receiving speech-language pathology services; increase number of resident's communication opportunities; non-verbal means of communication; review of the effect of medications on communication ability)?

- Is there sufficient staff time and assistance provided to maintain communication abilities?

- Were individual objectives of the plan of care periodically evaluated, and if the objectives were not met, were alternative approaches developed to encourage maintenance of communication abilities (e.g., if drill-oriented

therapy is frustrating the resident, a less didactic approach should be attempted)?

Probes: §483.25(a)(1)(v)

If the resident's speech, language, and other communication abilities have been maintained, what evidence is there that the resident could have improved if appropriate treatment and services were provided:

- Are there physical and psychosocial deficits that could affect improvement in functional abilities?
- Was the care plan driven by resident strengths identified in the comprehensive assessment?
- Was the care plan consistently implemented?
- What changes were made to treatment if the resident failed to progress or when initial rehabilitation goals were achieved, but additional progress seemed possible?

F311

§483.25(a)(2)

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

Intent §483.25(a)(2)

The intent of this regulation is to stress that the facility is responsible for providing maintenance and restorative programs that will not only maintain, but improve, as indicated by the resident's comprehensive assessment to achieve and maintain the highest practicable outcome.

Procedures §483.25(a)(2)

Use the survey procedures and probes at §483.25(a)(1)(i) through (v) to assist in making this determination

F312

§483.25(a)(3)

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

Intent §483.25(a)(3)

The intent of this regulation is that the resident receives the care and services needed because he/she is unable to do their own ADL care independently.

Interpretive Guidelines §483.25(a)(3)

This corresponds to MDS section L; MDS 2.0 section K when specified by the State.

"Unable to carry out ADLs" means those residents who need extensive or total assistance with maintenance of nutrition, grooming and personal and oral hygiene, receive this assistance from the facility.

Methods for maintenance of good nutrition may include hand feeding of foods served on dishes; tube feedings provided through naso-gastric, gastrostomy, or other external tubes; or total parenteral nutrition provided through a central intravenous line.

"Grooming" - See §483.25(a)(1)(i) for definition.

"Personal hygiene" - Those activities described in dressing and bathing as defined in §483.25(a)(1)(i).

"Oral hygiene" means maintaining the mouth in a clean and intact condition and treating oral pathology such as ulcers of the mucosa. Services to maintain oral hygiene may include brushing the teeth, cleaning dentures, cleaning the mouth and tongue either by assisting the resident with a mouth wash or by manual cleaning with a gauze sponge; and application of medication as prescribed.

Procedures §483.25(a)(3)

For residents selected for a comprehensive review, or focused review, as appropriate, who are unable to carry out these ADLs without extensive assistance, determine if poor nutritional status, poor grooming, or lack of effective personal and oral hygiene exist. To what extent are these negative outcomes attributable to the lack of receiving necessary services?

Identify if residents trigger RAPs for nutritional status, ADL functional/rehabilitation potential, behavior problems, and dental care. Consider whether the RAPs were used to assess causal factors for decline, potential for decline, or lack of improvement. Determine if the facility proceeded properly with care planning and delivery of care for these residents.

F313

§483.25(b) Vision and hearing

To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident --

1. **In making appointments, and**

2. **By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.**

Intent §483.25(b)

The intent of this regulation is to require a facility to assist residents in gaining access to vision and hearing services by making appointments and arranging for transportation, and assistance with the use of any devices needed to maintain vision and hearing.

Interpretive Guidelines §483.25(b)

This corresponds to MDS, sections C and O; MDS 2.0 sections C, D, and P when specified for use by the State.

Assistive devices to maintain vision include glasses, contact lenses, and magnifying glasses. Assistive devices to maintain hearing include hearing aids.

This requirement does not mean that the facility must provide refractions, glasses, contact lenses, conduct comprehensive audiological evaluations (although screening is a part of the required assessment in §483.20(b)) or provide hearing aids.

The facility's responsibility is to assist residents and their families in locating and utilizing any available resources (e.g., Medicare or Medicaid program payment, local health organizations offering items and services which are available free to the community) for the provision of the services the resident needs. This includes making appointments and arranging transportation to obtain needed services.

Probes: §483.25(b)

- Identify if resident triggers RAPs for visual function, and communication. Consider whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement.

- If the resident needs, and/or requests and does not have vision and/or hearing assistive devices, what has the facility done to assist the resident in making appointments and obtaining transportation to obtain these services?

- If the resident has assistive devices but is not using them, why not (e.g., are repairs or batteries needed)?

F314

(Rev. 4, Issued 11-12-2004, Effective: 11-12-2004, Implementation: 11-12-2004

§483.25(c) Pressure Sores

Based on the comprehensive Assessment of a resident, the facility must ensure that--

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

Intent: (F314) 42 CFR 483.25(c)

The intent of this requirement is that the resident does not develop pressure ulcers unless clinically unavoidable and that the facility provides care and services to:

- Promote the prevention of pressure ulcer development;

- Promote the healing of pressure ulcers that are present (including prevention of infection to the extent possible); and

- Prevent development of additional pressure ulcers.

NOTE: Although the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers.

DEFINITIONS

Definitions are provided to clarify clinical terms related to pressure ulcers and their evaluation and treatment.

- "Pressure Ulcer"- A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s).[1] Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers.

- "Avoidable/Unavoidable" Pressure Ulcers

    - "Avoidable" means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident's clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.

    - "Unavoidable" means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

- "Cleansing/Irrigation"

    - "Cleansing" refers to the use of an appropriate device and solution to clean the surface of the wound bed and to remove the looser foreign debris or contaminants in order to decrease microbial growth.[2]

    - "Irrigation" refers to a type of mechanical debridement, which uses an appropriate solution delivered under pressure to the wound bed to vigorously attempt to remove debris from the wound bed.[3]

- "Colonized/Infected" Wound [4, 5]

    - "Colonized" refers to the presence of bacteria on the surface or in the tissue of a wound without the signs and symptoms of an infection.

    - "Infected" refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.

- "Debridement"- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. [6, 7, 8] Various debridement methods include:

    - "Autolytic debridement" refers to the use of moisture retentive dressings to cover a wound and allow devitalized tissue to self-digest by the action of enzymes present in the wound fluids.

    - "Enzymatic (chemical) debridement" refers to the topical application of substances e.g., enzymes to break down devitalized tissue.

    - "Mechanical debridement" refers to the removal of foreign material and devitalized or contaminated tissue from a wound by physical rather than by chemical or autolytic means.

    - "Sharp or surgical debridement" refers to removal of foreign material or devitalized tissue by a surgical instrument.

    - "Maggot debridement therapy (MDT)" or medicinal maggots refers to a type of sterile intentional biological larval or biosurgical debridement that uses disinfected (sterile) maggots to clean wounds by dissolving the dead and infected tissue and by killing bacteria.[9]

- "Eschar/Slough"

    - "Eschar" is described as thick, leathery, frequently black or brown in color, necrotic (dead) or devitalized tissue that has lost its usual physical properties and biological activity. Eschar may be loose or firmly adhered to the wound.

    - "Slough" is necrotic/avascular tissue in the process of separating from the viable portions of the body and is usually light colored, soft, moist, and stringy (at times).

- "Exudate"
    - "Exudate" is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.
    - "Purulent exudate/drainage/discharge" is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).
    - "Serous drainage or exudate" is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.
- "Friction/Shearing"
    - "Friction" is the mechanical force exerted on skin that is dragged across any surface.
    - "Shearing" is the interaction of both gravity and friction against the surface of the skin. Friction is always present when shear force is present.[10] Shear occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.
- "Granulation Tissue"
    - "Granulation tissue" is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.
- "Tunnel/Sinus Tract/Undermining"-Tunnel and sinus tract are often used interchangeably.
    - "Tunneling" is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.
    - A "sinus tract" is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.
    - "Undermining" is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

OVERVIEW

A pressure ulcer can occur wherever pressure has impaired circulation to the tissue. Critical steps in pressure ulcer prevention and healing include: identifying the individual resident at risk for developing pressure ulcers, identifying and evaluating the risk factors and changes in the resident's condition, identifying and evaluating factors that can be removed or modified, implementing individualized interventions to attempt to stabilize, reduce or remove underlying risk factors, monitoring the impact of the interventions, and modifying the interventions as appropriate. It is important to recognize and evaluate each resident's risk factors and to identify and evaluate all areas at risk of constant pressure.

A complete assessment is essential to an effective pressure ulcer prevention and treatment program. A comprehensive individual evaluation helps the facility to:

- Identify the resident at risk of developing pressure ulcers, the level and nature of risk(s); and

- Identify the presence of pressure ulcers.

This information allows the facility to develop and implement a comprehensive care plan that reflects each resident's identified needs.

The care process should include efforts to stabilize, reduce or remove underlying risk factors; to monitor the impact of the interventions; and to modify the interventions as appropriate.

The facility should have a system/procedure to assure: assessments are timely and appropriate; interventions are implemented, monitored, and revised as appropriate; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The quality assessment and assurance committee may help the facility evaluate existing strategies to reduce the development and progression of pressure ulcers, monitor the incidence and prevalence of pressure ulcers within the facility, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices for the prevention, management and treatment of pressure ulcers, continues to evolve. As such, there are many recognized clinical resources regarding the prevention and management of pressure ulcers (including wound care, and complications such as infections and pain). Some of these resources include:

- The Clinical Practice Guidelines from the Agency for Healthcare Research and Quality (AHRQ) www.ahrq.gov (Guideline No. 15: Treatment of Pressure Ulcers and Guideline No.3: Pressure Ulcers in Adults: Prediction and Prevention)(AHRQ was previously known as the Agency for Health Care Policy and Research [AHCPR]);

- The National Pressure Ulcer Advisory Panel (NPUAP) www.npuap.org;

- The American Medical Directors Association (AMDA) www.amda.com (Clinical Practice Guidelines: Pressure Ulcers, 1996 and Pressure Ulcer Therapy Companion, 1999);

- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives site at www.medqic.org;

- The Wound, Ostomy, and Continence Nurses Society (WOCN) www.wocn.org; and

- The American Geriatrics Society guideline "The Management of Persistent Pain in Older Persons", www.healthinaging.org.

NOTE: References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

PREVENTION OF PRESSURE ULCERS

42 CFR 483.25 (c) requires that a resident who is admitted without a pressure ulcer doesn't develop a pressure ulcer unless clinically unavoidable, and that a resident who has an ulcer receives care and services to promote healing and to prevent additional ulcers.

The first step in prevention is the identification of the resident at risk of developing pressure ulcers. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

ASSESSMENT

An admission evaluation helps identify the resident at risk of developing a pressure ulcer, and the resident with existing pressure ulcer(s) or areas of skin that are at risk for breakdown. Because a resident at risk can develop a pressure ulcer within 2 to 6 hours of the onset of pressure,[11] the at-risk resident needs to be identified and have interventions implemented promptly to attempt to prevent pressure ulcers. The admission evaluation helps define those initial care approaches.

In addition, the admission evaluation may identify pre-existing signs (such as a purple or very dark area that is surrounded by profound redness, edema, or induration)[12] suggesting that deep tissue damage has already occurred and additional deep tissue loss may occur.

This deep tissue damage could lead to the appearance of an unavoidable Stage III or IV pressure ulcer or progression of a Stage I pressure ulcer to an ulcer with eschar or exudate within days after admission. Some situations, which may have contributed to this tissue damage, include pressure resulting from immobility during hospitalization or surgical procedures, during prolonged ambulance transport, or while waiting to be discovered or assisted after a debilitating event, such as a fall or a cerebral vascular accident.

Some evidence suggests that because it may be harder to identify erythema in an older adult with darkly pigmented skin, older individuals with darkly pigmented skin may be more at risk for developing pressure ulcers.[13, 14, 15, 16] It may be necessary, therefore, in a darker skinned individual to focus more on other evidence of pressure ulcer development, such as bogginess, induration, coolness, or increased warmth as well as signs of skin discoloration.

Multiple factors, including pressure intensity, pressure duration, and tissue tolerance, significantly affect the potential for the development and healing of pressure ulcers. An individual may also have various intrinsic risks due to aging, for example: decreased subcutaneous tissue and lean muscle mass, decreased skin elasticity, and impaired circulation or innervation.

The comprehensive assessment, which includes the Resident Assessment Instrument (RAI), evaluates the resident's intrinsic risks, the resident's skin condition, other factors (including causal factors) which place the resident at risk for developing pressure ulcers and/or experiencing delayed healing, and the nature of the pressure to which the resident may be subjected. The assessment should identify which risk factors can be removed or modified.

The assessment also helps identify the resident who has multi-system organ failure or an end-of-life condition or who is refusing care and treatment. If the resident is refusing care, an evaluation of the basis for the refusal, and the identification and evaluation of potential alternatives is indicated.

This comprehensive assessment should address those factors that have been identified as having an impact on the development, treatment and/or healing of pressure ulcers, including, at a minimum: risk factors, pressure points, under-nutrition and hydration deficits, and moisture and the impact of moisture on skin. Each of these factors is discussed in additional detail in the following sections.

Risk Factors

Many studies and professional documents identify risk factors that increase a resident's susceptibility to develop or to not heal pressure ulcers.[17, 18, 19] Examples of these risk factors include, but are not limited to:

- Impaired/decreased mobility and decreased functional ability;

- Co-morbid conditions, such as end stage renal disease, thyroid disease or diabetes mellitus;
- Drugs such as steroids that may affect wound healing;
- Impaired diffuse or localized blood flow, for example, generalized atherosclerosis or lower extremity arterial insufficiency;
- Resident refusal of some aspects of care and treatment;
- Cognitive impairment;
- Exposure of skin to urinary and fecal incontinence;
- Under nutrition, malnutrition, and hydration deficits; and
- A healed ulcer. The history of a healed pressure ulcer and its stage [if known] is important, since areas of healed Stage III or IV pressure ulcers are more likely to have recurrent breakdown.

Some residents have many risk factors for developing pressure ulcers, such as diabetic neuropathy, frailty, cognitive impairment, and under nutrition. Not all factors are fully modifiable and some potentially modifiable factors (e.g., under-nutrition) may not be corrected immediately, despite prompt intervention, while other factors such as pressure may be modified promptly. It may be necessary to stabilize, when possible, the underlying causes (e.g., control blood sugars or ensure adequate food and fluid intake).

Although the requirements do not mandate any specific assessment tool, other than the RAI, validated instruments are available to assess risk for developing pressure ulcers. Research has shown that a significant number of pressure ulcers develop within the first four weeks after admission to a long term care facility.[20] Therefore, many clinicians recommend using a standardized pressure ulcer risk assessment tool to assess a resident's pressure ulcer risks upon admission, weekly for the first four weeks after admission for each resident at risk, then quarterly, or whenever there is a change in cognition or functional ability.[21, 22] A resident's risk may increase due to an acute illness or condition change (e.g., upper respiratory infection, pneumonia, or exacerbation of underlying congestive heart failure) and may require additional evaluation.

Regardless of any resident's total risk score, the clinicians responsible for the resident's care should review each risk factor and potential cause(s) individually[23] to: a)Identify those that increase the potential for the resident to develop pressure ulcers; b) Decide whether and to what extent the factor(s) can be modified, stabilized, removed, etc., and c) Determine whether targeted management protocols need to be implemented. In other words, an overall risk score indicating the resident is not at high risk of developing

pressure ulcers does not mean that existing risk factors or causes should be considered less important or addressed less vigorously than those factors or causes in the resident whose overall score indicates he or she is at a higher risk of developing a pressure ulcer.

Pressure Points and Tissue Tolerance

Assessment of a resident's skin condition helps define prevention strategies. The skin assessment should include an evaluation of the skin integrity and tissue tolerance (ability of the skin and its supporting structures to endure the effects of pressure without adverse effects) after pressure to that area has been reduced or redistributed.

Tissue closest to the bone may be the first tissue to undergo necrosis. Pressure ulcers are usually located over a bony prominence, such as the sacrum, heel, the greater trochanter, ischial tuberosity, fibular head, scapula, and ankle (malleolus).

An at-risk resident who sits too long on a static surface may be more prone to get ischial ulceration. Slouching in a chair may predispose an at-risk resident to pressure ulcers of the spine, scapula, or elbow (elbow ulceration is often related to arm rests or lap boards). Friction and shearing are also important factors in tissue ischemia, necrosis and pressure ulcer formation.

Pressure ulcers may develop at other sites where pressure has impaired the circulation to the tissue, such as pressure from positioning or use of medical devices. For example, pressure ulcers may develop from pressure on an ear lobe related to positioning of the head; pressure or friction on areas (e.g., nares, urinary meatus, extremities) caused by tubes, casts, orthoses, braces, cervical collars, or other medical devices; pressure on the labia or scrotum related to positioning (e.g., against a pommel type cushion); pressure on the foot related to ill-fitting shoes causing blistering; or pressure on legs, arms and fingers due to contractures or deformity resulting from rheumatoid arthritis, etc.

While pressure ulcers on the sacrum remain the most common location, pressure ulcers on the heel are occurring more frequently,[24] are difficult to assess and heal, and require early identification of skin compromise over the heel.

It is, therefore, important for clinical staff to regularly conduct thorough skin assessments on each resident who is at risk for developing pressure ulcers.

Under-Nutrition and Hydration Deficits

Adequate nutrition and hydration are essential for overall functioning. Nutrition provides vital energy and building blocks for all of the body's structures and processes. Any organ or body system may require additional energy or structural materials for repair or function. The skin is the body's largest organ system. It may affect, and be affected by, other body processes and organs. Skin condition reflects overall body function; skin breakdown may be the most visible evidence of a general catabolic state.

Weight reflects a balance between intake and utilization of energy. Significant unintended weight loss may indicate under-nutrition or worsening health status. Weight stability (in the absence of fluid excess or loss) is a useful indicator of overall caloric balance. Severely impaired organs (heart, lungs, kidneys, liver, etc.) may be unable to use nutrients effectively. A resident with a pressure ulcer who continues to lose weight either needs additional caloric intake or correction (where possible) of conditions that are creating a hypermetabolic state. Continuing weight loss and failure of a pressure ulcer to heal despite reasonable efforts to improve caloric and nutrient intake may indicate the resident is in multi-system failure or an end-stage or end-of-life condition warranting an additional assessment of the resident's overall condition.

Before instituting a nutritional care plan, it helps to summarize resident specific evidence, including: severity of nutritional compromise, rate of weight loss or appetite decline, probable causes, the individual's prognosis and projected clinical course, and the resident's wishes and goals. Because there are no wound-specific nutritional measures, the interdisciplinary team should develop nutritional goals for the whole person. Unless contraindicated, nutritional goals for a resident with nutritional compromise who has a pressure ulcer or is at risk of developing pressure ulcers should include protein intake of approximately 1.2-1.5 gm/kg body weight daily (higher end of the range for those with larger, more extensive, or multiple wounds). A simple multivitamin is appropriate, but unless the resident has a specific vitamin or mineral deficiency, supplementation with additional vitamins or minerals may not be indicated.

NOTE: Although some laboratory tests may help clinicians evaluate nutritional issues in a resident with pressure ulcers, no laboratory test is specific or sensitive enough to warrant serial/repeated testing. Serum albumin, pre-albumin and cholesterol may be useful to help establish overall prognosis; however, they may not correlate well with clinical observation of nutritional status.[25, 26] At his or her discretion, a practitioner may order test(s) that provide useful additional information or help with management of treatable conditions.

Water is essential to maintain adequate body functions. As a major component of blood, water dissolves vitamins, minerals, glucose, amino acids, etc.; transports nutrients into cells; removes waste from the cells; and helps maintain circulating blood volume as well as fluid and electrolyte balance. It is critical that each resident at risk for hydration deficit or imbalance, including the resident with a pressure ulcer or at risk of developing an ulcer, be identified and that hydration needs be addressed.

(The surveyor should refer to the Guidance at 42 CFR 483.25 (i), F325, Nutrition, and 483.25(j), F327 Hydration for investigation of potential non-compliance with the nutrition and hydration requirements. A low albumin level combined with the facility's lack of supplementation, for example, is not sufficient to cite a pressure ulcer deficiency.)

Moisture and Its Impact

Both urine and feces contain substances that may irritate the epidermis and may make the skin more susceptible to breakdown. Some studies have found that fecal incontinence may pose a greater threat to skin integrity,[27] most likely due to bile acids and enzymes in the feces. Irritation or maceration resulting from prolonged exposure to urine and feces may hasten skin breakdown, and moisture may make skin more susceptible to damage from friction and shear during repositioning.

It may be difficult to differentiate dermatitis related to incontinence from partial thickness skin loss (pressure ulcer). This differentiation should be based on the clinical evidence and review of presenting risk factors. A Stage I pressure ulcer usually presents as a localized area of erythema or skin discoloration, while perineal dermatitis may appear as a more diffuse area of erythema or discoloration where the urine or stool has come into contact with the skin. The dermatitis may occur in the area where the incontinence brief or underpad has been used. Also, the dermatitis/rash more typically presents as intense erythema, scaling, itching, papules, weeping and eruptions.[28]

INTERVENTIONS

The comprehensive assessment should provide the basis for defining approaches to address residents at risk of developing or already having a pressure ulcer. A determination that a resident is at high risk to develop a pressure ulcer has significant implications for preventive and treatment strategies, but does not by itself indicate that development of a pressure ulcer was unavoidable. Effective prevention and treatment are based upon consistently providing routine and individualized interventions.

In the context of the resident’s choices, clinical condition, and physician input, the resident’s plan of care should establish relevant goals and approaches to stabilize or improve co-morbidities, such as attempts to minimize clinically significant blood sugar fluctuations and other interventions aimed at limiting the effects of risk factors associated with pressure ulcers. Alternatively, facility staff and practitioners should document clinically valid reasons why such interventions were not appropriate or feasible. Repeated hospitalizations or emergency room visits within a 6-month period may indicate overall decline or instability.

Resident Choice

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal representative) must discuss the resident’s condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility is expected to address the resident’s concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights at 42 CFR 483.10(b)(3) and (4), F154 and F155.)

Advance Directive

A resident at the end of life, in terminal stages of an illness or having multiple system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's surrogate or representative, in accordance with state law).

If a resident has a valid Advance Directive, the facility's care must reflect a resident's wishes as expressed in the Directive, in accordance with state law. However, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive. If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized) and to provide care to prevent or treat the pressure ulcer (including pertinent, routine, lesser aggressive approaches, such as, cleaning, turning, repositioning), then the development, continuation, or progression of a pressure ulcer may be consistent with regulatory requirements.

NOTE: The presence of a "Do Not Resuscitate" (DNR) order is not sufficient to indicate the resident is declining other appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

Based upon the assessment and the resident's clinical condition, choices and identified needs, basic or routine care should include interventions to: a) Redistribute pressure (such as repositioning, protecting heels, etc); b) Minimize exposure to moisture and keep skin clean, especially of fecal contamination; c) Provide appropriate, pressure-redistributing, support surfaces; d) Provide non-irritating surfaces; and e) Maintain or improve nutrition and hydration status, where feasible. Adverse drug reactions related to the resident's drug regimen may worsen risk factors for development of pressure ulcers or for non-healing pressure ulcers (for example, by causing lethargy or anorexia or creating/increasing confusion) and should be identified and addressed. These interventions should be incorporated into the plan of care and revised as the condition of the resident indicates.

Repositioning

Repositioning is a common, effective intervention for an individual with a pressure ulcer or who is at risk of developing one.[29, 30] Assessment of a resident's skin integrity after pressure has been reduced or redistributed should guide the development and implementation of repositioning plans. Such plans should be addressed in the comprehensive plan of care consistent with the resident's need and goals. Repositioning is critical for a resident who is immobile or dependent upon staff for repositioning. The care plan for a resident at risk of friction or shearing during repositioning may require the use of lifting devices for repositioning. Positioning the resident on an existing pressure ulcer should be avoided since it puts additional pressure on tissue that is already compromised and may impede healing.

Surveyors should consider the following repositioning issues:

- A resident who can change positions independently may need supportive devices to facilitate position changes. The resident also may need instruction about why repositioning is important and how to do it, encouragement to change positions regularly, and monitoring of frequency of repositioning.

- The care plan for a resident who is reclining and is dependent on staff for repositioning should address position changes to maintain the resident's skin integrity. This may include repositioning at least every 2 hours or more frequently depending upon the resident's condition and tolerance of the tissue load (pressure). Depending on the individualized assessment, more frequent repositioning may be warranted for individuals who are at higher risk for pressure ulcer development or who show evidence (e.g., Stage I pressure ulcers) that repositioning at 2-hour intervals is inadequate. With rare exception (e.g., both sacral and ischial pressure ulcers are present) the resident should not be placed directly on the greater trochanter for more than momentary placement. Elevating the head of the bed or the back of a reclining chair to or above a 30 degree angle creates pressure comparable to that exerted while sitting, and requires the same considerations regarding repositioning as those for a dependent resident who is seated.

- Many clinicians recommend a position change "off loading" hourly for dependent residents who are sitting or who are in a bed or a reclining chair with the head of the bed or back of the chair raised 30 degrees or more.[31] Based upon an assessment including evidence of tissue tolerance while sitting (checking for Stage I ulcers as noted above), the resident may not tolerate sitting in a chair in the same position for1 hour at a time and may require a more frequent position change.

- Postural alignment, weight distribution, sitting balance and stability, and pressure redistribution should all be considered when positioning a resident in a chair.[32] A teachable resident should be taught to shift his/her weight approximately every 15 minutes while sitting in a chair.

- Wheelchairs are often used for transporting residents, but they may severely limit repositioning options and increase the risk of pressure ulcer development. Therefore, wheelchairs with sling seats may not be optimal for prolonged sitting during activities or meals, etc. However, available modifications to the seating can provide a more stable surface and provide better pressure reduction.

- There isn't evidence that momentary pressure relief followed by return to the same position (that is a "microshift" of five or 10 degrees or a 10-15 second lift from a seated position) is beneficial. This approach does not allow sufficient capillary refill and tissue perfusion for a resident at risk of developing pressure ulcers. Ongoing monitoring of the resident's skin integrity and tissue tolerance is critical to prevent development or deterioration of pressure ulcers.

Support Surfaces and Pressure Redistribution

Pressure redistribution refers to the function or ability to distribute a load over a surface or contact area. Redistribution results in shifting pressure from one area to another and requires attention to all affected areas. Pressure redistribution has incorporated the concepts of both pressure reduction (reduction of interface pressure, not necessarily below capillary closure pressure) and pressure relief (reduction of interface pressure below capillary closure pressure).

Appropriate support surfaces or devices should be chosen by matching a device's potential therapeutic benefit with the resident's specific situation; for example, multiple ulcers, limited turning surfaces, ability to maintain position. The effectiveness of pressure redistribution devices (e.g., 4-inch convoluted foam pads, gels, air fluidized mattresses, and low loss air mattresses) is based on their potential to address the individual resident's risk, the resident's response to the product, and the characteristics and condition of the product. For example, an overinflated overlay product, or one that "bottoms out" (completely compressing the overlay, when, for example, the caregiver can feel less than one inch between the resident and support material) is unlikely to effectively reduce the pressure risk. These products are more likely to reduce pressure effectively if they are used in accord with the manufacturer's instructions. The effectiveness of each product used needs to be evaluated on an ongoing basis. Surveyors should consider the following pressure redistribution issues:

- Static pressure redistribution devices (e.g., solid foam, convoluted foam, gel mattress) may be indicated when a resident is at risk for pressure ulcer development or delayed healing. A specialized pressure redistribution cushion or surface, for example, might be used to extend the time a resident is sitting in a chair; however, the cushion does not eliminate the necessity for periodic repositioning.

- Dynamic pressure reduction surfaces may be helpful when: 1) The resident cannot assume a variety of positions without bearing weight on a pressure ulcer, 2) The resident completely compresses a static device that has retained its original integrity, or 3) The pressure ulcer is not healing as expected, and it is determined that pressure may be contributing to the delay in healing.

- Because the heels and elbows have relatively little surface area, it is difficult to redistribute pressure on these two surfaces. Therefore, it is important to pay particular attention to reducing the pressure on these areas for the resident at risk in accord with resident's overall goals and condition. Pillows used to support the entire lower leg may effectively raise the heel from contact with the bed, but use of the pillows needs to take into account the resident's other conditions. The use of donut-type cushions is not recommended by the clinicians.

- A resident with severe flexion contractures also may require special attention to effectively reduce pressure on bony prominences or prevent breakdown from skin-to-skin contact.

Some products serve mainly to provide comfort and reduce friction and shearing forces, e.g., sheepskin, heel and elbow protectors. Although these products are not effective at redistributing pressure, they (in addition to pillows, foam wedges, or other measures) may be employed to prevent bony prominences from rubbing together.

MONITORING

At least daily, staff should remain alert to potential changes in the skin condition and should evaluate and document identified changes. For example, a resident's complaint about pain or burning at a site where there has been pressure or a nursing assistant's observation during the resident's bath that there is a change in skin condition should be reported so that the resident may be evaluated further.

After completing a thorough evaluation, the interdisciplinary team should develop a relevant care plan to including prevention and management interventions with measurable goals. Many clinicians recommend evaluating skin condition (e.g., skin color, moisture, temperature, integrity, and turgor) at least weekly, or more often if indicated, such as when the resident is using a medical device that may cause pressure.

The resident should be monitored for condition changes that might increase the risk for breakdown and the defined interventions should be implemented and monitored for effectiveness.

ASSESSMENT AND TREATMENT OF PRESSURE ULCER(S)

It is important that each existing pressure ulcer be identified, whether present on admission or developed after admission, and that factors that influenced its development, the potential for development of additional ulcers or for the deterioration of the pressure ulcer(s) be recognized, assessed and addressed (see discussion under Prevention regarding overall assessment and interventions). Any new pressure ulcer suggests a need to reevaluate the adequacy of the plan for preventing pressure ulcers.

When assessing the ulcer itself, it is important to:

- Differentiate the type of ulcer (pressure-related versus non-pressure-related) because interventions may vary depending on the specific type of ulcer;

- Determine the ulcer's stage;

- Describe and monitor the ulcer's characteristics;

- Monitor the progress toward healing and for potential complications;
- Determine if infection is present;
- Assess, treat and monitor pain, if present; and
- Monitor dressings and treatments.

TYPES OF ULCERS

Three of the more common types of ulcers are pressure, vascular insufficiency/ischemia (venous stasis and arterial ischemic ulcers) and neuropathic. See Guidance to Surveyors at 42 CFR 483.25 (F309) for definition and description of ulcer types other than pressure ulcers.

At the time of the assessment, clinicians (physicians, advance practice nurses, physician assistants, and certified wound care specialists, etc.) should document the clinical basis (for example, type of skin injury/ulcer, location, shape, ulcer edges and wound bed, condition of surrounding tissues) for any determination that an ulcer is not pressure-related, especially if the injury/ulcer has characteristics consistent with a pressure ulcer, but is determined not to be one.

ULCER CHARACTERISTICS

It is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility.

When a pressure ulcer is present, daily monitoring, (with accompanying documentation, when a complication or change is identified), should include:

- An evaluation of the ulcer, if no dressing is present;
- An evaluation of the status of the dressing, if present (whether it is intact and whether drainage, if present, is or is not leaking);
- The status of the area surrounding the ulcer (that can be observed without removing the dressing);
- The presence of possible complications, such as signs of increasing area of ulceration or soft tissue infection (for example: increased redness or swelling around the wound or increased drainage from the wound); and
- Whether pain, if present, is being adequately controlled.

The amount of observation possible will depend upon the type of dressing that is used, since some dressings are meant to remain in place for several days, according to manufacturers' guidelines.

With each dressing change or at least weekly (and more often when indicated by wound complications or changes in wound characteristics), an evaluation of the pressure ulcer wound should be documented. At a minimum, documentation should include the date observed and:

- Location and staging;
- Size (perpendicular measurements of the greatest extent of length and width of the ulceration), depth; and the presence, location and extent of any undermining or tunneling/sinus tract;
- Exudate, if present: type (such as purulent/serous), color, odor and approximate amount;
- Pain, if present: nature and frequency (e.g., whether episodic or continuous);
- Wound bed: Color and type of tissue/character including evidence of healing (e.g., granulation tissue), or necrosis (slough or eschar); and
- Description of wound edges and surrounding tissue (e.g., rolled edges, redness, hardness/induration, maceration) as appropriate.

Photographs may be used to support this documentation, if the facility has developed a protocol consistent with accepted standards[33] (e.g., frequency, consistent distance from the wound, type of equipment used, means to assure digital images are accurate and not modified, inclusion of the resident identification/ulcer location/dates/etc. within the photographic image, and parameters for comparison).

STAGES OF PRESSURE ULCERS

The staging system is one method of summarizing certain characteristics of pressure ulcers, including the extent of tissue damage. This is the system used within the RAI.

Stage I pressure ulcers may be difficult to identify because they are not readily visible and they present with greater variability. Advanced technology (not commonly available in nursing homes) has shown that a Stage I pressure ulcer may have minimal to substantial tissue damage in layers beneath the skin's surface, even when there is no visible surface penetration. The Stage I indicators identified below will generally persist or be evident after the pressure on the area has been removed for 30-45 minutes.

The definitions for the stages of pressure ulcers identified below, are from the NPUAP and used with permission.[34]

- **"Stage I" -** An observable, pressure-related alteration of intact skin, whose indicators as compared to an adjacent or opposite area on the body may include changes in one or more of the following parameters:
    - Skin temperature (warmth or coolness);
    - Tissue consistency (firm or boggy);
    - Sensation (pain, itching); and/or
    - A defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.
- **"Stage II" -** Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
- **"Stage III" -** Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
- **"Stage IV" -** Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

NOTE: If eschar and necrotic tissue are covering and preventing adequate staging of a pressure ulcer, the RAI User's Manual Version 2 instructs the assessor to code the pressure ulcer as a Stage IV. These instructions must be followed for MDS coding purposes until they are revised. Although the AHCPR and NPUAP system for staging pressure ulcers indicates that the presence of eschar precludes accurate staging of the ulcer, the facility must use the RAI directions in order to code the MDS, but not necessarily to render treatment.

THE HEALING PRESSURE ULCER

Ongoing evaluation and research have indicated that pressure ulcers do not heal in a reverse sequence, that is, the body does not replace the types and layers of tissue (e.g., muscle, fat and dermis) that were lost during the pressure ulcer development.

There are different types of clinical documentation to describe the progression of the healing pressure ulcer(s). The regulation at 42 CFR 483.20(b)(1), F272, requires that facilities use the Resident Assessment Instrument (RAI), which includes direction to describe the healing of the pressure ulcer(s)for coding purposes for the MDS: The RAI User's Manual Version 2.0, instructs staff to identify the stages of pressure ulcer(s) by describing depth in reverse order from deepest to lesser stages to describe the healing or improvement of a pressure ulcer (e.g., a Stage IV becomes a Stage III and so forth. This has been referred to as "reverse staging" or "back staging").

Some clinicians utilize validated instruments to describe the healing of a pressure ulcer. Although such instruments are appropriate for making treatment decisions, they may not be utilized for coding the MDS. Until the MDS is revised, the present coding system (reverse staging) must be used for completion of the RAI.

Clinicians may use the National Pressure Ulcer Advisory Panel - Pressure Ulcer Scale for Healing (NPUAP-PUSH) tool. The NPUAP always refers to a healed pressure ulcer as a healed ulcer at the deepest stage of its development (e.g., a healed Stage IV or a healing Stage IV). The NPUAP cautions that the tool does not represent a comprehensive pressure ulcer assessment, and other factors may need to be considered when selecting pressure ulcer treatment options.

Since surveyors may encounter clinician's notes in which the NPUAP-PUSH tool is used as part of the facility's documentation protocol, the following description of the tool is provided. The NPUAP-PUSH tool documents pressure ulcer healing consistent with the healing process, describes a healing pressure ulcer in terms of three ulcer characteristics, and assigns a numeric value to the characteristics: length (cm) x width (cm), exudate amount, and type of tissue (closed with epithelium; new pink, shiny epithelial tissue; clean, pink or beefy red, shiny, moist granulation tissue; slough tissue; or necrotic, eschar tissue).

The 1994 AHCPR Guidelines and current literature[35] indicate that a clean pressure ulcer with adequate blood supply and innervation should show evidence of stabilization or some healing within 2-4 weeks. Evidence accumulating since 1962 indicates that management of wound exudate coupled with a clean, moist wound environment allows a chronic wound (e.g., pressure ulcer) to lay down healthy granulating tissue more efficiently.[36, 37]

If a pressure ulcer fails to show some evidence of progress toward healing within 2-4 weeks, the pressure ulcer (including potential complications) and the resident's overall clinical condition should be reassessed. Re-evaluation of the treatment plan including

determining whether to continue or modify the current interventions is also indicated. Results may vary depending on the resident's condition and interventions/treatments used. The complexity of the resident's condition may limit responsiveness to treatment or tolerance for certain treatment modalities. The clinicians, if deciding to retain the current regimen, should document the rationale for continuing the present treatment (for example, why some, or all, of the plan's interventions remain relevant despite little or no apparent healing).

Pressure ulcers may progress or may be associated with complications such as infection of the soft tissues around the wound (cellulitis), infection of the bone (osteomyelitis), infection of a joint (septic arthritis), abscess, spread of bacteria into the bloodstream (bacteremia/septicemia), chronic infection, or development of a sinus tract. Sometimes these complications may occur despite apparent improvement in the pressure ulcer itself. The physician's involvement is integral whenever significant changes in the nature of the wound or overall resident condition are identified.

INFECTIONS RELATED TO PRESSURE ULCERS

Current literature reports that all Stage II, III, and IV pressure ulcers are colonized with bacteria but may not be infected. Identification, diagnosis and treatment of infection, when present, are critical to healing a pressure ulcer.[38] The infection occurs when the bacteria have invaded the tissue surrounding or within the pressure ulcer.

As with any infection, classic signs and symptoms of infection may include purulent exudate, peri-wound warmth, swelling, induration or erythema (erythema may not be readily determined in individuals with dark skin pigmentation), increasing pain or tenderness around the site or delayed wound healing. These classic signs may not be as evident in someone with a granulating, chronic wound or an immuno-compromised or aged resident. Some infections may present primarily with pain or delayed healing without other typical clinical signs of infection.[39] Clinicians have developed some tools, which may facilitate identifying and assessing an infection[40, 41] and documenting progress toward healing.

Wounds may be classified as infected if the signs and symptoms of infection are present and/or a wound culture (obtained in accord with accepted standards, such as sterile tissue aspirate, a "quantitative surface swab" using the Levine technique or semi-quantitative swab) contains 100,000 (10^5) or greater micro-organisms per gram of tissue. A superficial swab may show the presence of bacteria, but is not a reliable method to identify infection.

Findings such as an elevated white blood cell count, bacteremia, sepsis, or fever may signal an infection related to a pressure ulcer area or a co-existing infection from a different source.

PAIN

The assessment and treatment of a resident's pain are integral components of pressure ulcer prevention and management. "The goal of pain management in the pressure ulcer patient is to eliminate the cause of pain, to provide analgesia, or both."[42] Pain that interferes with movement and/or affects mood may contribute to immobility and contribute to the potential for developing a pressure ulcer or for delayed healing or non-healing of an already existing ulcer.

It may be difficult to assess the degree of pain in a resident who is cognitively impaired. Some strategies and tools exist to help determine the presence and characteristics of pain (e.g., nature, intensity and frequency).[43, 44] Recent research suggests that a resident with a Stage IV pressure ulcer can feel as much pain as those with a Stage I or II ulcer.[45] The relationship of pain to the pressure ulcer healing process is not yet clear. Pain is an individual perception and response and an individual's report of pain is a generally valid indicator of pain. One resident may experience pain of varying intensity and frequency (e.g., continually or periodically) or episodically in association with treatments (e.g., debridement, dressing changes) or movement or infection, while another resident may not have or report pain.

DRESSINGS AND TREATMENTS

Research has found that chronic wounds such as pressure ulcers heal differently from acute wounds, primarily because of differing biochemical and cellular characteristics. Current clinical practice indicates that Stage III and Stage IV ulcers should be covered. Determination of the need for a dressing for a Stage I or Stage II ulcer is based upon the individual practitioner's clinical judgment and facility protocols based upon current clinical standards of practice. No particular dressing promotes healing of all pressure ulcers within an ulcer classification.[46]

For those pressure ulcers with significant exudate, management of the exudate is critical for healing. A balance is needed to assure that the wound is moist enough to support healing but not too moist to interfere with healing.[47] Since excess wound exudate generally impairs wound healing, selecting an appropriate absorptive dressing is an important part of managing chronic wound exudate.

Product selection should be based upon the relevance of the specific product to the identified pressure ulcer(s) characteristics, the treatment goals, and the manufacturer's recommendations for use. Current literature does not indicate significant advantages of any single specific product over another, but does confirm that not all products are appropriate for all pressure ulcers. Wound characteristics should be assessed throughout the healing process to assure that the treatments and dressings being used are appropriate to the nature of the wound.

Present literature suggests that pressure ulcer dressing protocols may use clean technique rather than sterile, but that appropriate sterile technique may be needed for those wounds that recently have been surgically debrided or repaired.[48]

Debridement of non-viable tissue is frequently performed to reduce the amount of wound debris or non-viable tissue and to reduce the risk of sepsis. A variety of debridement methods (e.g., mechanical, sharp or surgical, enzymatic, autolytic, MDT) are available. Removal of necrotic tissue should enhance wound healing. Ongoing monitoring (and timely intervention in case of change in the character of the wound) is critical for areas with eschar and those areas that have been debrided.[49] Many clinicians believe that stable, dry, adherent and intact eschar on the foot/heel should not be debrided, unless signs and symptoms of local infection or instability are detected.[50]

Some facilities may use "wet to dry gauze dressings" or irrigation with chemical solutions to remove slough. The use of wet-to-dry dressings or irrigations may be appropriate in limited circumstances, but repeated use may damage healthy granulation tissue in healing ulcers and may lead to excessive bleeding and increased resident pain.

A facility should be able to show that its treatment protocols are based upon current standards of practice and are in accord with the facility's policies and procedures as developed with the medical director's review and approval.

ENDNOTES

(For more information on the references below, visit the CMS Sharing Innovations in Quality website: www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp.

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INVESTIGATIVE PROTOCOL

PRESSURE ULCER

Objectives

- To determine if the identified pressure ulcer(s) is avoidable or unavoidable; and
- To determine the adequacy of the facility's interventions and efforts to prevent and treat pressure ulcers.

Use

Use this protocol for a sampled resident having--or at risk of developing-- a pressure ulcer.

If the resident has an ulcer, determine if it was identified as non-pressure related, e.g., vascular insufficiency or a neuropathic ulcer. If record review, staff and/or physician interview, and observation (unless the dressing protocol precludes observing the wound) support the conclusion that the ulcer is not pressure related, do not proceed with this protocol unless the resident is at risk for developing, or also has, pressure ulcers. Evaluate care and services regarding non-pressure related ulcers at F309, Quality of Care.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. For a newly admitted resident either at risk or with a pressure ulcer, the staff is expected to assess and provide appropriate care from the day of admission. Corroborate observations by interview and record review.

1. Observation

Observe whether staff consistently implements the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan as well as potential negative outcomes, including but not limited to the following:

- Erythema or color changes on areas such as the sacrum, buttocks, trochanters, posterior thigh, popliteal area, or heels when moved off an area:
    - If erythema or color change are noted, return approximately ½ - ¾ hours later to determine if the changes or other Stage I characteristics persist;
    - If the changes persist and exhibit tenderness, hardness, or alteration in temperature from surrounding skin, ask staff how they determine repositioning schedules and how they evaluate and address a potential Stage I pressure ulcer;

- Previously unidentified open areas;

- Whether the positioning avoids pressure on an existing pressure ulcer(s);

- Measures taken to prevent or reduce the potential for shearing or friction during transfers, elevation, and repositioning; and

- Whether pressure-redistributing devices for the bed and/or chair, such as gel-type surfaces or overlays are in place, working, and used according to the manufacturer's recommendations.

Observation of Existing Ulcer/Wound Care

If a dressing change is scheduled during the survey, observe the wound care to determine if the record reflects the current status of the ulcer(s) and note:

- Characteristics of the wound and surrounding tissues such as presence of granulation tissue, the Stage, presence of exudates, necrotic tissue such as eschar or slough, or evidence of erythema or swelling around the wound;

- The form or type of debridement, if used;

- Whether treatment and infection control practices reflect current standards of practice; and

- Based on location, steps taken to cleanse and protect the wound from likely contamination by urine or fecal incontinence.

If unable to observe the dressing change due to the dressing protocol, observe the area surrounding the ulcer(s). For ulcers with dressings that are not scheduled to be changed, the surveyor may request that the dressing be removed to observe the wound and surrounding area if other information suggests a possible treatment or assessment problem.

If the resident expresses (or appears to be in) pain related to the ulcer or treatment, determine if the facility:

- Assessed for pain related to the ulcer, addressed and monitored interventions for effectiveness; and/or

- Assessed and took preemptive measures for pain related to dressing changes or other treatments, such as debridement/irrigations, and monitored for effectiveness.

2. Resident/Staff Interviews

Interview the resident, family or responsible party to the degree possible to identify:

- Involvement in care plan, choices, goals, and if interventions reflect preferences;
- Awareness of approaches, such as pressure redistribution devices or equipment, turning/repositioning, weight shifting to prevent or address pressure ulcer(s);
- Presence of pain, if any, and how it is managed;
- If treatment(s) was refused, whether counseling on alternatives, consequences, and/or other interventions was offered; and
- Awareness of current or history of an ulcer(s). For the resident who has or has had a pressure ulcer, identify, as possible, whether acute illness, weight loss or other condition changes occurred prior to developing the ulcer.

Interview staff on various shifts to determine:

- Knowledge of prevention and treatment, including facility-specific guidelines/protocols and specific interventions for the resident;
- If nursing assistants know what, when, and to whom to report changes in skin condition; and
- Who monitors for the implementation of the care plan, changes in the skin, the development of pressure ulcers, and the frequency of review and evaluation of an ulcer.

3. Record Review

Assessment

Review the RAI and other documents such as physician orders, progress notes, nurses' notes, pharmacy or dietary notes regarding the assessment of the resident's overall condition, risk factors and presence of a pressure ulcer(s) to determine if the facility identified the resident at risk and evaluated the factors placing the resident at risk:

- For a resident who was admitted with an ulcer or who developed one within 1 to 2 days, review the admission documentation regarding the wound site and characteristics at the time of admission, the possibility of underlying tissue damage because of immobility or illness prior to admission, skin condition on or within a day of admission, history of impaired nutrition; and history of previous pressure ulcers; and

- For a resident who subsequently developed or has an existing pressure ulcer, review documentation regarding the wound site, characteristics, progress and complications including reassessment if there were no signs of progression towards healing within 2 to 4 weeks.

In considering the appropriateness of a facility's response to the presence, progression, or deterioration of a pressure ulcer, take into account the resident's condition, complications, time needed to determine the effectiveness of a treatment, and the facility's efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

Care Plan

For the resident at risk for developing or who has a pressure ulcer, determine if the facility developed an individualized care plan that addresses prevention, care and treatment of any existing pressure ulcers, including specific interventions, measurable objectives and approximate time frames.

If the facility's care of a specific resident refers to a treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol. The care plan should clarify any major deviations from, or revisions to, that protocol in a specific resident.

A specific care plan intervention for risk of pressure ulcers is not needed if other components of the care plan address related risks adequately. For example, the risk of skin breakdown posed by fecal/urinary incontinence might be addressed in that part of the care plan that deals with incontinence management.

If the resident refuses or resists staff interventions to reduce risk or treat existing pressure ulcers, determine if the care plan reflects efforts to seek alternatives to address the needs identified in the assessment.

Revision of the Care Plan

Determine if the staff have been monitoring the resident's response to interventions for prevention and/or treatment and have evaluated and revised the care plan based on the resident's response, outcomes, and needs. Review the record and interview staff for information and/or evidence that:

- Continuing the current approaches meets the resident's needs, if the resident has experienced recurring pressure ulcers or lack of progression toward healing and staff did not revise the care plan; and

- The care plan was revised to modify the prevention strategies and to address the presence and treatment of a newly developed pressure ulcer, for the resident who acquired a new ulcer.

4. Interviews with Health Care Practitioners and Professionals

If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

- How it was determined that chosen interventions were appropriate;
- Risks identified for which there were no interventions;
- Changes in condition that may justify additional or different interventions; or
- How they validated the effectiveness of current interventions.

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F314)

The pressure ulcer requirement has two aspects. The first aspect requires the facility to prevent the development of pressure ulcer(s) in a resident who is admitted without pressure ulcer(s), unless the development is clinically unavoidable. The second aspect requires the facility to provide necessary treatment and services to promote healing, prevent infection and prevent new ulcers from developing. A facility may have non-compliance in either or both aspects of this requirement.

Criteria for Compliance

- Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sore
    - For a resident who developed a pressure ulcer after admission, the facility is in compliance with this requirement, if staff have:
        - Recognized and assessed factors placing the resident at risk for developing a pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;

- Defined and implemented interventions for pressure ulcer prevention in accordance with resident needs, goals and recognized standards of practice;
- Monitored and evaluated the resident's response to preventive efforts; and
- Revised the approaches as appropriate.

If not, the development of the pressure ulcer is avoidable, cite at F314.

- Compliance with 42 CFR 483.25(c)(2), F314, Pressure Sore
  - For a resident who was admitted with a pressure ulcer, who has a pressure ulcer that is not healing, or who is at risk of developing subsequent pressure ulcers, the facility is in compliance with this requirement if they:
    - Recognized and assessed factors placing the resident at risk of developing a new pressure ulcer or experiencing non-healing or delayed healing of a current pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
    - Defined and implemented interventions for pressure ulcer prevention and treatment in accordance with resident needs, goals and recognized standards of practice;
    - Addressed the potential for infection;
    - Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
    - Revised the approaches as appropriate.

    If not, cite at F314.

Non-compliance for F314

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Non-compliance for F314 may include (but is not limited to) one or more of the following, including failure to:

- Accurately or consistently assess a resident's skin integrity on admission and as indicated thereafter;
- Identify a resident at risk of developing a pressure ulcer(s);

- Identify and address risk factors for developing a pressure ulcer, or explain adequately why they could not or should not do so;

- Implement preventive interventions in accord with the resident's need and current standards of practice;

- Provide clinical justification for the unavoidable development or non-healing/ delayed healing or deterioration of a pressure ulcer;

- Provide appropriate interventions, care and treatment to an existing pressure ulcer to minimize infections and to promote healing;

- Implement interventions for existing wounds;

- Notify the physician of the resident's condition or changes in the resident's wound(s);

- Adequately implement pertinent infection management practices in relation to wound care; and

- Identify or know how to apply relevant policies and procedures for pressure ulcer prevention and treatment.

Potential Tags for Additional Investigation

During the investigation of F314, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- 42 CFR 483.10(b)(11)(i)(B)&(C), F157, Notification of Changes

    - Determine if staff notified the physician of significant changes in the resident's condition or failure of the treatment plan to prevent or heal pressure ulcers; or the resident's representative (if known) of significant changes in the resident's condition in relation to the development of a pressure ulcer or a change in the progression of healing of an existing pressure ulcer.

- 42 CFR 483.20(b)(1), F272, Comprehensive Assessments

    - Determine if the facility comprehensively assessed the resident's skin condition, including existing pressure ulcers, and resident-specific risk

factors (including potential causative factors) for the development of a pressure ulcer or non-healing of the ulcer.

- 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
    - Determine if the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and current standards of practice and included measurable objectives and timetables, specific interventions/services to prevent the development of pressure ulcers and/or to treat existing pressures ulcers.
- 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
    - Determine if the care plan was periodically reviewed and revised as necessary to prevent the development of pressure ulcers and to promote the healing of existing pressure ulcers.
- 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
    - Determine if pressure ulcer care was provided in accordance with accepted professional standards.
- 42 CFR 483.25, F309, Quality of Care
    - Determine if staff identified and implemented appropriate measures for the management of pain as indicated as related to pressure ulcers and pressure ulcer treatment.
- 42 CFR 482.30(a), F353, Sufficient Staff
    - Determine if the facility had qualified staff in sufficient numbers to assure the resident was provided necessary care and services, based upon the comprehensive assessment and care plan, to prevent or treat pressure ulcers.
- 42 CFR 483.40(a)(1), F385, Physician Supervision
    - Determine if the physician has assessed and developed a treatment regimen relevant to preventing or healing a pressure ulcer and responded appropriately to the notice of changes in condition.
- 42 CFR 483.75(i)(2), F501, Medical Director

- Determine whether the medical director assisted the facility in the development and implementation of policies and procedures for pressure ulcer prevention and treatment, and that these are based on current standards of practice; and whether the medical director interacts with the physician supervising the care of the resident if requested by the facility to intervene on behalf of the resident with a pressure ulcer(s).

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified the deficient practices that demonstrate that the facility failed to provide care and treatment to prevent or treat pressure ulcers and that non-compliance exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F314 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F314 may include but is not limited to:

- Potential for development of, occurrence or recurrence of (an) avoidable pressure ulcer(s);
- Complications such as sepsis or pain related to the presence of avoidable pressure ulcer(s); and/or
- Pressure ulcers that fail to improve as anticipated or develop complications such as sepsis or pain because of the lack of appropriate treatment and care.

2. Degree of harm (actual or potential) related to the non-compliance

Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise or discomfort; and
- If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F314. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's non-compliance:

- With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment or death to a resident; and

- Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible avoidable negative outcomes may include:

- Development of avoidable Stage IV pressure ulcer(s): As a result of the facility's non-compliance, permanent tissue damage (whether or not healing occurs) has compromised the resident, increasing the potential for serious complications including osteomyelitits and sepsis.

- Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility's non-compliance, a Stage IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.

- Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility's failure to assess or treat a resident with an infectious complication of a pressure ulcer. (See discussion in guidelines and definitions that distinguishes colonization from infection.)

- Extensive failure in multiple areas of pressure ulcer care: As a result of the facility's extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include but are not limited to:

- **The development of avoidable Stage III pressure ulcer(s):** As a result of the facility's non-compliance, Stage III pressure ulcers occurred, which are open wounds in which damage has occurred into the subcutaneous level and may be painful.

- **The development of recurrent or multiple avoidable Stage II pressure ulcer(s):** As a result of the facility's non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.

- **Failure to implement the comprehensive care plan for a resident who has a pressure ulcer**: As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable negative outcomes may include but are not limited to:

- **The development of a single avoidable Stage II pressure ulcer that is receiving appropriate treatment:** As a result of the facility's non-compliance, a resident developed an avoidable Stage II pressure ulcer.

- **The development of an avoidable Stage I pressure ulcer**: As a result of the facility's non-compliance, a resident developed an avoidable Stage I pressure ulcer.

- **Failure to implement an element of the care plan for a resident who has a pressure ulcer however, there has been no evidence of decline or failure to heal.**

- **Failure to recognize or address the potential for developing a pressure ulcer:** As a result of the facility's non-compliance, staff failed to identify the risks, develop a plan of care and/or consistently implement a plan that has been developed to prevent pressure ulcers.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to prevent pressure ulcers or heal existing pressure ulcers is more than minimal harm. Therefore, Severity Level 1 doesn't apply for this regulatory requirement.

F315
§483.25(d) Urinary Incontinence

(Rev.8, Issued: 06-28-05, Effective: 06-28-05, Implementation: 06-28-05)

Based on the resident's comprehensive assessment, the facility must ensure that --

§483.25(d) (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

§483.25(d) (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

INTENT: (F315) 42 CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters

The intent of this requirement is to ensure that:

- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal urinary function as possible;

- An indwelling catheter is not used unless there is valid medical justification;

- An indwelling catheter for which continuing use is not medically justified is discontinued as soon as clinically warranted;

- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter; and

- A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

DEFINITIONS

Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

- "Bacteremia" is the presence of bacteria in the bloodstream.

- "Bacteriuria" is defined as the presence of bacteria in the urine.

- "Urinary Incontinence" is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:

    - "Functional Incontinence" refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);

    - "Mixed Incontinence" is the combination of stress incontinence and urge incontinence;

    - "Overflow Incontinence" is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;

    - "Stress Incontinence" (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;

    - "Transient Incontinence" refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and

    - "Urge Incontinence" (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).

- "Urinary Retention" is the inability to completely empty the urinary bladder by micturition.

- "Urinary Tract Infection" (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

- "Urosepsis" refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

OVERVIEW

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.

Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles[1] and data currently available, including CMS data (e.g., MDS Active Resident Information Report (Item H1b) at www.cms.hhs.gov/states/mdsreports), indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing, and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation, and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple antibiotic usage), conditions that cause incontinence, and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. Urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often related to an indwelling urinary catheter**.** Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident's own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

Resources

It is important for the facility to have in place systems/procedures to assure: assessments are timely and appropriate; interventions are defined, implemented, monitored, and revised as appropriate in accordance with current standards of practice; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The medical director and the quality assessment and assurance committee may help the facility evaluate existing strategies for identifying and managing incontinence, catheter use, and UTIs, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) at www.amda.com (Clinical Practice Guidelines: Clinical Practice Guidelines, 1996);

- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives at www.medqic.org;

- The CMS Sharing Innovations in Quality website at www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp;

- Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;

- Centers for Disease Control at www.cdc.gov;

- The Annals of Long Term Care publications at www.mmhc.com;

- American Foundation for Urologic Disease, Inc. at www.afud.org; and

- The American Geriatrics Society at www.americangeriatrics.org.

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U. S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Resident Choice

In the course of developing and implementing care plan interventions for treatment and services related to achieving the highest practicable level of urinary continence, preventing and treating urinary tract infections, and avoiding the use of indwelling catheters without medical justification, it is important to involve the resident and/or her or his surrogate in care decisions and to consider whether the resident has an advance directive in place.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility should address the resident's concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights 483.10(b) (3) and (4) (F154 and F155).)

Advance Directive. A resident who is at the end of life or in terminal stages of an illness or who has multiple organ system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's surrogate or representative, in accordance with State law).

Although a facility's care must reflect a resident's wishes as expressed in the Directive, in accordance with State law, the presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive. The presence of a "Do Not Resuscitate" (DNR) order does not indicate that the resident is declining appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized), and has provided care based on the assessed needs of the resident, then the development, continuation, or progression of urinary incontinence; the insertion and prolonged use of an indwelling urinary catheter; the development of infection or skin-related complications from urine or an indwelling catheter may be consistent with regulatory requirements.

URINARY INCONTINENCE

42 CFR 483.25 (d) (2) Urinary Incontinence requires that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident's capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner, may at his or her option, refer residents to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

Assessment

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident's quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability, or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence. If the resident has urinary incontinence that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the Resident Assessment Instrument (RAI). The location of RAI assessment information is identified on the Resident Assessment Protocol (RAP) summary form. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and

characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;

- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;

- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);[2]

- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;

- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);[3]

- Pelvic and rectal examination to identify physical features that may directly affect urinary incontinence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;

- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with movement;

- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;

- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson’s Disease or tumors that could affect the urinary tract or its function);

- Identification of and/or potential of developing complications such as skin irritation or breakdown;

- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and

- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence. Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence.

- Urge Incontinence is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's Disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.

- Stress Incontinence is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.

- Mixed Incontinence is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.

- Overflow Incontinence occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to

determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.

- Functional Incontinence refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e) (1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).

  NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident's continence, may fail to solve the incontinence problem.

- Transient Incontinence refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying medical conditions, an inaccurate assessment of the resident's type of incontinence (or lack of knowledge about the resident's voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;

- Removing or improving environmental impediments that affect the resident's level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);

- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);

- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and

- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral Programs - Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident's behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident's ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void.[4] Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident's cooperation and motivation in order for learning and practice to occur include the following:

- "Bladder Rehabilitation/Bladder Retraining" is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident's successful ability

to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining; and

- "Pelvic Floor Muscle Rehabilitation," also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periuretheral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- "Prompted Voiding" is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit—provided that they at least are able to say their name or reliably point to one of two objects.[5] Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training, motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

  Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident's cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program; and

- "Habit Training/Scheduled Voiding" is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident's voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident's usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

Intermittent Catheterization - Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in "Catheterization".

Medication Therapy - Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the education and discussion with the resident (or the resident's surrogate) regarding the benefits and risks of pharmacologic therapies is important.

Pessary - A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

Absorbent Products, Toileting Devices, and External Collection Devices - Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident's dignity and comfort.

NOTE: Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

The potential disadvantages of absorbent products are the impact on the resident's dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.[6]

It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, accepted standards of practice, and the manufacturer's recommendations.

Skin-Related Complications

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes "soggy" texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly depressed area of skin.

One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers.[7] Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly—if at all—on already macerated or excessively moist skin.

CATHETERIZATION

42 CFR 483.25 (d) (1) Urinary Incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical

condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

Assessment

A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident's medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal. The clinician's decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility's documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

Intermittent Catheterization

Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

Indwelling Catheter Use

The facility's documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:[8]

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
    - Documented post void residual (PVR) volumes in a range over 200 milliliters (ml);
    - Inability to manage the retention/incontinence with intermittent catheterization; and
    - Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.
- Contamination of Stage III or IV pressure ulcers with urine which has impeded healing, despite appropriate personal care for the incontinence; and
- Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.

Catheter-Related Complications

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, indwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident's individualized assessment, the catheter may need to be changed more or less often than every 30 days.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder. Additional care practices related to catheterization include:

- Educating the resident or responsible party on the risks and benefits of catheter

use;

- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;

- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;

- Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;

- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and

- Securing the catheter to facilitate flow of urine.

Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal.[9] The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;

- Assessing whether other treatments and services would appropriately address those conditions; and

- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

URINARY TRACT INFECTIONS

Catheter-Related Bacteriuria and UTIs/Urosepsis

Most individuals with indwelling catheters for more than 7 days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long term indwelling catheter (>2 to 4 weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.[10]

Clinical Evidence That May Suggest UTI

Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings such as fever with hematuria are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis, or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.[11]

In someone with nonspecific symptoms such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual's normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.[12]

Indications to Treat a UTI

Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:[13]

- Residents without a catheter should have at least three of the following signs and symptoms:
    - Fever (increase in temperature of >2 degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (37.8 degrees C));[14]
    - New or increased burning pain on urination, frequency or urgency;
    - New flank or suprapubic pain or tenderness;
    - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or

microscopic hematuria); and/or

  - Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).[15]

- Residents with a catheter should have at least two of the following signs and symptoms:

  - Fever or chills;

  - New flank pain or suprapubic pain or tenderness;

  - Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or

  - Worsening of mental or functional status. Local findings such as obstruction, leakage, or mucosal trauma (hematuria) may also be present.[16]

Follow-Up of UTIs

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ standard infection control practices in managing catheters and associated drainage system;

- Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);

- Take measures to maintain free urine flow through any indwelling catheter; and

- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

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INVESTIGATIVE PROTOCOL

URINARY CONTINENCE AND CATHETERS

Objectives

- To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;
- To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and
- To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use

Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review.

NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.

1. Observation

Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.

Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.

For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:

- The frequency of breakthrough or transient incontinence;
- How staff respond to the incontinence episodes; and
- Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:

Whether the resident is on a scheduled check and change program; and

Whether staff check and change in a timely fashion.

For a resident who has experienced an incontinent episode, observe:

The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles, saturated linens/clothing, odors, etc.);

The resident's physical condition (such as skin integrity, maceration, erythema, erosion);

The resident's psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);

- Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine; and

Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident’s dignity.

For a resident with an indwelling catheter, observe the delivery of care to evaluate:

- Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;

- Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);

- How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;

- If the resident has catheter-related pain, how staff assess and manage the pain; and

- What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.

For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids to meet the resident's hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident's clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews

Interview the resident, family or responsible party to the degree possible to identify:

- Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;

- Their awareness of the existing continence program and how to use devices or equipment;

- If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;

- If the resident comprehends and applies information and instructions to help improve or maintain continence (where cognition permits);

- Presence of urinary tract-related pain, including causes and management;

- If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed; and

- Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:

Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);

Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and

Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review

Assessment and Evaluation. Review the RAI, the history and physical, and other information such as physician orders, progress notes, nurses' notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident's voiding history, including the assessment of the resident's overall condition, risk factors and information about the resident's continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident's responses to catheter/continence services. Request staff assistance, if the information is not readily available.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:

- Patterns of incontinent episodes, daily voiding patterns or prior routines;
- Fluid intake and hydration status;
- Risks or conditions that may affect urinary continence;
- Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;
- Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;
- Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;

- Type and frequency of physical assistance necessary to facilitate toileting;
- Clinical rationale for use of an indwelling catheter;
- Alternatives to extended use of an indwelling catheter (if possible); and
- Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

Care Plan. If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:

- Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;
- Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
- Is based upon resident choices and preferences;
- Promotes maintenance of resident dignity;
- Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
- Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
- Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
- Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;

- Identifies and addresses the potential impact on continence of medication and urinary tract stimulants or irritants (e.g., caffeine) in foods and beverages;

- Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care); and

- Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.

For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.

For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine whether the care plan:

- Identifies the type of urinary incontinence and bases the program on the resident's voiding/elimination patterns; and

- Has been developed by considering the resident's medical/health condition, cognitive and functional ability to participate in a relevant continence program, and needed assistance.

For the resident with a catheter, determine whether the care plan:

- Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;

- Provides for assessment and removal of the indwelling catheter when no longer needed; and

- Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.

Care Plan Revision. Determine if the resident's condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:

- The outcome and/or effects of goals and interventions;

- A decline or lack of improvement in continence status;

- Complications associated with catheter usage;

- Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;

- Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;

- Input by the resident and/or the responsible person; and

- An evaluation of the resident's level of participation in, and response to, the continence program.

4. Interviews with Health Care Practitioners and Professionals

If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident's care. Determine:

- How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;

- If the resident resists toileting, how staff have been taught to respond;

- Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);

- If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;

- For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:

    - The type of incontinence;

    - The interventions to address that specific type;

    - How it is determined that the schedule and program is effective (i.e., how continence is maintained or if there has been a decline or improvement in continence, how the program is revised to address the changes); and

    - Whether the resident has any physical or cognitive limitations that influence potential improvement of his/her continence;

- For residents with urinary catheters, whether the nursing staff:
    - Can provide appropriate justification for the use of the catheter;
    - Can identify previous attempts made (and the results of the attempts) to remove a catheter; and
    - Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

- How it was determined that the chosen interventions were appropriate;
- Risks identified for which there were no interventions;
- Changes in condition that may justify additional or different interventions; or how they validated the effectiveness of current interventions; and
- How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident's responses, etc.).

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F315)

The urinary incontinence requirement has three aspects. The first aspect requires that a resident who does not have an indwelling urinary catheter does not have one inserted unless the resident's clinical condition demonstrates that it was necessary. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

Criteria for Compliance

- Compliance with 42 CFR 483.25(d)(1) and (2), F315, Urinary Incontinence

- For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have:

    - Recognized and assessed factors affecting the resident's urinary function and identified the medical justification for the use of an indwelling urinary catheter;

    - Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident conditions, goals, and recognized standards of practice;

    - Monitored and evaluated the resident's response to interventions; and

    - Revised the approaches as appropriate.

  If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident's needs. Cite F315.

- For a resident who is incontinent of urine, the facility is in compliance with this requirement if they:

    - Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;

    - Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice;

    - Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and

    - Revised the approaches as appropriate.

  If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

- For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have:

  - Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;

  - Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice;

  - Monitored and evaluated the resident's responses to preventive efforts and treatment interventions; and

  - Revised the approaches as appropriate.

  If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

Noncompliance for F315

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

- Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;

- Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;

- Assess, prevent (to the extent possible) and treat a symptomatic urinary tract infection (as indicated by the resident's choices, clinical condition and physician treatment plan);

- Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;

- Identify and address risk factors for developing urinary incontinence;

- Implement interventions (such as bladder rehabilitative programs) to try to improve bladder function or prevent urinary incontinence, consistent with the resident's assessed need and current standards of practice;

- Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;

- Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;

- Implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures;

- Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;

- Notify the physician of the resident's condition or changes in the resident's continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria).

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:

- 42 CFR 483.10(b)(11), F157, Notification of Changes

    - Determine if staff notified the physician of significant changes in the resident's continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident's representative (where one exists) of significant changes as noted above.

- 42 CFR 483.15(a), F241, Dignity

    - Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.

- 42 CFR 483.20(b)(1), F272, Comprehensive Assessments

    - Determine if the facility comprehensively assessed the resident's continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.

- 42 CFR 483.20(k), F279, Comprehensive Care Plans
    - Determine if the facility developed a care plan (1) that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs to the extent possible.
- 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
    - Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.
- 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
    - Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.
- 42 CFR 483.25, F309, Quality of Care
    - Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.
- 42 CFR 483.25 (a)(3) F312, Quality of Care
    - Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.
- 42 CFR 483.40(a), F385, Physician Supervision
    - Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.
- 42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing

    - Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.

- 42 CFR 483.75(f), F498, Proficiency of Nurse Aides

    - Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.

- 42 CFR 483.30(a), F353, Sufficient Staff

    - Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.

- 42 CFR 483.75(i)(2), F501, Medical Director

    - Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F315 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F315 may include, but is not limited to:

    - Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions;

    - Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified;

- Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification; and

- Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

   - If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and

   - If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

   The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F315. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and

- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible negative outcomes as a result of the facility's deficient practices may include:

- **Complications resulting from utilization of urinary appliance(s) without medical justification:** As a result of incorrect or unwarranted (i.e., not medically indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.

- **Extensive failure in multiple areas of incontinence care and/or catheter management:** As a result of the facility's noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include, but are not limited to:

- **The development of a symptomatic UTI:** As a result of the facility's noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.

- **The failure to identify, assess and mange urinary retention:** As a result of the facility's noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.

- **The failure to provide appropriate catheter care:** As a result of the facility's noncompliance, the catheter was improperly managed, resulting in catheter-related pain, bleeding, urethral tears or urethral erosion.

- **Medically unjustified use of an indwelling catheter with complications:** As a result of the facility's noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.

- **Decline or failure to improve continence status:** As a result of the facility's failure to assess and/or re-assess the resident's continence status, utilize sufficient

staffing to implement continence programs and provide other related services based on the resident's assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.

- **Complications due to urinary incontinence:** As a result of the facility's failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to embarrassment or humiliation related to unmanaged urinary incontinence.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of potentially avoidable negative outcomes may include, but are not limited to:

- **Medically unjustified use of an indwelling catheter:** As a result of the facility's noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.

- **Complications associated with inadequate care and services for an indwelling catheter:** As a result of the facility's noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.

- **Potential for decline or complications:** As a result of the facility's failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

Severity Level 1: No actual harm with potential for minimal harm

The failures of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome

places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

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§483.25(e) Range of motion.

Based on the comprehensive assessment of a resident, the facility must ensure that

(see Tag **F318** for intent, guidelines, procedures, and probes for §483.25(e))

F317

§483.25(e)(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

SEE INTERPRERTIVE GUIDELINES AT TAG F318

F318

§483.25(e)(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion

Intent §483.25(e)

The intent of this regulation is to ensure that the resident reaches and maintains his or her highest level of range of motion and to prevent avoidable decline of range of motion.

Interpretive Guidelines §483.25(e)

This corresponds to MDS 2.0 sections G and P when specified for use by the State.

"Range of motion (ROM)" is defined as the extent of movement of a joint.

The clinical condition that may demonstrate that a reduction in ROM is unavoidable is: limbs or digits immobilized because of injury or surgical procedures (e.g., surgical adhesions).

Adequate preventive care may include active ROM performed by the resident's passive ROM performed by staff; active-assistive ROM exercise performed by the resident and staff; and application of splints and braces, if necessary.

Examples of clinical conditions that are the primary risk factors for a decreased range of motion are:

- Immobilization (e.g., bedfast);
- Deformities arising out of neurological deficits (e.g., strokes, multiple sclerosis, cerebral palsy, and polio); and
- Pain, spasms, and immobility associated with arthritis or late state Alzheimer's disease.

This clinical condition may demonstrate that a reduction in ROM is unavoidable only if adequate assessment, appropriate care planning, and preventive care was provided, and resulted in limitation in ROM or muscle atrophy.

Procedures §483.25(e)

For each resident selected for a comprehensive review, or focused review, as appropriate, who needs routine preventive care:

- Observe staff providing routine ROM exercises. Are they done according to the care plan?

Probes: §483.25(e)

Is there evidence that there has been a decline in sampled residents' ROM or muscle atrophy that was avoidable?

- Was the resident at risk for decline in ROM? If so, why?
- What care did the facility provide, including routine preventive measures that addressed the resident's unique risk factors (e.g., use muscle strengthening exercises in residents with muscle atrophy)?
    - Was this care provided consistently?

For all sampled residents who have limited ROM, what is the facility doing to prevent further declines in ROM?

- Are passive ROM exercises provided and active ROM exercises supervised per the plan of care?
- Have care plan objectives identified resident's needs and has resident progress been evaluated?

- Is there evidence that care planning is changed as the resident's condition changes?

- Identify if resident triggers RAPs for ADL functional/rehabilitation potential, visual function, and communication. Consider whether the RAPs used to assess causal factors for decline, potential for decline or lack of improvement.

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§483.25(f) Mental and Psychosocial Functioning

Based on the comprehensive assessment of a resident, the facility must ensure that--

(See **Tag F319** for intent, guidelines, and probes for §483.25(f))

F319

§483.25(f)(1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem; and

Intent §483.25(f)

The intent of this regulation is that the resident receives care and services to assist him or her to reach and maintain the highest level of mental and psychosocial functioning.

Interpretive Guidelines §483.25(f)

This corresponds to MDS 2.0 sections B, F, E, and I when specified for use by the State.

"Mental and psychosocial adjustment difficulties" refer to problems residents have in adapting to changes in life's circumstances. The former focuses on internal thought processes; the latter, on the external manifestations of these thought patterns.

Mental and psychosocial adjustment difficulties are characterized primarily by an overwhelming sense of loss of one's capabilities; of family and friends; of the ability to continue to pursue activities and hobbies; and of one's possessions. This sense of loss is perceived as global and uncontrollable and is supported by thinking patterns that focus on helplessness and hopelessness; that all learning and essentially all meaningful living ceases once one enters a nursing home. A resident with a mental adjustment disorder will have a sad or anxious mood, or a behavioral symptom such as aggression.

The "Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM/IV)," specifies that adjustment disorders develop within 3 months of a stressor (e.g., moving to

another room) and are evidenced by significant functional impairment. Bereavement with the death of a loved one is not associated with adjustment disorders developed within 3 months of a stressor.

Other manifestations of mental and psychosocial adjustment difficulties may, over a period of time, include:

- Impaired verbal communication;
- Social isolation (e.g., loss or failure to have relationships);
- Sleep pattern disturbance (e.g., disruptive change in sleep/rest pattern as related to one's biological and emotional needs);
- Spiritual distress (disturbances in one's belief system);
- Inability to control behavior and potential for violence (aggressive behavior directed at self or others); and
- Stereotyped response to any stressor (i.e., the same characteristic response, regardless of the stimulus).

Appropriate treatment and services for psychosocial adjustment difficulties may include providing residents with opportunities for self-governance; systematic orientation programs; arrangements to keep residents in touch with their communities, cultural heritage, former lifestyle, and religious practices; and maintaining contact with friends and family Appropriate treatment for mental adjustment difficulties may include crisis intervention services; individual, group or family psychotherapy, drug therapy and training in monitoring of drug therapy and other rehabilitative services. (See §483.45(a).)

Clinical conditions that may produce apathy, malaise, and decreased energy levels that can be mistaken for depression associated with mental or psychosocial adjustment difficulty are: (This list is not all inclusive.)

- Metabolic diseases (e.g., abnormalities of serum glucose, potassium, calcium, and blood urea nitrogen, hepatic dysfunction);
- Endocrine diseases (e.g., hypothyroidism, hyperthyroidism, diabetes, hypoparathyroidism, hyperparathyroidism, Cushing's disease, Addison's disease);
- Central nervous system diseases (e.g., tumors and other mass lesions, Parkinson's disease, multiple sclerosis, Alzheimer's disease, vascular disease);

- Miscellaneous diseases (e.g., pernicious anemia, pancreatic disease, malignancy, infections, congestive heart failure);

- Over-medication with anti-hypertensive drugs; and

- Presence of restraints.

Probes: §483.25(f)(1)

For sampled residents selected for a comprehensive or focused review, determine, as appropriate, for those residents exhibiting difficulties in mental and psychosocial adjustment:

- Is there a complete accurate assessment of resident's usual and customary routines?

- What evidence is there that the facility makes accommodations for the resident's usual and customary routines?

- What programs/activities has the resident received to improve and maintain maximum mental and psychosocial functioning?

- Has the resident's mental and psychosocial functioning been maintained or improved (e.g., fewer symptoms of distress)? Have treatment plans and objectives been re-evaluated?

- Has the resident received a psychological or psychiatric evaluation to evaluate, diagnose, or treat her/his condition, if necessary?

- Identify if resident triggers RAPs for activities, mood state, psychosocial well-being, and psychotropic drug use. Consider whether the RAPs were used to assess the causal factors for decline, potential for decline or lack of improvement.

- How are mental and psychosocial adjustment difficulties addressed in the care plan?

See §483.45(a), F406 for health rehabilitative services for mental illness and mental retardation.

Psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

F320

§483.25(f)(2)

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern is unavoidable.

Procedures §483.25(f)(2)

For sampled residents whose assessment did not reveal a mental or psychosocial adjustment difficulty, but who display decreased social interaction or increased withdrawn, angry, or depressed behaviors, determine, as appropriate, was this behavior unavoidable.

Probes: §483.25(f)(2)

- Did the facility attempt to evaluate whether this behavior was attributable to organic causes or other risk factors not associated with adjusting to living in the nursing facility?

- What care did the resident receive to maintain his/her mental or psychosocial functioning?

- Were individual objectives of the plan of care periodically evaluated, and if progress was not made in reducing, maintaining, or increasing behaviors that assist the resident to have his/her needs met, were alternative treatment approaches developed to maintain mental or psychosocial functioning?

- Identify if resident triggers RAPs for behavior problem, cognitive loss/dementia, and psychosocial well-being. Consider whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement.

- Did the facility use the RAPs for behavior problems, cognitive loss/dementia, and psychosocial well-being to assess why the behaviors or change in mental or psychosocial functioning was occurring?

§483.25(g) Naso-Gastric Tubes

Based on the comprehensive assessment of a resident, the facility must ensure that --

(See Tag F322 for intent, guidelines, and probes for §483.25(g))

F321

§483.25(g)(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

F322

§483.25(g)(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

Intent §483.25(g)

The intent of this regulation is that a naso-gastric tube feeding is utilized only after adequate assessment, and the resident's clinical condition makes this treatment necessary.

Interpretive Guidelines §483.25(g)

This corresponds to MDS 2.0 sections G, K, P when specified for use by the State.

This requirement is also intended to prevent the use of tube feeding when ordered over the objection of the resident. Decisions about the appropriateness of tube feeding for a resident are developed with the resident or his/her family, surrogate or representative as part of determining the care plan.

Complications in tube feeding are not necessarily the result of improper care, but assessment for the potential for complications and care and treatment are provided to prevent complications in tube feeding by the facility.

Clinical conditions demonstrating that nourishment via an naso-gastric tube is unavoidable include:

- The inability to swallow without choking or aspiration, i.e., in cases of Parkinson's disease, pseudobulbar palsy, or esophageal diverticulum;

- Lack of sufficient alertness for oral nutrition (e.g., resident comatose); and

- Malnutrition not attributable to a single cause or causes that can be isolated and reversed. There is documented evidence that the facility has not been able to maintain or improve the resident's nutritional status through oral intake.

Probes: §483.25(g)

For sampled residents who, upon admission to the facility, were not tube fed and now have a feeding tube, was tube feeding unavoidable? To determine if the tube feeding was unavoidable, assess the following:

- Did the facility identify the resident at risk for malnutrition?

- What did the facility do to maintain oral feeding, prior to inserting a feeding tube? Did staff provide enough assistance in eating? Did staff cue resident as needed, assist with the use of assistive devices, or feed the resident, if necessary?

- Is the resident receiving therapy to improve or enhance swallowing skills, as need, is identified in the comprehensive assessment?

- Was an assessment done to determine the cause of decreased oral intake/weight loss or malnutrition?

- If there was a dietitian consultation, were recommendations followed?

- For all sampled residents who are tube fed:

- Is the NG tube properly placed?

- Are staff responsibilities for providing enteral feedings clearly assigned (i.e., who administers the feeding, formula, amount, feeding intervals, flow rate)?

- Do staff monitor feeding complications (e.g., diarrhea, gastric distension, aspiration) and administer corrective actions to allay complications (e.g., changing rate of formula administration)?

- Are there negative consequences of tube use (e.g., agitation, depression, self-extubation, infections, aspiration and restraint use without a medical reason for the restraint)?

- When long term use is anticipated, is G tube placement considered?

Is the potential for complications from feedings minimized by:

- Use of a small bore, flexible naso-gastric tube, unless contraindicated;
- Securely attached the tube to the nose/face;
- Checking for correct tube placement prior to beginning a feeding or administering medications and after episodes of vomiting or suctioning;
- Checking a resident with a newly inserted gastric tube for gastric residual volume every 2-4 hours until the resident has demonstrated an ability to empty his/her stomach;
- Properly elevating the resident's head;
- Providing the type, rate and volume of the feeding as ordered;
- Using universal precautions and clean technique and as per facility/manufacturer's directions when stopping, starting, flushing, and giving medications through the tube;
- Using hang time recommendations by the manufacturer to prevent excessive microbial growth;
- Implement the procedures to ensure cleanliness of supplies, e.g. irrigating syringes changed on a regular bases as per facility policy. It is not necessary to change the irrigating syringe each time it is used;
- Using a pump equipped with a functional alarm (if pump used);
- The facility's criteria for determining that a resident may be able to return to eating by mouth (e.g., a resident whose Parkinson's symptoms have been controlled);
- There are sampled residents meet these criteria;
- If so, the facility has assisted them in returning to normal eating; and
- Identify if resident triggers RAPs for feeding tubes, nutritional status, and dehydration/fluid maintenance. Consider whether the RAPs were used to assess causal factors for decline, potential for decline and lack of improvement.

F323

§483.25(h) Accidents

The facility must ensure that --

§483.25(h)(1) The resident environment remains as free of accident hazards as is possible; and

Intent §483.25(h)(1)

The intent of this provision is that the facility prevents accidents by providing an environment that is free from hazards over which the facility has control.

Interpretive Guidelines §483.25(h)(1)

This corresponds to MDS version 2.0 section J, when specified for use by the State.

"**Accident hazards**" are defined as physical features in the NF environment that can endanger a resident's safety, including but not limited to:

- Physical restraints (see physical restraints §483.13);
- Equipment or devices that are defective, poorly maintained, or not used in accordance with manufacturer's specifications (e.g., wheelchairs or geri-chairs with nonworking brakes, and loose nuts and bolts on walkers);
- Bathing facilities that do not have nonslip surfaces;
- Hazards (e.g., electrical appliances with frayed wires, cleaning supplies easily accessible to cognitively impaired residents, wet floors that are not obviously labeled and to which access is not blocked);
- Defective or improperly latched side rails or spaces within side rails, between upper and lower rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed that can entrap limbs, neck or thorax, and can cause injury or death;
- Handrails not securely fixed to the wall, difficult to grasp, and/or with sharp edges/splinters; and
- Water temperatures in hand sinks or bath tubs which can scald or harm residents.

Probes: §483.25(h)(1)

(See F221 for guidance concerning the use of bedrails.) See also §483.70(h), Safe Environment.

F324

§483.25(h)(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

Intent §483.25(h)(2)

The intent of this provision is that the facility identifies each resident at risk for accidents and/or falls, and adequately plans care and implements procedures to prevent accidents.

An "**accident**" is an unexpected, unintended event that can cause a resident bodily injury. It does not include adverse outcomes associated as a direct consequence of treatment or care, (e.g., drug side effects or reactions).

Procedures §483.25(h)(2)

- If a resident(s) selected for a comprehensive or focused review has had an accident, review the facility's investigation of that accident and their response to prevent the accident from recurring.

- Identify if the resident triggers RAPs for falls, cognitive loss/dementia, physical restraints, and psychotropic drug use and whether the RAPs were used to assess causal factors for decline or lack of improvement.

- If the survey team identifies a number of or pattern of accidents, in Phase II sampling, review the quality assurance activities of the facility to determine the facility's response to accidents.

Probes: §483.25(h)(2):

1. Are there a number of accidents or injuries of a specific type or on any specific shift (e.g., falls, skin injuries)?

2. Are residents who smoke properly supervised and monitored?

3. If the survey team identifies residents repeatedly involved in accidents or sampled residents who have had an accident:

    a. Is the resident assessed for being at risk for falls?

b. What care-planning and implementation is the facility doing to prevent accidents and falls for those residents identified at risk?

c. How did the facility fit, and monitor, the use of that resident's assistive devices?

d. How were drugs that may cause postural hypotension, dizziness, or visual changes monitored?

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§483.25(i) Nutrition

Based on a resident's comprehensive assessment, the facility must ensure that a resident--
(See F326 for intent, guidelines, procedures and probes for §483.25(i))

F325

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

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F326

§483.25(i)(2) Receives a therapeutic diet when there is a nutritional problem

Intent §483.25(i)

The intent of this regulation is to assure that the resident maintains acceptable parameters of nutritional status, taking into account the resident's clinical condition or other appropriate intervention, when there is a nutritional problem.

Interpretive Guidelines §483.25(i)

This corresponds to MDS 2.0 sections G, I, J, K and L when specified for use by the State.

Parameters of nutritional status which are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

Weight

Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should be examined in light of the individual's former life style as well as the current diagnosis.

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The following formula determines percentage of loss:

% of body weight loss = (usual weight - actual weight) / (usual weight) x 100

In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food?

Suggested laboratory values are:

Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion)

Plasma Transferrin >60 yr.:180-380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.)

Hemoglobin	Males: 14-17 g/dl
	Females: 12-15 g/dl
Hematocrit	Males: 41 - 53
	Females: 36 - 46
Potassium	3.5 - 5.0 mEq/L
Magnesium	1.3 - 2.0 mEg/L

Some laboratories may have different "normals." Determine range for the specific laboratory.

Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.

NOTE: There is no requirement that facilities order the tests referenced above.

Clinical Observations

Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting.

Risk factors for malnutrition are:

1. Drug therapy that may contribute to nutritional deficiencies such as:

    a. Cardiac glycosides;

    b. Diuretics;

    c. Anti-inflammatory drugs;

    d. Antacids (antacid overuse);

    e. Laxatives (laxative overuse);

    f. Psychotropic drug overuse;

    g. Anticonvulsants;

    h. Antineoplastic drugs;

    i. Phenothiazines;

    j. Oral hypoglycemics;

2. Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations;

3. Depression or dementia;

4. Therapeutic or mechanically altered diet;

5. Lack of access to culturally acceptable foods;

6. Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and

7. Cancer.

Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to:

- Refusal to eat and refusal of other methods of nourishment;
- Advanced disease (i.e., cancer, malabsorption syndrome);
- Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns);
- Radiation or chemotherapy;
- Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;
- Gastrointestinal surgery; and
- Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice.

"**Therapeutic diet**" means a diet ordered by a physician as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

Procedures §483.25(i)

Determine if residents selected for a comprehensive review or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed?

Probes: §483.25(i)

For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable:

- Did the facility identify factors that put the resident at risk for malnutrition?
- Identify if resident triggered RAPs for nutritional status, ADL functional/rehabilitation potential, feeding tubes, psychotropic drug use, and dehydration/fluid balance. Consider whether the RAPs were used to assess the causal factors for decline, potential for decline or lack of improvement.
- What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)?

- Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes?

- Was this care provided consistently?

- Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?

F327

§483.25(j) Hydration

§483.25(j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health

Intent §483.25(j)

The intent of this regulation is to assure that the resident receives sufficient amount of fluids based on individual needs to prevent dehydration.

Interpretive Guidelines §483.25(j)

This corresponds to MDS 2.0 sections G, K, I, J and L when specified for use by the State.

"**Sufficient fluid**" means the amount of fluid needed to prevent dehydration (output of fluids far exceeds fluid intake) and maintain health. The amount needed is specific for each resident, and fluctuates as the resident's condition fluctuates (e.g., increase fluids if resident has fever or diarrhea).

Risk factors for the resident becoming dehydrated are:

- Coma/decreased sensorium;

- Fluid loss and increased fluid needs (e.g., diarrhea, fever, uncontrolled diabetes);

- Fluid restriction secondary to renal dialysis;

- Functional impairments that make it difficult to drink, reach fluids, or communicate fluid needs (e.g., aphasia);

- Dementia in which resident forgets to drink or forgets how to drink;

- Refusal of fluids; and

- Did the MDS trigger RAPs on hydration? What action was taken based on the RAP?

Consider whether assessment triggers RAPs and are RAPs used to assess the causal factors for decline, potential for decline or lack of improvement.

A general guideline for determining baseline daily fluids needs is to multiply the resident's body weight in kg times 30cc (2.2 lbs = 1kg), except for residents with renal or cardiac distress. An excess of fluids can be detrimental for these residents.

Procedures §483.25(j)

Identify if resident triggers RAPs for dehydration/fluid maintenance, and cognitive loss.

Probes: §483.25(j)

Do sampled residents show clinical signs of possible insufficient fluid intake (e.g., dry skin and mucous membranes, cracked lips, poor skin turgor, thirst, fever), abnormal laboratory values (e.g., elevated hemoglobin and hematocrit, potassium, chloride, sodium, albumin, transferrin, blood urea nitrogen (BUN), or urine specific gravity)?

Has the facility provided residents with adequate fluid intake to maintain proper hydration and health? If not:

- Did the facility identify any factors that put the resident at risk of dehydration?

- What care did the facility provide to reduce those risk factors and ensure adequate fluid intake (e.g., keep fluids next to the resident at all times and assisting or cuing the resident to drink)? Is staff aware of need for maintaining adequate fluid intake?

- If adequate fluid intake is difficult to maintain, have alternative treatment approaches been developed, attempt to increase fluid intake by the use of popsicles, gelatin, and other similar non-liquid foods?

F328

§483.25(k) Special Needs

The facility must ensure that residents receive proper treatment and care for the following special services

Intent 483.25(k)

The intent of this provision is that the resident receives the necessary care and treatment including medical and nursing care and services when they need the specialized services as listed below.

Interpretive Guidelines §483.25(k)

This corresponds to MDS 2.0 section P when specified by for use by the State.

The non-availability of program funding does not relieve a facility of its obligation to ensure that its residents receive all needed services listed in §1819(b)(4)(A) of the Act for Medicare and §1919(b)(4)(A) of the Act for Medicaid. For services not covered, a facility is required to assist the resident in securing any available resources to obtain the needed services.

§483.25(k)(1) Injections

Probes: §483.25(k)(1)

For sampled residents receiving one or more of these services within 7 days of the survey:

- Is proper administration technique used (i.e., maintenance of sterility; correct needle size, route)?
- Are there signs of redness, swelling, lesions from previous injections?
- If appropriate, is resident observed for adverse reaction after the injection?
- Are syringes and needles disposed of according to facility policy and accepted Practice (e.g., Centers for Disease Control and Prevention and Occupational Safety and Health Administration guidelines)?
- Do nursing notes indicate, as appropriate, the resident's response to treatment (e.g., side effects/adverse actions; problems at the injection site(s); relief of pain)?

§483.25(k)(2) Parenteral and Enteral Fluids

Probes: §483.25(k)(2)

This corresponds to MDS 2.0 sections K5 and 6 and P1 when specified for use by the State

For residents selected for a comprehensive review, or focused review as appropriate, receiving one or more of these services within 7 days of the survey:

- Are there signs of inflammation or infiltration at the insertion site?
- If the IV site, tubing, or bottle/bag is changed, is sterile technique maintained?
- Is the rate of administration that which is ordered by the Physician
- Has the resident received the amount of fluid during the past 24 hours that he/she should have received according to the physician's orders (allow flexibility up to 150cc unless an exact fluid intake is critical for the resident)?

Procedures §483.25(k)(2)

See §483.25(g) for enteral feedings (includes gastrostomy).

§483.25(k)(3) Colostomy, Ureterostomy, or Ileostomy care

Procedures §483.25(k)(3)

This corresponds to MDS 2.0 sections G, H, and P when specified for use by the State.

Identify if resident triggers RAPs for urinary incontinence, nutritional status, pressure ulcers (skin care).

Probes: §483.25(k)(3)

- If appropriate, is the resident provided with self-care instructions?
- Does the staff member observe and respond to any signs of resident's discomfort about the ostomy or its care?
- Is skin surrounding the ostomy free of excoriation (abrasion, breakdown)?
- If excoriation is present, does the clinical record indicate an onset and a plan of care to treat the excoriation?

§483.25(k)(4) Tracheostomy Care

Procedures §483.25(k)(4) (Includes care of the tracheostomy site)

This corresponds to MDS 2.0 sections M and P when specified for use by the State.

Observations for tracheostomy care are most appropriate for residents with new or relatively new tracheostomies, and may not be appropriate for those with tracheostomies of long standing.

Probes: §483.25(k)(4) (Includes care of the tracheostomy site)

- Is the skin around the tracheostomy clean and dry? Are the dressing and the ties clean and dry, with the cannula secure?

- Does the resident have signs of an obstructed airway or need for suctioning (e.g., secretions draining from mouth or tracheotomy; unable to cough to clear chest; audible crackles or wheezes; dyspneic, restless or agitated)?

- If appropriate for a specific resident, is there a suction machine and catheter immediately available?

- Is there an extra cannula of the correct size at the bedside or other place easily accessible if needed in an emergency?

For sampled residents receiving one or more of these services within 7 days of the survey:

- Is suction machine available for immediate use, clean, working, and available to a source of emergency power?

- Is there an adequate supply of easily accessible suction catheters?

§483.25(k)(5) Standard: Tracheal Suctioning

Probes: §483.25(k)(5)

This corresponds to MDS 2.0 section P when specified for use by the State

§483.25(k)(6) Standard: Respiratory Care

Procedures §483.25(k)(6)

This corresponds to MDS 2.0 section P when specified for use by the State.

Includes use of respirators/ventilators, oxygen, intermittent positive pressure breathing (IPPB) or other inhalation therapy, pulmonary care, humidifiers, and other methods to treat conditions of the respiratory tract.

Identify if resident triggers RAPs for delirium and dehydration/fluid maintenance.

Probes: §483.25(k)(6)

For sampled residents receiving one or more of these services within 7 days of the survey:

- If oxygen is in use, are precautions observed (e.g., proper storage and handling of oxygen cylinders secured)? Secondary "No Smoking" signs are not required in facilities that prohibit smoking and have signs at all major entrances that the facility does not allow smoking.

- If the survey team observes a treatment being administered, is the resident encouraged and instructed on how to assist in the treatment?

- Is the staff following the facility's protocol and/or written procedures for ventilators (e.g., functioning alarms); frequency of staff monitoring; monitoring of resident response (e.g., use of accessory muscles to breathe, cleanliness of mouth, skin irritation), and availability of manual resuscitators?

- If the resident is ventilator dependent, is routine machine maintenance and care done (e.g., water changes/tubing changes, safety checks on alarms, and machine functioning checks)?

§483.25(k)(7) Foot Care

Procedures §483.25(k)(7)

This corresponds with MDS 2.0 sections G and M when specified for use by the State.

Includes treatment of foot disorders by qualified persons, e.g., podiatrist, Doctor of Medicine, Doctor of Osteopathy), including, but not limited, to corns, neuroma, calluses, bunions, heel spurs, nail disorders, preventive care, to avoid foot problems in diabetic residents and residents with circulatory disorders.

Probes: §483.25(k)(7)

For residents selected for a comprehensive review, or focused review, as appropriate:

- Do nails, corns, calluses, and other foot problems appear unattended; do these foot problems interfere with resident mobility?

- Are residents able to see a qualified person when they want?

- What preventive foot care do staff provide diabetic residents?

§483.25(k)(8) Prostheses

Probes: §483.25(k)(8)

MDS 2.0 sections D, G, L, M, and P when specified for use by the State.

Includes artificial limbs, eyes, teeth.

For residents selected for a comprehensive review, or focused review, as appropriate:

- Is resident able to put on the prosthesis by himself/herself or with some assistance?
- Are residents wearing their prostheses?
- Does the prosthesis fit correctly?
- Is skin/mucous membrane in contact with the prosthesis free of abrasions, wounds, irritation?

F329

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.25(l) Unnecessary Drugs

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or
(ii) For excessive duration; or
(iii) Without adequate monitoring; or
(iv) Without adequate indications for its use; or
(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
(vi) Any combinations of the reasons above.

Interpretive Guidelines §483.25(l)(1)

It is important to note that these regulations and interpretive guidelines are not meant to cast a negative light on the use of psychopharmacological drugs in long term care facilities. The use of psychopharmacological drugs can be therapeutic and enabling for residents suffering from mental illnesses such as schizophrenia or depression. The goal of these regulations and guidelines is to stimulate appropriate differential diagnosis of "behavioral symptoms" so the underlying **cause** of the symptoms is recognized and

treated appropriately. This treatment may include the use of environmental and/or behavioral therapy, as well as, psychopharmacological drugs. The goal of these regulations is also to **prevent** the use of psychopharmacological drugs when the "behavioral symptom" is caused by conditions such as: (1) environmental stressors (e.g., excessive heat, noise, overcrowding); (2) psychosocial stressors (e.g., abuse, taunting, not following a resident's customary daily routine); or (3) treatable medical conditions (e.g., heart disease, diabetes, Chronic Obstructive Pulmonary Disease). Behavioral symptoms resulting from these causes should not be "covered up" with sedating drugs.

An excellent differential diagnostic process for behavioral symptoms is described in the RAP on Behavior Problems (soon to be known as behavioral symptoms). Also, a number of very practical manuals are now available that teach nursing personnel how to assess and provide individualized care for behavioral symptoms, which leads to the avoidance of physical restraints, and unnecessary drugs. These manuals include, but are not limited to, the following list:

1. "Managing Behavior Problems in Nursing Home Residents"

   Department of Preventive Medicine
   Vanderbilt University School of Medicine

2. "Retrain, Don't Restrain"

   American Association of Homes and Services for the Aging, or
   The American Health Care Association

3. "Innovations in Restraint Reduction"

   American Health Care Association

4. "Avoiding Physical Restraint Use: New Standards in Care,"

   National Citizens' Coalition for Nursing Home Reform

5. "Avoiding Drugs Used as Chemical Restraints: New Standards in Care"

   National Citizens' Coalition for Nursing Home Reform

Interpretive Guidelines §483.25(l)(1):

A. Long-Acting Benzodiazepine Drugs

The following long-acting benzodiazepine drugs should not be used in residents unless an attempt with a shorter-acting drug (i.e., those listed under B. Benzodiazepine or Other Anxiolytic/Sedative Drugs, and under C. Drugs Used for Sleep Induction) has failed.

After an attempt with a shorter-acting benzodiazepine drug has failed, a long-acting benzodiazepine drug should not be used unless:

- Evidence exists that other possible reasons for the resident's distress have been considered and ruled out. (See §483.25(l)(1)(iv);)

- Its use results in maintenance or improvement in the resident's functional status (to evaluate functional status, see §483.25(a) through (k) and MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);)

- Daily use is less than four continuous months unless an attempt at a **gradual** dose reduction is unsuccessful (see §483.25(l)(1)(ii)); and

- Its use is less than, or equal to, the following listed total **daily** doses unless higher doses (as evidenced by the resident's response and/or the resident's clinical record) are necessary for the maintenance, or improvement in the resident's functional status. (See §483.25(l)(1)(i).)

Long-Acting Benzodiazepines - Not Maximum Doses

Generic	**Brand**	**Daily Oral Dosage**
Flurazepam	(Dalmane)	15mg
Chlordiazepoxide	(Librium)	20mg
Clorazepate	(Tranxene)	15mg
Diazepam	(Valium)	5mg
Clonazepam	(Klonopin)	1.5mg
Quazepam	(Doral)	7.5mg
Halazepam	(Paxipam)	40mg

NOTES: When diazepam is used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia or seizure disorders), this guideline does not apply.

When long-acting benzodiazepine drugs are being used to withdraw residents from short-acting benzodiazepine drugs, this guideline does not apply.

When clonazepam is used in bi-polar disorders, management of tardive dyskinesia, nocturnal myoclonus or seizure disorders, this guideline does not apply.

The daily doses listed under long-acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and

Probes) to show why it was necessary for the maintenance or improvement in the resident's functional status.

"**Duplicate drug therapy**" is any drug therapy that duplicates a particular drug **effect** on the resident. For example, any two or more drugs, whether from the same drug category or not, which have a sedative effect. Duplicate drug therapy should prompt the facility to evaluate the resident for accumulation of the adverse effects.

For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated.

B. Benzodiazepine or other Anxiolytic/Sedative Drugs

Use of listed Anxiolytic/Sedative drugs for purposes other than sleep induction should only occur when:

1. Evidence exists that other possible reasons for the resident's distress have been considered and ruled out. (See §483.25(l)(1)(iv);)

2. Use results in a maintenance or improvement in the resident's functional status, (to evaluate functional status, see §483.25(a) through (k) and MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);)

3. Daily use (at any dose) is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful. (See §483.25(l)(1)(ii);)

4. Use is for one of the following indications as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or subsequent editions. (See §483.25(l)(1)(iv):)

    a. Generalized anxiety disorder;

    b. Organic mental syndromes (now called "delirium, dementia, and amnestic and other cognitive disorders" by DSM-IV) with associated agitated behaviors, which are quantitatively and objectively documented (see note number one) which are persistent and not due to preventable reasons and which constitute sources of distress or dysfunction to the resident or represent a danger to the resident or others;

    c. Panic disorder;

    d. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); and

5. Use is equal to or less than the following listed total **daily** doses, unless higher doses (as evidenced by the resident response and/or the resident's clinical record) are necessary for the improvement or maintenance in the resident's functional status. (See §483.25(l)(1)(i), F342.)

Short-Acting Benzodiazepines - Not Maximum Doses

Generic	**Brand**	**Dose By Mouth**
Generic	**Brand**	**Daily Oral Dosage**
Lorazepam	(Ativan)	2 mg
Oxazepam	(Serax)	30mg
Alprazolam	Xanax)	0.75mg
Estazolam	(ProSom)	0.5mg

Other Anxiolytic And Sedative Drugs

Generic	**Brand**	**Dose By Mouth**
Diphenhydramine	(Benadryl)	50mg
Hydroxyzine	(Atarax,Vistaril	50mg
Chloral Hydrate	(Many Brands)	750mg

NOTES

1. This documentation is often referred to as "behavioral monitoring charts" and is necessary to assist in: (a) assessing whether the resident's behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, etc., (e) ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be know as behavioral symptoms).

2. The daily doses listed under Short-Acting Benzodiazepines are doses (usually administered in divided doses) for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and, when necessary, only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident's functional status.

3. For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that a gradual dose reduction is clinically contraindicated.

4. Diphenhydramine, hydroxyzine and chloral hydrate are not necessarily drugs of choice for treatment of anxiety disorders. They are only listed here in the event of their potential use.

C. Drugs for Sleep Induction

Drugs used for sleep induction should only be used if:

- Evidence exists that other possible reasons for insomnia (e.g., depression, pain, noise, light, caffeine) have been ruled out. (See §483.25(l)(1)(iv));

- The use of a drug to induce sleep results in the maintenance or improvement of the resident's functional status (to evaluate functional status, see §483.25(a) through (k) and MDS 2.0 sections B through P). (See §483.25(l)(1)(iv);)

- Daily use of the drug is less than ten continuous days unless an attempt at a gradual dose reduction is unsuccessful. (See §483.25(l)(1)(ii);) and

- The dose of the drug is equal or less than the following listed doses unless higher doses (as evidenced by the resident response and/or the resident's clinical record) are necessary for maintenance or improvement in the residents functional status. (See §483.25(l)(1)(i).)

Hypnotic Drugs - Not Maximum Doses

Generic	Brand	Dose By Mouth
Temazepam	(Restoril)	7.5mg
Triazolam	(Halcion)	0.125mg
Lorazepam	(Ativan)	1mg
Oxazepam	(Serax)	15mg
Alprazolam	(Xanax)	0.25mg
Estazolam	(ProSom)	0.5mg
Diphenhydramine	(Benadryl)	25mg
Hydroxyzine	(Atarax,Vistaril)	50mg
Chloral Hydrate	(Many Brands)	500mg
Zolpidem	(Ambien)	5mg

NOTES

1. Diminished sleep in the elderly is not necessarily pathological.

2. The doses listed are doses for "geriatric" or "elderly" residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident's functional status.

3. Diphenhydramine, hydroxyzine, and chloral hydrate are not necessarily drugs of choice for sleep disorders. They are listed here only in the event of their potential use.

4. For drugs in this category, a gradual dose reduction should be attempted at least three times within six months before one can conclude that a gradual dose reduction is clinically contraindicated.

D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs

The **initiation** of the following hypnotic/sedative/anxiolytic drugs should not occur in any dose for any resident. (See Notes for exceptions.) Residents currently using these drugs or residents admitted to the facility while using these drugs should receive **gradual** dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed. A gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. Newly admitted residents using these drugs may have a period of adjustment before a **gradual** dose reduction is attempted.

(CAUTION: DO NOT ENCOURAGE **RAPID** WITHDRAWAL OF THESE DRUGS. THIS MIGHT RESULT IN SEVERE PHYSIOLOGICAL WITHDRAWAL SYMPTOMS.

Barbiturates (Examples)

Generic	**Brand**
Amobarbital	(Amytal)
Butabarbital	(Butisol, others)
Pentobarbital	(Nembutal)
Secobarbital	(Seconal)
Phenobarbitol	(Many Brands)
Amobarbital-Secobarbital	(Tuinal)
Barbiturates with other drugs	(e.g., Fiorinal)

Miscellaneous Hypnotic/Sedative/Anxiolytics

Generic	Brand
Glutethimide	(Doriden)
Methprylon	(Noludar)
Ethchlorvynol	(Placidyl)
Meprobamate	(Equinal, Miltown)
Paraldehyde brands	(Manybrands)

1. Any sedative drug is excepted from this Guideline when used as a single dose sedative for dental or medical procedures.

2. Phenobarbital is excepted from this Guideline when used in the treatment of seizure disorders.

3. When Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs are used outside these Guidelines they may be unnecessary drugs as a result of inadequate indications for use. (See Survey Procedures and Probes.)

E. ANTIPSYCHOTIC DRUG DOSAGE LEVELS

The following examples of antipsychotic drugs should not be used in excess of the listed doses for residents with organic mental syndromes (now called "delirium, dementia, and amnestic and other cognitive disorders" by DSM-IV) unless higher doses (as evidenced by the resident's response or the resident's clinical record) are necessary to maintain or improve the resident's functional status. To evaluate functional status, see §§483.25(a) through (k) and MDS 2.0 sections B through P.

SCREEN FOR HIGHER DOSES OF ANTIPSYCHOTIC DRUGS

These dose levels are **NOT MAXIMUM DOSES.** These daily dose levels are given to establish a point at which higher doses should be explained. If a resident is prescribed a higher dose than shown, the facility should explain the specific clinical circumstance requiring the higher dose.

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	**Brand**	**Dose**
Chlorpromazine	(Thorazine)	75

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	**Brand**	**Dose**
Promazine	(Sparine)	150
Triflupromazine	(Vesprin)	20
Thioridazine	(Mellaril)	75
Mesoridazine	(Serentil)	25
Acetophenazine	(Tindal)	20
Perphenazine	(Trilafon)	8
Fluphenazine	(Prolixin, Permitil 4	
Trifluoperazine	(Stelazine)	8
Chlorprothixene	(Taractan)	75
Thiothixene	(Navane)	7
Haloperidol	(Haldol)	4
Molindone	(Moban)	10
Loxapine	Loxitane)	10
Clozapine	(Clozaril)	50
Prochlorperazine	(Compazine)	10
Risperidone	(Risperdal)	2
Olanzapine	(Zyprexa)	10
Quetiapine	(Seroquel)	200

1. The doses listed are **daily** doses (usually administered in divided doses) for residents with organic mental syndromes (now called “Delirium, Dementia, and Amnestic and other cognitive disorders by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it is necessary for the maintenance or improvement in the resident’s functional status.

2. The “specific conditions” for use of antipsychotic drugs are listed under the Guideline for §§483.25(l)(1) and (2).

3. The dose of prochlorperazine may be exceeded for short term (seven days) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time.

4. When antipsychotic drugs are used outside these Guidelines without valid reasons for the higher dose, they may be deemed unnecessary drugs as a result of excessive dose.

F. Monitoring for Antipsychotic Drug Side Effects

The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following:

- Tardive dyskinesia;
- Postural (orthostatic) hypotension;
- Cognitive/behavior impairment;
- Akathisia; and
- Parkinsonism.

NOTES: For a more detailed description of these side effects, see the RAP: Psychotropic Drug Use, pg. C-91, “Revised Long Term Care Resident Assessment Instrument User’s Manual,” Version 2.0, December 2002.

When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring.

G. Antidepressant Drugs

The under diagnosis and under treatment of depression in nursing homes has been documented in a Journal of the American Medical Association paper entitled “Depression and Mortality in the Nursing Home” (JAMA, February 27, l991-vol. 265, No. 8). CMS continues to support the accurate identification and treatment of depression in nursing homes.

The following is a list of commonly used antidepressant drugs:

Antidepressant Drugs

Generic Name	Brand Name
Amitriptyline*	(Elavil)
Amoxapine	(Asendin)
Desipramine	(Norpramin, Pertofrane)
Doxepin*	(Sinequan)
Imipramine*	(Tofranil)
Maprotiline	(Ludiomil)
Nortriptyline	(Aventyl, Pamelor)
Protriptyline	(Vivactil)
Trimipramine*	(Surmontil)
Fluoxetine	(Prozac)
Sertraline	(Zoloft)
Trazodone	(Desyrel)
Clomipramine*	(Anafranil)
Paroxetine	(Paxil)
Bupropion	(Wellbutrin)
Isocarboxazid*	(Marplan)
Phenelzine*	(Nardil)
Tranylcypromine*	(Parnate)
Venlafaxine	(Effexor)
Nefazodone	(Serzone)
Fluvoxamine	(Luvox)

* These are not necessarily drugs of choice for depression in the elderly. They are listed here only in the event of their potential use.

Procedures 483.25(l)(1)

Consider drug therapy "unnecessary" only after determining that the facility's use of the drug is:

- In excessive dose (including duplicate drug therapy);
- For excessive duration;

- Without adequate monitoring;

- Without adequate indications of use;

- In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

- Any combination of the reasons above.

Allow the facility the opportunity to provide a rationale for the use of drugs prescribed outside the preceding Guidelines. The facility may not justify the use of a drug prescribed outside the proceeding Guidelines solely on the basis of "the doctor ordered it." This justification would render the regulation meaningless. The rationale must be based on sound risk-benefit analysis of the resident's symptoms and potential adverse effects of the drug.

Examples of evidence that would support a justification of why a drug is being used outside these Guidelines but in the best interests of the resident may include, but are not limited to:

- A physician's note indicating for example, that the dosage, duration, indication, and monitoring are clinically appropriate, **and the reasons why they are clinically appropriate**; this note should demonstrate that the physician has carefully considered the risk/benefit to the resident in using drugs outside the Guidelines.

- A medical or psychiatric consultation or evaluation (e.g., Geriatric Depression Scale) that confirms the physician's judgment that use of a drug outside the Guidelines is in the best interest of the resident.

- Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the drug therapy;

- Documentation confirming that previous attempts at dosage reduction have been unsuccessful;

- Documentation (including MDS documentation) showing resident's subjective or objective improvement, or maintenance of function while taking the medication;

- Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine whether a particular drug, or a particular dose, or duration of therapy, may be the cause;

- Documentation showing why the resident's age, weight, or other factors would require a unique drug dose or drug duration, indication, monitoring; and

- Other evidence the survey team may deem appropriate.

If the survey team determines that there is a deficiency in the use of antipsychotics, cite the facility under either the "unnecessary drug" regulation or the "antipsychotic drug" regulation, but not both.

NOTE: The unnecessary drug criterion of "adequate indications for use" does not simply mean that the **physician's order** must include a reason for using the drug (although such order writing is encouraged). It means that the **resident** lacks a valid clinical reason for use of the drug as evidenced by the survey team's evaluation of some, but not necessarily all, of the following: resident assessment, plan of care, reports of significant change, progress notes, laboratory reports, professional consults, drug orders, observation and interview of the resident, and other information.

H. Miscellaneous Drugs That are Potentially Inappropriate in the Elderly:

The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, M.D. This paper was published in the Archives of Internal Medicine, Vol. 157, July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times:

1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit"; and

2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur."

These criteria are divided into two broad categories. Drug therapy that is classified as having "high severity" and therapy that is considered as not having "high severity." Severity is defined as: "a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur." The survey guidelines are ocated in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation.

1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with 483.25(l)(1), Unnecessary Drug (F329); and

2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with 483.60(c)(1), Drug Regimen Review Report, (F429) which are located under guidance to surveyors for drug regimen review.

It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety. These guidelines do not supercede the unnecessary drug guidelines and drug regimen review guidelines.

List of Drugs With High Potential for Severe Adverse Outcomes

1. Pentazocine (Talwin)

Risk: "Pentazocine is a narcotic analgesic that causes more central nervous system side effects, including confusion and hallucinations, more commonly than other narcotic drugs." Dizziness, lightheadedness, euphoria, and sedation are also common side effects of pentazocine.

2. Long-Acting Benzodiazepines

NOTE: Surveyor guidance for unnecessary drugs (§483.25(l)(1), F329) already has guidelines for Long Acting Benzodiazepine Drugs. The Surveyor should use that guideline. This guideline is repeated here to give emphasis to potential side effects of these drugs.

Risk: "These benzodiazepine drugs have an extremely long half-life in the elderly (often days), producing prolonged sedation and increased incidence of falls and fractures." Other common side effects of benzodiazepine drugs include drowsiness, ataxia, fatigue, confusion, weakness, dizziness, vertigo, syncope, and psychological changes.

3. Amitriptyline (Elavil)

Also include combination products such as: Amitriptyline and chlordiazepoxide (Limbitrol) Amitriptyline and Perphenazine (Triavil).

Risk: "Because of its strong anticholinergic and sedating properties, amitriptyline is rarely the antidepressant of choice in the elderly." Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention,

constipation, confusion, and sometimes, delirium or hallucinations. Amitriptyline can also cause cardiac arrhythmias and orthostatic hypotension.

Exception: Surveyor review is not required if:

- The resident is being treated for neurogenic pain (that is trigeminal neuralgia, peripheral neuropathy);
- There is evidence in the record that the resident has experienced this type of pain; and
- That a risk/benefit has been considered, including alternative pain therapies that may have fewer side effects in the individual.

4. Doxepin (Sinequan)

Risk: "Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice in the elderly**."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. Doxepin may also cause cardiac arrhythmias.

5. Meprobamate (Miltown), (Equanil)

NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1), F329) already has guidelines for this drug under "D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs." This guideline is provided here to further emphasize the risk of using this drug.

Risk: "Meprobamate is a highly addictive and sedating anxiolytic (i.e., antianxiety drug). Avoid in elderly patients. Those using memprobamate for prolonged periods may be addicted and may need to be withdrawn slowly." The most frequent side effects of meprobamate are drowsiness and ataxia.

6. Disopyramide (Norpace), (Norpace CR)

Risk: "Disopyramide, of all antiarrhythmic drugs, is the most potent negative inotrope (decreased force of heart contraction) and therefore may induce heart failure in the elderly. It is also strongly anticholinergic." Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. In addition to the anticholinergic side effects, disopyramide has the following cardiovascular side effects: edema, weight gain, chest pain, dyspnea, syncope and hypotension.

7. Digoxin (Lanoxin)

Risk: Because of decreased renal clearance of digoxin, doses in the elderly should rarely exceed 0.125 mg daily, except when treating atrial arrhythmias. (NOTE: the panelists' review of the literature has revealed countless studies showing that low dose digoxin is effective, but higher dose digoxin adds risks without improving outcomes.) Side effects may include anorexia, nausea and vomiting are the common early signs of digoxin toxicity. Nervous system symptoms include headache, fatigue, malaise, drowsiness, depression, and generalized muscle weakness. Visual disturbances also occur, including blurred vision, yellow or green vision, diplopia, photophobia, and flashing lights.

High Severity: Yes, if recently started. The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month, it should be treated as a High Potential for Less Severe Outcomes under F429. It should be noted that validating when the drug was started is often a complex issue, and may be too much of a burden for the facility to accurately determine.

If there is a diagnosis of an atrial arrhythmia, (e.g., atrial flutter, atrial fibrillation, supraventricular tachycardia), the survey must view the higher dose as acceptable.

Exception: Higher doses may be used for up to seven days before the facility would have to justify the risk versus benefit in writing. The surveyor need not review the higher dose during the seven day period unless an immediate threat to health and safety, for example, digoxin toxicity, is suspected.

8. Methyldopa (Aldomet)

Also combination products such as: Methyldopa and hydrochlorothiazide (Aldoril).

Risk: "Methyldopa may cause bradycardia and exacerbate depression in the elderly. Alternate treatments for hypertension are generally preferred."

High Severity: Yes if recently started. The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month it should be treated as a High Potential for Less Severe Outcomes under F429. It should be noted that validating when the drug was started is often a complex issue, and may be too much of a burden for the facility to accurately determine

9. Chlorpropamide (Diabinese)

Risk: "Chlorpropamide has a prolonged half-life in the elderly and can cause prolonged and serious hypoglycemia. Hypoglycemic symptoms are as follows:

Hypoglycemic Symptoms: Weakness, sweating, tachycardia, palpitations, tremor, nervousness, irritability, tingling in the mouth and tongue, hunger, nausea (unusual) and vomiting (unusual), headache, hypothermia, visual disturbances, mental dullness, confusion, amnesia, seizures, coma.

Additionally, chlorpropamide is the only hypoglycemic agent that causes SIADH (syndrome of inappropriate antidiuretic hormone release). SIADH causes hyponatremia. Chlorpropamide should be avoided in the elderly.

10. Gastrointestinal antispasmodic drugs such as: Dicyclomine (Bentyl), Hyoscyamine (Levsin, Levsinex), Propantheline (Probanthine), Belladonna Alkaloids (Donnatal & others), Clidinium and chlordiazepoxide (Librax)

Risk: "Gastrointestinal antispasmodic drugs are highly anticholinergic and generally produce substantial toxic effects in the elderly. Additionally, their effectiveness at doses tolerated by the elderly is questionable. All these drugs are best avoided in the elderly, especially for long term use." Anticholinergic side effects can include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short period (not over seven days) for symptoms of an acute, self-limiting illness.

11. Barbiturates

NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1), F329) already has guidelines for these drugs under: D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs. This guideline is provided here to further emphasize the risk of using these drugs.

Risk: "Barbiturates cause more side effects than most other sedative or hypnotic drugs in the elderly and are highly addictive. They should not be started as new therapy in the elderly except when used to control seizures." Common side effects from barbiturates include: drowsiness, lethargy, vertigo, headache, severe CNS depression, mental depression, nausea, vomiting, diarrhea, and constipation. When discontinued, these drugs must be tapered very slowly to avoid potentially life-threatening withdrawal effects.

12. Meperidine (Demerol)

Risk: "Meperidine is not an effective analgesic when administered orally, and has many disadvantages to other narcotic drugs. Avoid oral use in the elderly." Respiratory , the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under F329. After 1 month it should be treated as a High Potential for Less Severe Outcomes under F429.

13. Ticlopidine (Ticlid)

Risk: "Ticlopidine has been shown to be no better than aspirin in preventing clotting and is considerably more toxic. Avoid in the elderly." The most serious side effects of eyor is not necessary in individuals who receive ticlopidine because they have had a previous stroke or have evidence of stroke precursors, that is, transient ischemic attacks (TIAs), and cannot tolerate aspirin.

List of Diagnosis/Drug Combinations With High Potential for Severe Adverse Outcomes

1. Chronic Obstructive Pulmonary Disease (COPD)

Drugs(s): Hypnotic/sedatives such as:

- Long-Acting Benzodiazepines such as Flurazepam (Dalmane), Chlordiazepoxide (Librium), Clorazepate (Tranxene), Diazepam (Valium), Clonazepame (Klonopin), Quazepam (Doral), and Halazepam (Paxipam).

- Barbiturates such as Amobarbital (Amytal), Butabarbital (Butisol), Pentobarbital (Nembutal), and Secobarbital (Seconal).

- Miscellaneous Hypnotic/sedatives such as Glutethimide (Doriden), Methprylon (Noludar), Ethchlorvynol (Placidyl), Meprobamate (Equinal, Miltown), Paraldehyde (many brands), and Chloral Hydrate (Noctec).

Risk: "May slow respirations and increase carbon dioxide retention in persons with chronic obstructive pulmonary disease (COPD)."

NOTE: After review of the literature, the Panelists, in consultation with pulmonologists, determined, despite common usage of hypnotic/sedative drug use in persons with COPD, there is no data to support this practice, and pulmonologists virtually all agree that such drugs should be avoided in COPD patients for the reasons mentioned above.

Potential Side Effects: Exacerbation of COPD symptoms. The most common symptoms of COPD are cough, increased sputum production, shortness of breath, tightness in the chest, burning sensation, and wheezing.

Exception: The use of Short Acting Benzodiazepines such as Lorazapam (Ativan), Oxazepam (Serax) Alprazolam (Xanax) to relieve anxiety, preferably on an as needed basis, after thorough assessment and optimal treatment of the symptoms of COPD.

2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease (GERD).

Drugs: Non-Steroidal Anti-inflammatory Drugs (NSAIDs) such as Diclofenac (Cataflam & Voltaren), Diflunisal (Dolobid), Etodolac (Lodine), Fenoprofen (Nalfon), Ibuprofen (Motrin & Advil), Indomethacin (Indocin), Ketoprofen (Orudis), Nabumetone (Relafen), Naproxen (Anaprox), Oxaprozin (Daypro), Phenylbutazone (many brands), Piroxicam (Feldene), Sulindac (Clinoril), Tolmetin (Tolectin).

Risk: "May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD)."

Potential Side Effects: Nausea, Dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, and flatulence.

3. Seizures or epilepsy.

Drug: Metoclopramide (Reglan).

Risk: May Lower seizure threshold.

4. Blood Clotting Disorders.

Drugs: Aspirin, NSAIDs (see #2 above for list), Dipyridamole (Persantine) and Ticlopidine (Ticlid).

Risk: "May cause bleeding in those using anticoagulants."

Potential Side Effects: Bleeding (e.g., from gums while brushing teeth or from small abrasions or contusions), and GI bleeding, indicated by black tarry stools, occult blood in the stool, or coffee ground like vomitus. A low hematocrit could be a sign of internal bleeding.

5. Benign Prostatic Hypertrophy (BPH)

Drugs: Anticholinergic antihistamines such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril and Atarax), Cyproheptadine

(Periactin), Promethazine (Phenergan), Tripelanamine (PBZ), Dexchlorpheniramine (Polaramine);

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anti-Parkinson medications such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemardren), Biperiden (Akineton);

GI antispasmodics such as dicyclomine (Bentyl) Hyoscyamine (Levsin & Levsinex), Propantheline (Probanthine), belladonna alkaloids (Donnatal), Clidinium containing products such as Librax;

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anticholinergic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

Risk: "Anticholinergic drugs may impair micturition and cause obstruction in persons with Benign Prostatics Hypertrophy (BPH)."

Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, and low back pain.

6. Arrhythmias

Drugs: Tricyclic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

Risk: "May induce arrhythmias."

Potential Side Effects: Cardiac arrhythmias.

High Severity: **YES, if recently started.** The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should treat it as a High Potential for Severe Outcomes drug under

F329. After 1 month, it should be treated as a high potential for less severe outcomes drug under F429.

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§ 483.25(l)(2) Antipsychotic drugs

Based on a comprehensive assessment of a resident, the facility must assure that-
Guidelines § 483.25(l)(2)(i)

For a list of examples of commonly used antipsychotic drugs, seeE. Under Interpretive Guidelines for § 483.25(l)(1), Unnecessary Drug.

F330

§483.25(l)(2)(i)

Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

Antipsychotic drugs should not be used unless the clinical record documents that the resident has one or more of the following "specific conditions":

1. Schizophrenia;
2. Schizo-affective disorder;
3. Delusional disorder;
4. Psychotic mood disorders (including mania and depression with psychotic features);
5. Acute psychotic episodes;
6. Brief reactive psychosis;
7. Schizophreniform disorder;
8. Atypical psychosis;
9. Tourette's disorder;
10. Huntington's disease;
11. Organic mental syndromes (now called delirium, dementia, and amnestic and other cognitive disorders by DSM-IV) **with associated psychotic and/or agitated behaviors:**

    a. Which have been quantitatively and objectively documented. This documentation is necessary to assist in:

        (1) Assess whether the resident's behavioral symptom is in need of some form of intervention,
        (2) Determining whether the behavioral symptom is transitory or permanent,

(3) Relating the behavioral symptom to other events in the resident's life in order to learn about potential causes (e.g., death in the family, not adhering to the resident's customary daily routine),
(4) Ruling out environmental causes such as excessive heat, noise, overcrowding,
(5) Ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be known as behavioral symptoms); and

b. Which are persistent, and
c. Which are not caused by preventable reasons; and
d. Which are causing the resident to:

(1) Present a danger to himself/herself or to others, or
(2) **Continuously** scream, yell, or pace if these specific behaviors cause an impairment in functional capacity (to evaluate functional capacity, see §483.25 (a) through (k) and MDS 2.0 sections B through P), or
(3) Experience psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as dangerous behaviors or as screaming, yelling, or pacing but which cause the resident distress or impairment in functional capacity; or

12. Short-term (7 days) symptomatic treatment of hiccups, nausea, vomiting or pruritus. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can be treated for longer periods of time.

Antipsychotics should not be used if one or more of the following is/are the **only** indication:

- Wandering;
- Poor self care;
- Restlessness;
- Impaired memory;
- Anxiety;
- Depression (without psychotic features);
- Insomnia;
- Unsociability;
- Indifference to surroundings;
- Fidgeting;
- Nervousness;
- Uncooperativeness; or
- Agitated behaviors which **do not** represent danger to the resident or others.

F331

§483.25(l)(2)(ii)

Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

Interpretive Guidelines §483.25(l)(2)(ii)

Residents must, unless clinically contraindicated, have gradual dose reductions of the antipsychotic drug. The gradual does reduction should be under close supervision. If the gradual dose reduction is causing an adverse effect on the resident and the gradual dose reduction is discontinued, documentation of this decision and the reasons for it should be included in the clinical record. Gradual dose reductions consist of tapering the resident's daily dose to determine if the resident's symptoms can be controlled by a lower dose or to determine if the dose can be eliminated altogether.

"**Behavioral interventions**" means modification of the resident's behavior or the resident's environment, including staff approaches to care, to the largest degree possible to accommodate the resident's behavioral symptoms.

"**Clinically contraindicated**" means that a resident NEED NOT UNDERGO a "gradual dose reduction" or "behavioral interventions" IF:

1. The resident has a "specific condition" (as listed under 1 through 10 on page P-185) and has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations), which have been stabilized with a maintenance dose of an antipsychotic drug without incurring significant side effects;

2. The resident has organic mental syndrome (now called "Delirium, Dementia, and Amnestic and other Cognitive Disorders" by DSM IV) and has had a gradual dose reduction attempted TWICE in one year and that attempt resulted in the return of symptoms for which the drug was prescribed to a degree that a cessation in the gradual dose reduction, or a return to previous dose reduction was necessary; or

3. The resident's physician provides a justification why the continued use of the drug and the dose of the drug is clinically appropriate. This justification should include: (s) a diagnosis, but not simply a diagnostic label or code, but the description of symptoms, (b) a discussion of the differential psychiatric and medical diagnosis (e.g., why the resident's behavioral symptom is thought to be a result of a dementia with associated psychosis and/or agitated behaviors, and not the result of an unrecognized painful medical condition of a psychosocial or environmental stressor), (c) a description of the justification for the choice of a

particular treatment, or treatments, and (d) a discussion of why the present dose is necessary to manage the symptoms of the resident. This information need not necessarily be in the physician's progress notes, but must be a part of the resident's clinical record.

Procedures §483.25(l)(2)(i) and (ii)

In determining whether an antipsychotic drug is without a specific condition or that gradual dose reduction and behavioral interventions have not been performed, allow the facility an opportunity to justify why using the drug outside the Guidelines is in the best interest of the resident.

Examples of evidence that would support a justification of why a drug is being used outside the Guidelines, but in the best interest of the resident, may include, but are not limited to:

- A physician's note indicating that the use of the drug, or continued use of the drug is clinically appropriate, and the reasons why this use is clinically appropriate. This note must demonstrate that the physician has carefully considered the risk/benefit to the resident in using drugs outside these Guidelines.
- A medical or psychiatric consultation or evaluation (e.g., Geriatric Depression Scale) that confirms the physician's judgment that use of a drug outside the Guidelines is in the best interest of the resident.
- Physician, nursing, or other health professional documentation indicating that the resident is being monitored for adverse consequences or complications of the drug therapy.
- Documentation confirming that previous attempts at dosage reduction have been unsuccessful.
- Documentation (including MDS documentation) showing resident's subjective or objective improvement or maintenance of function while taking the medication.
- Documentation showing that a resident's decline or deterioration is evaluated by the interdisciplinary team to determine whether a particular drug, or a particular dose, or duration of therapy, may be the cause.
- Documentation showing why the resident's age, weight, or other factors would require a unique drug dose or drug duration.
- Other evidence the surveyor may deem appropriate.

The facility can refer to a prescriber's (or appropriately trained health professional's) justification as a valid justification for the use of a drug. It may not justify the use of a drug, its dose, its duration, solely on the basis that "it was ordered" without supportive information.

If the survey team determines that there is a deficiency in the use of antipsychotics, cite the facility under either the unnecessary drug regulation or the antipsychotic drug regulation, but not both quality of care tags.

F332 and F333

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.25(m) Medication Errors

The facility must ensure that--

[F332] §483.25(m)(1) It is free of medication error rates of 5 percent or greater; and

[F333] §483.25(m)(2) Residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m)

Medication Error -- The observed preparation or administration of drugs or biologicals which is not in accordance with:

1. Physician's orders;

2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological;

3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

"**Significant medication error**" means one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or relative term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a drug error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

"**Medication error rate**" is determined by calculating the percentage of errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and nonsignificant. The denominator is called "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses

ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

"**Medication error rate**" -- A medication error rate of 5% or greater includes both significant and nonsignificant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written.

The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted.

Significant and Nonsignificant Medication Errors

"**Determining Significance**" -- The relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

"**Resident Condition**" -- The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

"**Drug Category**" -- If the drug is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows: Anticonvulsant: phenytoin (Dilantin),carbamazepine (Tegretol), Anticoagulants: warfarin (Coumadin) Antiarrhythmic (digoxin)Lanoxin) Antiasthmatics: theophylline (TheoDur) Antimanic Drigs: lithium salts (Eskalith, Lithobid).

"**Frequency of Error**" -- If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the drug category.

"**Examples of Significant and Non-Significant Medication Errors**" -- Some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as nonsignificant have also been

designated primarily on the basis of the nature of the drug. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors Detected

Omissions Examples (Drug ordered but not administered at least once):

Drug Order	Significance
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Quinidine 200mg TID	S**
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS
Nitrol Oint. one inch	S

* Not Significant

**Significant

Unauthorized Drug Examples (Drugs administered without a physician's order):

Drug Order	Significance
Feosol	NS
Coumadin 4mg	S
Zyloprim 100mg	NS
Tylenol 5 gr	NS
Motrin 400mg	NS

Wrong Dose Examples:

Drug Order	Administered	Significance
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Digoxin 0.125mg everyday	0.25mg	S
Amphojel 30ml QID	15ml	NS
Dilantin 125 SUSP 12ml	2ml	S

Wrong Route of Administration Examples:

Drug Order	Administered	Significance
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Drug Order	Administered	Significance
Colace Liquid 100mg BID	Capsule	NS

Drug Order	Administered	Significance
Mellaril Tab 10mg	Liquid Concentrate	NS*
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S

* If correct dose was given.
** Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.

Wrong Drug Examples:

Drug Order	Administered	Significance
Tums	Oscal	NS
Vibramycin	Vancomycin	S

Wrong Time Examples:

Drug Order	Administered	Significance
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given 3 after treatment	S

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

The following situations in drug administration may be considered medication errors:

- Failure to "Shake Well": The failure to "shake" a drug product that is labeled "shake well." This may lead to an under dose or over dose depending on the drug product and the elapsed time since the last "shake." The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some drugs, for example dilantin, are more critical to achieve correct dosage delivery than others.

- Insulin Suspensions: Also included under this category is the failure to "mix" the suspension without creating air bubbles. Some individuals "roll" the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.

- Crushing Medications that should not be Crushed: Crushing tablets or capsules that the manufacturer states "do not crush."

Exceptions to the "Do Not Crush" rule:

- If the prescriber orders a drug to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the

clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.

- If the facility can provide literature from the drug manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.

- Adequate Fluids with Medications: The administration of medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication. For example:

    - Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);

    - Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces. The surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes). If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted; and

    - Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.

- Medications that Must be Taken with Food or Antacids: The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used drugs that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	**Brand Name**
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

- Medications Administered with Enteral Nutritional Formulas: Administering medications immediately before, immediately after, or during the administration of enteral nutritional formulas (ENFs) without achieving the following minimum objectives:

    - Check the placement of the naso-gastric or gastrostomy tube in accordance with the facility's policy on this subject. **NOTE:** If the placement of the tube is not checked, this is not a medication error; it is a failure to follow accepted professional practice and should be evaluated under Tag F281 requiring the facility to meet professional standards of quality.

    - Flush the enteral feeding tube with at least 30 ml of preferably warm water before and after medications are administered. While it is noted that some facility policies ideally adopt flushing the tube after each individual medication is given, as opposed to after the group of multiple medications is given, unless there are known compatibility problems between medicines being mixed together, a minimum of one flushing before and after giving the medications is all the surveyor need review. There may be cases where flushing with 30 ml after each single medication is given may overload an individual with fluid,

raising the risk of discomfort or stress on body functions. Failure to flush, before and after, would be counted as one medication error and would be included in the calculation for medication errors exceeding 5 percent.

  - The administration of enteral nutrition formula and administration of dilantin should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of dilantin, then the surveyor should consider simultaneous administration a medication error.

- Medications Instilled into the Eye: The administration of eye drops without achieving the following critical objectives:

  - **Eye Contact**: The eye drop, but not the dropper, must make full contact with the conjunctival sac and then be washed over the eye when the resident closes the eyelid; and

  - **Sufficient Contact Time**: The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications can be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)

- Allowing Resident to Swallow Sublingual Tablets: If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this drug.

- Medication Administered Via Metered Dose Inhalers (MDI): The use of MDI in other than the following ways (this includes use of MDI by the resident). This is an error if the person administering the drug did not do all the following:

  - Shake the container well;

  - Position the inhaler in front of or in the resident's mouth. Alternatively a spacer may be used;

  - For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be

successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used; and

- If more than one puff is required, (whether the same medication or a different medication) wait approximately a minute between puffs.

NOTE: If the person administering the drug follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be called a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors -- If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders -- he latest recapitulation of drug orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the drug.

Procedures §483.25(m)

Medication Error Detection Methodology -- Use an observation technique to determine medication errors. The survey team should observe the administration of drugs, on several different drug "passes," when necessary. Record what is observed; and reconcile the record of observation with the prescriber's drug orders to determine whether or not medication errors have occurred.

Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual

medication errors. Paper review only identifies possible errors in most cases. In some cases paper review can help identify actual errors but research has shown that the procedure is time consuming for the number of actual errors detected.

Observation Technique --The survey team must know without doubt, what drugs, in what strength, and dosage forms, are being administered. This is accomplished prior to drug administration and may be done in a number of ways depending on the drug distribution system used (e.g. unit dose, vial system, punch card).

1. Identify the drug product. There are two principal ways to do this. In most cases, they are used in combination:

    - Identify the product by its size, shape, and color. Many drug products are identifiable by their distinctive size, shape, or color. This technique is problematic because not all drugs have distinctive sizes, shapes, or color.

    - Identify the product by observing the label. When the punch card or the unit dose system is used, the survey team can usually observe the label and adequately identify the drug product. When the vial system is used, observing the label is sometimes more difficult. Ask the nurse to identify the medication being administered.

2. Observe and record the administration of drugs ("pass"). Follow the person administering drugs and observe residents receiving drugs (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible during this process.

    - Make every effort to observe residents during several different drug "passes," if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one drug pass.

    - Identifying residents can present a problem. The surveyor should ask appropriate staff to explain the facility policy or system for the identification of residents.

3. Reconcile the surveyor's record of observation with physician's orders. Compare the record of observation with the most current orders for drugs. This comparison involves two distinct activities:

    - For each drug on the surveyor's list: Was it administered according to the prescriber's orders? For example, in the correct strength, by the correct route? Was there a valid order for the drug? Was the drug the correct one?

    - For drugs not on the surveyor's list: Are there orders for drugs that should have been administered, but were not? Examine the record for drug orders

that were not administered and should have been. Such circumstances may represent omitted doses, one of the most frequent types of errors.

- Ask the person administering drugs, if possible, to describe the system for administering the drugs given. Occasionally, a respiratory therapist may administer inhalers, a designated treatment person may only administer topical treatments, a hospice nurse may administer hospice medications, another person may administer eye drops or as needed drugs, etc. Sometimes people may share medication carts. Under these circumstances, these individuals should be interviewed about the omitted dose, if they were involved, if possible. When persons that were actually responsible for administering the drugs are not available, ask their supervisor for clarification.

The surveyor should now have a complete record of what was observed and what should have occurred according to the prescribers' orders. Determine the number of errors by adding the errors on each resident. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the drugs if possible. There may be a logical explanation for an apparent error. For example, the surveyor observed that a resident had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with a 20 mg order.

4. Reporting Errors -- Describe to the facility each error that the survey team detects (e.g., Mary Jones received digoxin in 0.125 instead of 0.25 mg). The survey team is not required to analyze the errors and come to any conclusions on how the facility can correct them. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong resident). Stress that an error occurred and that future errors must be avoided.

5. Observe Many Individuals Administering Medications. Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire drug distribution system.

Dose Reconciliation Technique Supplement to the Observation Technique -- When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable the survey team to learn how frequently an error has occurred in the past. Learning about the frequency of an error can assist in judging the significance of the error. (See Significant and Non Significant Medication Errors above.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of drugs with the number of days the drug has been in use and the directions for use. For example, if a drug were in use for 5 days with direction to administer the drug 4 times a day, then 20 doses should have been used. If a count of the supply of that drug shows that only 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., resident refused the dose, or resident was hospitalized), then two omission errors may have occurred.

Use the dose reconciliation technique in facilities that indicate the number of drugs received, and the date and the specific "pass" when that particular drug was started. Unless this information is available, do not use this technique. If this information is not available, there is no Federal authority under which the survey team may require it, except for controlled drugs.

F353

§483.30 Nursing Services

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

Intent §483.30

To assure that sufficient qualified nursing staff are available on a daily basis to meet residents' needs for nursing care in a manner and in an environment which promotes each resident's physical, mental and psychosocial well-being, thus enhancing their quality of life.

Procedures §483.30

§483.30(a) and (b) are to be reviewed during the standard survey whenever quality of care problems have been discovered (see Appendix P, Survey Protocol, Task 4, for further information and Task 5C for the investigative protocol to complete this review). In addition, fully review requirements of nursing services during an extended survey or when a waiver of RN and/or licensed nurse (RN/LPN) staffing has been requested or granted. Except as licensed nursing personnel are specifically required by the regulation (e.g., an RN for 8 consecutive hours a day, 7 days a week), the determination of sufficient staff will be made based on the staff's ability to provide needed care to residents that enable them to reach their highest practicable physical, mental and psychosocial well-being. The ability to meet the requirements of §§483.13, 483.15(a), 483.20, 483.25 and 483.65 determines sufficiency of nurse staffing.

§483.30(a) Sufficient Staff

§483.30(a)(1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

> **(i) Except when waived under paragraph (c) of this section, licensed nurses; and**
> **(ii) other nursing personnel.**

§483.30(a)(2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

For Interpretive Guidelines and Probes on §483.30(a) see tag F354

F354

§483.30(b) Registered Nurse

§483.30(b)(1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

§483.30(b)(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

§483.30(b)(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

Interpretive Guidelines §483.30(a) and (b)

At a minimum, "**staff**" is defined as licensed nurses (RNs and/or LPNs/LVNs), and nurse aides. Nurse aides must meet the training and competency requirements described in §483.75(e).

"**Full-time**" is defined as working 35 or more hours a week.

Except for licensed staff noted above, the determining factor in sufficiency of staff (including both numbers of staff and their qualifications) will be the ability of the facility to provide needed care for residents. A deficiency concerning staffing should ordinarily provide examples of care deficits caused by insufficient quantity and quality of staff. If, however, inadequate staff (either the number or category) presents a clear threat to residents reaching their highest practicable level of well-being, cite this as a deficiency. Provide specific documentation of the threat.

The facility is required to designate an RN to serve as DON on a full time basis. This requirement can be met when RNs share the position. If RNs share the DON position, the total hours per week must equal 40. Facility staff must understand the shared responsibilities. The facility can only be waived from this requirement if it has a waiver under subsection (c) or (d).

Probes: §483.30(a) and (b)

Determine nurse staffing sufficiency for each unit:

- Is there adequate staff to meet direct care needs, assessments, planning, evaluation, supervision?
- Do work loads for direct care staff appear reasonable?
- Do residents, family, and ombudsmen report insufficient staff to meet resident needs?
- Are staff responsive to residents' needs for assistance, and call bells answered promptly?
- Do residents call out repeatedly for assistance?
- Are residents, who are unable to call for help, checked frequently (e.g., each half hour) for safety, comfort, positioning, and to offer fluids and provision of care?
- Are identified care problems associated with a specific unit or tour of duty?
- Is there a licensed nurse that serves as a charge nurse (e.g., supervises the provision of resident care) on each tour of duty (if facility does not have a waiver of this requirement)?
- What does the charge nurse do to correct problems in nurse staff performance?
- Does the facility have the services of an RN available 8 consecutive hours a day, 7 days a week (if this requirement has not been waived)?
- How does the facility assure that each resident receives nursing care in accordance with his/her plan of care on weekends, nights, and holidays?
- How does the sufficiency (numbers and categories) of nursing staff contribute to identified quality of care, resident rights, quality of life, or facility practices problems?

F355 – Nursing Waivers

§483.30(c) Nursing facilities

Waiver of requirement to provide licensed nurses on a 24-hour basis.

To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if--

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307 (a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

Intent §483.30(c)

To give the facility flexibility, in limited circumstances, when the facility cannot meet nurse staffing requirements.

Interpretive Guidelines §483.30(c)

The facility may request a waiver of the RN requirement, and/or the 24-hour licensed nurse requirement. If the facility is Medicaid-certified only, the State has the authority to

grant the waiver. If the facility is dually-participating, CMS has the delegated authority to grant the waiver. (See guidelines for §483.30(d).)

A survey of Nursing Services must be conducted if a waiver has been granted or requested.

Probes: §483.30(c)

Before granting a continuation of this waiver, or during the annual review, at a minimum, determine:

- Is a continuing effort being made to obtain licensed nurses?
- How does the facility ensure that residents' needs are being met?
- Are all nursing policies and procedures followed on each shift during times when licensed services are waived?
- Is there a qualified person to assess, evaluate, plan and implement resident care?
- Is care being carried out according to professional practice standards on each shift?
- Can the survey team ensure the State that the absence of licensed nurses will NOT endanger the health or safety of residents?
- Are there trends in the facility, which might be indicators of decreased quality of care as a result of insufficient staffing to meet resident needs (e.g., increases in incident reports, the infection rate, hospitalizations)?
- Are there increases in loss of function, pressure sores, tube feedings, catheters, weight loss, mental status?
- Is there evidence that preventive measures (e.g., turning, ambulating are taken to avoid poor quality of care outcomes and avoidable sudden changes in health status?
- Is there evidence that sudden changes in resident health status and emergency needs are being properly identified and managed by appropriate facility staff and in a timely manner?
- If the facility has a waiver of the requirement to provide licensed nurses on a 24-hour basis, have they notified the ombudsman, residents, surrogates or legal representatives, and members of their immediate families of the waiver,

and are there services residents need that are not provided because licensed nurses are not available?

- Is there an increase in hospitalizations because licensed personnel are not available to provide appropriate services?
- Does the facility meet all applicable requirements to continue to receive a waiver?
- Does the staff indicate that an RN or physician is available to respond immediately to telephone calls when licensed nurses are not available?

§483.30(d) SNFs

Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.

§483.30(d)(1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that --

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either--

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period or;

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.

Interpretive Guidelines §483.30(d)

CMS is delegated the waiver authority for SNFs, including dually-participating facilities (SNF/NFs). The Medicare waiver authority is far more limited than is the States' authority under Medicaid since a State may waive any element of the nurse staffing requirement, whereas the Secretary may waive only the RN requirement. The requirements that a registered nurse provide services for 8 hours a day, 7 days a week (more than 40 hours a week), and that there be an RN designated as director of nursing on a full-time basis, may be waived by the Secretary in the following circumstances:

- The facility is located in a rural area with an inadequate supply of SNF services to meet area needs. Rural is defined as "all areas not delineated as `urban` by the Bureau of Census, based on the most recent census;

- The facility has one full-time registered nurse regularly working 40 hours a week. This may be the same individual, or part-time individuals. This nurse may or may not be the DON, and may perform some DON and some clinical duties if the facility so desires; **and either**;

- The facility has only residents whose physicians have noted, in writing, do not need RN or physician care for a 48 hour period. This does not relieve the facility from responsibility for providing for emergency availability of a physician, when necessary, nor does it relieve the facility from being responsible for meeting all needs of the residents during those 48 hours;

OR

- A physician or RN will spend the necessary time at the facility to provide care residents need during the days that an RN is not on duty. This requirement refers to clinical care of the residents that need skilled nursing services.

- If a waiver of this requirement has been granted, conduct a survey of nursing services during each certification survey. Dually-participating facilities must meet the waiver provisions of the SNF.

Probes: §483.30(d)

If the SNF has a waiver of the more than 40 hours a week RN requirement:

- Is there an RN on duty 40 hours a week?
- If more than one RN provides the 40 hour per week coverage, how is information exchanged that maintains continuity of resident care?
- Does each clinical record have documentation by the physician that the resident does not need services of a physician or an RN for a 48 hour period each week.
- Are there any emergency or routine services that should be, but are not, provided to residents during the days that a registered nurse is not on duty?
- If specific skilled care is necessary for a resident during the time that an RN is not on duty, does an RN or physician provide that service on an "as needed" basis?
- Did the facility notify residents (or their legal guardians) and their immediate families about the waiver and the ombudsman?

See also probes at §483.30(c).

If the SNF requests continuation of the waiver to provide the services of a registered nurse for more than 40 hours a week, the survey team is to provide the Secretary with information needed to grant this continuation.

- Does the SNF meet all requirements necessary for continuation of the waiver?

Procedures §483.30(a)-(d)

If the facility has an approved nurse staffing waiver, it is **not** considered a deficiency. The facility does not need to submit a POC.

The following procedure should be used to document that a facility has a waiver of nurse staffing requirements.

When a facility does not meet the nurse staffing requirements, cite the appropriate tag. If the facility does have a waiver, reference the tag number based on the type of facility. The type of facility (SNF, NF, or SNF/NF) determines what type of waiver is granted:

- For SNFs and SNF/NFs which may be waived from the requirement to provide more than 40 hours of registered nurse services a week, and for NFs

which have been granted a waiver from the 56 hour registered nurse requirement, cite F354;

- For NFs that have a waiver of the 24-hour licensed nursing requirement, cite F353, or

- Both facility types could be waived for the requirement to designate a registered nurse as the director of nursing on a full-time basis. Cite F355.

When the Form CMS-2567 is entered into OSCAR, code the waived tag as a "W." Enter the tag number, leave the correction date blank, and enter a "W" in the CP field. This will indicate that this is not a deficiency--that the requirement has been waived.

F360

§483.35 Dietary Services

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

F361

§483.35(a) Staffing

The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

§483.35(a)(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

§483.35(a)(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

Intent §483.35(a)

The intent of this regulation is to ensure that a qualified dietitian is utilized in planning, managing and implementing dietary service activities in order to assure that the residents receive adequate nutrition.

A director of food services has no required minimum qualifications, but must be able to function collaboratively with a qualified dietitian in meeting the nutritional needs of the residents.

Interpretive Guidelines §483.35(a)

A dietitian qualified on the basis of education, training, or experience in identification of dietary needs, planning and implementation of dietary programs has experience or training which includes:

- Assessing special nutritional needs of geriatric and physically impaired persons;
- Developing therapeutic diets;
- Developing "regular diets" to meet the specialized needs of geriatric and physically impaired persons;
- Developing and implementing continuing education programs for dietary services and nursing personnel;
- Participating in interdisciplinary care planning;
- Budgeting and purchasing food and supplies; and
- Supervising institutional food preparation, service and storage.

Procedures §483.35(a)

If resident reviews determine that residents have nutritional problems, determine if these nutritional problems relate to inadequate or inappropriate diet nutrition/assessment and monitoring. Determine if these are related to dietitian qualifications.

Probes: §483.35(a)

If the survey team finds problems in resident nutritional status:

- Do practices of the dietitian or food services director contribute to the identified problems in residents' nutritional status? If yes, what are they?
- What are the educational, training, and experience qualifications of the facility's dietitian?

F362

§483.35 (b) Standard Sufficient Staff

The facility must employ sufficient support personnel competent to carry out the functions of the dietary service

Interpretive Guidelines §483.35(b)

"**Sufficient support personnel**" is defined as enough staff to prepare and serve palatable, attractive, nutritionally adequate meals at proper temperatures and appropriate times and support proper sanitary techniques being utilized.

Procedures §483.35(b)

For residents who have been triggered for a dining review, do they report that meals are palatable, attractive, served at the proper temperatures and at appropriate times?

Probes: §483.35(b)

Sufficient staff preparation:

- Is food prepared in scheduled timeframes in accordance with established professional practices?

Observe food service:

- Does food leave kitchen in scheduled timeframes? Is food served to residents in scheduled timeframes?

F363

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.35(c) Standard Menus and Nutritional Adequacy

Menus must:

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

Intent §483.35(c)(1)(2)(3)

The intent of this regulation is to assure that the meals served meet the nutritional needs of the resident in accordance with the recommended dietary allowances (RDAs) of the Food and Nutrition Board of the National Research Council, of the National Academy of Sciences. This regulation also assures that there is a prepared menu by which nutritionally adequate meals have been planned for the resident and followed.

Procedures §483.35(c)(1)

For sampled residents who have a comprehensive review or a focused review, as appropriate, observe if meals served are consistent with the planned menu and care plan in the amounts, types and consistency of foods served.

If the survey team observes deviation from the planned menu, review appropriate documentation from diet card, record review, and interviews with food service manager or dietitian to support reason(s) for deviation from the written menu.

Probes: §483.35(c)(1)

Are residents receiving food in the amount, type, consistency and frequency to maintain normal body weight and acceptable nutritional values?

If food intake appears inadequate based on meal observations, or resident's nutritional status is poor based on resident review, determine if menus have been adjusted to meet the caloric and nutrient-intake needs of each resident.

If a food group is missing from the resident's daily diet, does the facility have an alternative means of satisfying the resident's nutrient needs? If so, does the facility perform a follow-up?

Menu adequately provides the daily basic food groups:

- Does the menu meet basic nutritional needs by providing daily food in the groups of the food pyramid system and based on individual nutritional assessment taking into account current nutritional recommendations?

NOTE: A standard meal planning guide (e.g., food pyramid) is used primarily for menu planning and food purchasing. It is not intended to meet the nutritional needs of all residents. This guide must be adjusted to consider individual differences. Some residents will need more due to age, size, gender, physical activity, and state of health. There are many meal planning guides from reputable sources, i.e., American Diabetes Association, American Dietetic Association, American Medical Association, or U.S. Department of Agriculture, that are available and appropriate for use when adjusted to meet each resident's needs.

§483.35(c)(2) and (3) Menus and Nutritional Adequacy

§483.35(c)(2) Be prepared in advance; and
Probes: §483.35(c)(2)

Menu prepared in advance:
Are there preplanned menus for both regular and therapeutic diets?

§483.35(c)(3) Be followed.

Probes: §483.35(c)(3)

Menu followed:

- Is food served as planned? If not, why? There may be legitimate and extenuating circumstances why food may not be available on the day of the survey and must be considered before a concern is noted.

F364

§483.35(d) Food

Each resident receives and the facility provides:

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;
(2) Food that is palatable, attractive, and at the proper temperature;

Intent §483.35(d)(1)(2)

The intent of this regulation is to assure that the nutritive value of food is not compromised and destroyed because of prolonged food storage, light, and air exposure; prolonged cooking of foods in a large volume of water and prolong holding on steam table, and the addition of baking soda. Food should be palatable, attractive, and at the proper temperature as determined by the type of food to ensure resident's satisfaction. Refer to §483.15(e) and/or §483.15(a).

Interpretive Guidelines §483.35(d)(1)

"**Food-palatability**" refers to the taste and/or flavor of the food.

"**Food attractiveness**" refers to the appearance of the food when **served** to residents.

Procedures §483.35(d)(1)

Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as: additional observation, resident and staff interviews, and review of resident council minutes. Review nutritional adequacy in §483.25(i)(l).

Probes: §483.35(d)(1)(2)

Does food have a distinctly appetizing aroma and appearance, which is varied in color and texture?

Is food generally well seasoned (use of spices, herbs, etc.) and acceptable to residents?

Conserves nutritive value:

- Is food prepared in a way to preserve vitamins? Method of storage and preparation should cause minimum loss of nutrients.

Food temperature:

- Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the resident and customary practice? Not to be confused with the proper holding temperature.

F365

§483.35(d)(3) Food prepared in a form designed to meet individual needs; and

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F366

§483.35(d)(4) Substitutes offered of similar nutritive value to residents who refuse food served

Therapeutic diets must be prescribed by the attending physician.

Procedures §483.35(d)(3)(4)

Observe trays to assure that food is appropriate to resident according to assessment and care plan. Ask the resident how well the food meets their taste needs. Ask if the resident is offered or is given the opportunity to receive substitutes when refusing food on the original menu.

Probes: §483.35(d)(3)(4)

Is food cut, chopped, or ground for individual resident's needs?

Are residents who refuse food offered substitutes of similar nutritive value?

Interpretive Guidelines §483.35(d)(4)

A food substitute should be consistent with the usual and ordinary food items provided by the facility. For example, if a facility never serves smoked salmon, they would not be required to serve this as a food substitute; or the facility may, instead of grapefruit juice, substitute another citrus juice or vitamin C rich juice that the resident likes.

F367

§483.35(e) Therapeutic Diets

Intent §483.35(e)

The intent of this regulation is to assure that the resident receives and consumes foods in the appropriate form and/or the appropriate nutritive content as prescribed by a physician and/or assessed by the interdisciplinary team to support the treatment and plan of care.

Interpretive Guidelines §483.35(e)

"**Therapeutic Diet**" is defined as a diet ordered by a physician as part of treatment for a disease or clinical condition, or to eliminate or decrease specific nutrients in the diet, (e.g., sodium) or to increase specific nutrients in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet).

"**Mechanically altered diet**" is one in which the texture of a diet is altered. When the texture is modified, the type of texture modification must be specific and part of the physicians' order.

Procedures §483.35(e)

If the resident has inadequate nutrition or nutritional deficits that manifests into and/or are a product of weight loss or other medical problems, determine if there is a therapeutic diet that is medically prescribed.

Probes: §483.35(e)

Is the therapeutic diet that the resident receives prescribed by the physician?

Also, see §483.25(i), Nutritional Status.

F368

§483.35(f) Frequency of Meals

(1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.

(3) The facility must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.

Intent §483.35(f)(1-4)

The intent of this regulation is to assure that the resident receives his/her meals at times most accepted by the community and that there are not extensive time lapses between meals. This assures that the resident receives adequate and frequent meals.

Interpretive Guidelines §483.35(f)(1-4)

A "**substantial evening meal**" is defined as an offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal should represent no less than 20 percent of the day's total nutritional requirements.

"**Nourishing snack**" is defined as a verbal offering of items, single or in combination, from the basic food groups. Adequacy of the "nourishing snack" will be determined both by resident interviews and by evaluation of the overall nutritional status of residents in the facility, (e.g., Is the offered snack usually satisfying?)

Procedures §483.35(f)(1-4)

Observe meal times and schedules and determine if there is a lapse in time between meals. Ask for resident input on meal service schedules, to verify if there are extensive lapses in time between meals

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F369

§483.35(g) Assistive Devices

The facility must provide special eating equipment and utensils for residents who need them.

Intent §483.35(g)

The intent of this regulation is to provide residents with assistive devices to maintain or improve their ability to eat independently. For example, improving poor grasp by enlarging silverware handles with foam padding, aiding residents with impaired coordination or tremor by installing plate guards, or providing postural supports for head, trunk, and arms.

Procedures §483.35(g)

Review sampled residents comprehensive assessment for eating ability. Determine if recommendations were made for adaptive utensils and if they were, determine if these utensils are available and utilized by resident. If recommended but not used, determine if this is by resident's choice. If utensils are not being utilized, determine when these were recommended and how their use is being monitored by the facility and if the staff is developing alternative recommendations

§483.35(h) Sanitary Conditions

The facility must--

F370

§483.35(h)(1) Procure food from sources approved or considered satisfactory by Federal, State or local authorities;

F371

§483.35(h)(2) Store, prepare, distribute, and serve food under sanitary conditions; and

Intent §483.35(h)(2)

The intent of this regulation is to prevent the spread of food borne illness and reduce those practices which result in food contamination and compromised food safety in

nursing homes. Since foodborne illness is often fatal to nursing home residents, it can and must be avoided.

Interpretive Guidelines §483.35(h)(2)

"**Sanitary conditions**" is defined as storing, preparing, distributing, and serving food properly to prevent food borne illness. Potentially hazardous foods must be subject to continuous time/temperature controls in order to prevent either the rapid and progressive growth of infectious or toxigenic micro-organisms such as Salmonella or the slower growth of Clostridium Botulinum. In addition, foods of plant origin become potentially hazardous when the skin, husk, peel, or rind is breached, thereby possibly contaminating the fruit or vegetable with disease causing micro-organisms. Potentially hazardous food tends to focus on animal products, including but not limited to milk, eggs and poultry.

Improper holding temperature is a common contributing factor of foodborne illness. The facility must follow proper procedures in cooking, cooling, and storing food according to time, temperatures, and sanitary guidelines. Improper handling of food can cause salmonella and E-Coli contamination. The 1993 FDA Food Code advises the following precautions:

NOTE: The 1993 FDA Food Code is not regulation and cannot be enforced as such. The food temperatures cited that are recommended in the 1993 FDA Food Code are target temperatures and give a margin of safety in temperature ranges and to avoid known harmful temperatures.

Refrigerator storage of food to prevent food borne illness includes storing raw meat away from vegetables and other foods. Raw meat should be separated from cooked foods and other foods when refrigerated on its own tray on a bottom shelf so meat juices do not drip on other foods. Foods of both plant and animal origin must be cooked, maintained and stored at appropriate temperatures.

- Foods of both plant and animal origin must be cooked, and maintained, and stored at appropriate temperatures. These temperatures are better utilized as food hold temperatures rather than the food temperatures as residents receive the food.

- Hot foods which are potentially hazardous should leave the kitchen (or steam table) above 140° F, and cold foods at or below 41° F and freezer temperatures should be at 0° F or below. Refrigerator temperatures should be maintained at 41° F or below. The 1993 FDA Food Code can be used as an authoritative guide to clarify regulatory requirements on how to prepare and serve food to prevent foodborne illness. As the public becomes more informed and educated on how to prevent foodborne illness, this code will become the standard of practice the same as the 1976 Food Service Sanitation Manual did prior to 1993.

Procedures §483.35(h)(2)

Observe storage, cooling, and cooking of food. Record the time and date of all observations. If a problem is noted, conduct additional observations to verify findings.

Observe that employees are effectively cleaning their hands prior to preparing, serving and distributing food. Observe that food is covered to maintain temperature and protect from other contaminants when transporting meals to residents.

Refrigerated storage:

- Check all refrigerators and freezers for temperatures. Use the facility's or the surveyor's own properly sanitized thermometer to evaluate the internal temperatures of potentially hazardous foods with a focus on the quantity of leftovers and the container sizes in which bulk leftovers are stored.

Food preparation:

- Use a sanitized thermometer to evaluate food temperatures.

In addition, how do kitchen staff process leftovers?

- Are they heated to the appropriate temperatures?
- How is frozen food thawed?
- How is potentially hazardous food handled during multi-step food preparation (e.g., chicken salad, egg salad)?
- Is hand contact with food minimized?

Food service:

- Using a properly sanitized thermometer, check the temperatures of hot and cold food prior to serving.
- How long is milk held without refrigeration prior to distribution?

Food distribution:

- Is the food protected from contamination as it is transported to the dining rooms and residents' rooms?

Pest free:

- Is the area pest free? (See §483.70(h)(4).) Look for signs of pests such as mice, roaches, rates, flies.

Preventing Contamination:

- Are handwashing facilities convenient and properly equipped for dietary services staff Use? (Staff uses good hygienic practices and staff with communicable disease or infected skin lesions do not have contact with food if that contact will transmit the disease.)

Hazard Free

- Are toxic items (such as insecticides, detergent, polishes) properly stored, labeled, and used separate from the food?

Probes: §483.35(h)(2)

Observe food storage rooms and food storage in the kitchen.

- Are containers of food stored off the floor and on clean surfaces in a manner that protects it from contamination?

- Are other areas under storage shelves monitored for cleanliness to reduce attraction of pest.

- Are potentially hazardous foods stored at 41° F or below and frozen foods kept at 0° F or below?

- Do staff handle and cook potentially hazardous foods properly?

- Are potentially hazardous foods kept at an internal temperature of 41° F or below in cold food storage unit, or at an internal temperature of 140° F or above in a hot food storage unit during display and service?

- Is food transported in a way that protects against contamination (i.e., covered containers, wrapped, or packaged)?

- Is there any sign of rodent or insect infestation.

Dishwashing:

- The current 1993 Food Code, DHHS, FDA, PHS recommends the following water temperature and manual washing instructions:

Machine:

1. Hot Water:

    a. 140° F Wash (or according to the manufacturer's specifications or instructions).

    b. 180° F Rinse (180°, 160° or greater at the rack and dish/utensils surfaces.

2. Low Temperature:

    a. 120° F +25 ppm (parts per million) Hypochlorite (household bleach) on dish Surface.

Manual:

1. 3 Compartment Sink (wash, rinse and sanitize): Sanitizing solution used according to manufacturer's instructions.

    a. 75 degrees F - 50 ppm Hypochlorite (household bleach) or equivalent, or 12.5 ppm of Iodine.

    b. Hot Water Immersion at 170 F for at least 30 seconds.

Are food preparation equipment, dishes, and utensils effectively sanitized and cleaned to destroy potential disease carrying organisms and stored in a protected manner?

F372

§483.35(h)(3) Dispose of Garbage and Refuse Properly

Interpretive Guidelines §483.35(h)(3)

The intent of this regulation is to assure that garbage and refuse be properly disposed.

Procedures §483.35(h)(3)

Garbage/refuse:

Observe garbage and refuse container construction, and outside storage receptacles.

Probes: §483.35(h)(3)

Are garbage and refuse containers in good condition (no leaks) and is waste properly contained in dumpsters or compactors with lids or otherwise covered?

Are areas such as loading docks, hallways, and elevators used for both garbage disposal and clean food transport kept clean, free of debris and free of foul odors and waste fat?

Is the garbage storage area maintained in a saunter condition to prevent the harborage and feeding of pests?

Are garbage receptacles covered when being removed from the kitchen area to the dumpster?

F385

§483.40 Physician Services

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

§483.40(a) Physician Supervision

The facility must ensure that--

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

Intent §483.40

The intent of this regulation is to ensure the medical supervision of the care of nursing home residents by a personal physician.

Interpretive Guidelines §483.40

A physician's "personal approval" of an admission recommendation must be in written form. The physician's admission orders for the resident's immediate care as required in §483.20(a) will be accepted as "personal approval" of the admission.

"**Supervising the medical care of residents**" means participating in the resident's assessment and care planning, monitoring changes in resident's medical status, and providing consultation or treatment when called by the facility. It also includes, but is not limited to, prescribing new therapy, ordering a resident's transfer to the hospital, conducting required routine visits or delegating and supervising follow-up visits to nurse practitioners or physician assistants. Each resident should be allowed to designate a personal physician. (See §483.10(d)(1).) The facility's responsibility in this situation is

to simply assist the resident, when necessary, in his or her efforts to obtain those services. For example, the facility could put the resident in touch with the county medical society for the purpose of obtaining referrals to practicing physicians in the area.

Facilities should share MDS and other assessment data with the physician.

Procedures §483.40

If there is a deficiency in §483.10, Resident Rights; §483.13, Resident Behavior and Facility Practices; §483.15, Quality of Life; or §483.25, Quality of Care, fully review all of the tags under this requirement.

Probes: §483.40(a)

- How was the supervising physician involved in the resident's assessment and care planning?
- If staff reported a significant change in medical status to the supervising physician, did the physician respond?
- If the supervising physician was unavailable and could not respond, did the facility have a physician on call? Did this physician respond?
- Are residents sent to hospital emergency rooms routinely because the facility does not always have a physician on call?

F386

§483.40(b) Physician Visits

The physician must--

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

Intent §483.40(b)

The intent of this regulation is to have the physician take an active role in supervising the care of residents. This should not be a superficial visit, but should include an evaluation of the resident's condition and a review of and decision about the continued appropriateness of the resident's current medical regime.

Interpretive Guidelines §483.40(b)

Total program of care includes all care the facility provides residents to maintain or improve their highest practicable mental and physical functional status, as defined by the comprehensive assessment and plan of care. Care includes medical services and medication management, physical, occupational, and speech/language therapy, nursing care, nutritional interventions, social work and activity services that maintain or improve psychosocial functioning.

The physician records residents' progress and problems in maintaining or improving their mental and physical functional status. The physician need not review the total plan of care at each visit, but must review the total plan of care at visits required by §483.40(c). There is no requirement for physician renewal of orders.

In cases where facilities have created the option for a resident's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. See Guidelines for §483.75(l)(1) for information on facility safeguards concerning electronic signatures.

Physician orders may be transmitted by facsimile machine if the following conditions are met:

- The physician should have signed and retained the original copy of the order from which the facsimile was transmitted and be able to provide it upon request. Alternatively, the original may be sent to the facility at a later time and substituted for the facsimile.

- The facility should photocopy the faxed order since some facsimiles fade over time. The facsimile copy can be discarded after facility photocopies it.

- A facility using such a system should establish adequate safeguards to assure that it is not subject to abuse.

It is not necessary for a physician to re-sign the facsimile order when he/she visits the facility.

When rubber stamp signatures are authorized by the facility's management, the individual whose signature the stamp represents shall place in the administrative offices of the facility a signed statement to the effect that he/she is the only one who has the

stamp and uses it. A list of computer codes and written signatures must be readily available and maintained under adequate safeguards.

Probes: §483.40(b)

- Do services ordered by a physician show a pattern of care to maintain or improve the resident's level of independent functioning? For example, how do physician orders reflect the resident's nutritional status and needs?

- Does documentation reflect continuity of care in maintaining or improving a resident's mental and physical functional status? For example, do the attending physician's rehabilitation service orders show a pattern of consistent restorative programming?

F387

§483.40(c) Frequency of Physician Visits

(1) The residents must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

F388

§483.40(c)(3) Expect as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

§483.40(c) (4) At the option of the physician, required visits in SNFs, after the initial visit, may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner or clinical nurse specialist in accordance with paragraph (e) of this section.

Interpretive Guidelines §483.40(c)

"**Must be seen**" means that the physician must make actual face-to-face contact with the resident. There is no requirement for this type of contact at the time of admission, since the decision to admit an individual to a nursing facility (whether from a hospital or from the individual's own residence) generally involves physician contact during the period immediately preceding the admission.

After the initial physician visit in SNFs, where States allow their use, a qualified nurse practitioner (NP), clinical nurse specialist or physician assistant (PA) may make every other required visit. (See §483.40(e) Physician delegation of tasks in SNFs.)

In a NF, the physician visit requirement, in accordance with the State law, may be satisfied by NP, clinical nurse specialist or PA. (See §483.40(f).)

The timing of physician visits is based on the admission date of the resident. Visits will be made within the first 30 days, and then at 30 day intervals up until 90 days after the admission date. Visits will then be at 60 day intervals. Permitting up to 10 days slippage of a due date will not affect the next due date. However, do not specifically look at the timetables for physician visits unless there is indication of inadequate medical care. The regulation states that the physician (or his/her delegate) must visit the resident **at least** every 30 or 60 days. There is no provision for physicians to use discretion in visiting at intervals longer than those specified at §483.40(c).

Policy that allows an NP, clinical nurse specialist, or PA to make every other required visit, and that allows a 10 day slippage in the time of the visit, does not relieve the physician of the obligation to visit a resident when the resident's medical condition makes that visit necessary.

It is expected that visits will occur at the facility rather than the doctor's office unless office equipment is needed or a resident specifically requests an office visit. If the facility has established policy that residents leave the grounds for medical care, the resident does not object, and this policy does not infringe on his/her rights, there is no prohibition to this practice. The facility should inform the resident of this practice, in accordance with §483.10(b).

Probes: §483.40(c)

- How does the scheduling and frequency of physician visits relate to any identified quality of care problems?

- When a PA, clinical nurse specialist, or NP performs a delegate physician visit, and determines that the resident's condition warrants direct contact between the physician and the resident, does the physician follow-up promptly with a personal visit?

F389

§483.40(d) Availability of Physicians for Emergency Care

The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

Interpretive Guidelines §483.40(d)

If a resident's own physician is unavailable, the facility should attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility.

Probes: §483.40(d)

- Does the facility have a physician on call for medical emergencies? Does this physician respond?
- For what reasons are residents sent to hospital emergency rooms?
- Did medical management of the emergency affect the resident's maintaining or improving their functional abilities?
- If the resident refused the physician's visit, what has the facility done to explain to the resident the results and alternatives that may be available?

F390

§483.40(e) Physician Delegation of Tasks in SNFs

(1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who--

(i) Meets the applicable definition in §491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

Interpretive Guidelines §483.40(e)

"**Nurse practitioner**" is a registered professional nurse now licensed to practice in the State and who meets the State's requirements governing the qualification of nurse practitioners.

"**Clinical nurse specialist**" is a registered professional nurse currently in practice in the State and who meets the State's requirements governing the qualifications of clinical nurse specialists.

"**Physician assistant**" is a person who meets the applicable State requirements governing the qualifications for assistants to physician.

When **personal** performance of a particular task by a physician is specified in the regulations, performance of that task cannot be delegated to anyone else. The tasks of examining the resident, reviewing the resident's total program of care, writing progress notes, and signing orders may be delegated according to State law. The extent to which physician services are delegated to physician extenders in SNFs will continue to be determined by the provisions of §483.40(e), while the extent to which these services are performed by physician extenders in NFs will be determined by the individual States under §483.40(f).

Probes: §483.40(e)

- Do the facility's attending physicians delegate to NPs, clinical nurse specialists, or PAs?

- Do NP/clinical nurse specialist/PA progress notes and orders follow the scope of practice allowed by State law?

- What evidence is there of physician supervision of NPs or PAs? For example, do physicians countersign NP/PA orders, if required by State law?

§483.40(f) Performance of Physician Tasks in NFs

At the option of State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

Interpretive Guidelines §483.40(f)

If delegation of physician tasks is permitted in your State and the physician extender does not meet the qualifications listed here, cite F388.

Procedures §483.40(f)

If a nurse practitioner, clinical nurse specialist, or physician assistant is performing required physician tasks in a NF, is this allowed by the State? Is this person an employee of the facility? (Facility employees are prohibited from serving in this capacity.)

Probes: §483.40(f)

Is this person working in collaboration with the physician?

§483.45 Specialized Rehabilitative Services

F406

§483.45(a) Provision of Services

If specialized rehabilitative services such as, but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must--

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.

Intent §483.45(a)(1)(2)

The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psycho-social well-being.

"**Specialized rehabilitative services**" are differentiated from restorative services which are provided by nursing staff. Specialized rehabilitative services are provided by or coordinated by qualified personnel.

Specialized rehabilitative services are considered a facility service and are, thus, included within the scope of facility services. They must be provided by or coordinated by qualified personnel. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the services from an outside resource.

For a resident with MI or MR to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self-determination as possible. They are:

"**Specialized services for MI or MR**" refers to those services to be **provided by the State** which can only be delivered by personnel or programs other than those of the NF (e.g., outside the NF setting), because the overall level of NF services is not as intense as necessary to meet the individual's needs.

The Preadmission Screening and Annual Resident Review (PASARR) report indicates specialized services required by the resident. The State is required to list those services in the report, as well as provide or arrange for the provision of the services. If the State determines that the resident does not require specialized services, the facility is responsible to provide all services necessary to meet the resident's mental health or mental retardation needs.

"**Mental health rehabilitative services for MI and MR**" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they are required to be subject to the PASARR process and whether or not they require additional services to be provided or arranged for by the State as specialized services.

The facility should provide interventions which complement, reinforce and are consistent with any specialized services (as defined by the resident's PASARR) the individual is receiving or is required to receive by the State. The individual's plan of care should specify how the facility will integrate relevant activities throughout all hours of the individual's day at the NF to achieve this consistency and enhancement of PASARR goals. The surveyor should see competent interaction by staff at all times, in both formal and informal settings in accordance with the individual's needs.

Mental health rehabilitative services for MI and MR may include, but are not limited to:

- Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behaviors;

- Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness;

- Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);

- Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self-determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment;

- Crisis intervention service;

- Individual, group, and family psychotherapy;

- Development of appropriate personal support networks; and

- Formal behavior modification programs.

Procedures §483.45(a)(1)(2)

For sampled residents, whose comprehensive assessment indicates physical, psychosocial, and/or communications rehabilitation potential (See MDS 2.0, sections G, C, F, E), observe for unmet needs for rehabilitative services. Determine the extent of follow through with comprehensive care plan using probes outlined below. Verify from the chart that resident is receiving frequency and type of therapy as outlined in the care plan.

Probes: §483.45(a)(1)(2)

1. For physical therapy

    a. What did the facility do to improve the resident's muscle strength? The resident's balance?

    b. What did the facility do to determine if as assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?

    c. If the resident has an assistive device, is he/she encouraged to use it on a regular basis?

d. What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?

e. What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

2. For occupational therapy

a. What did the facility do to decrease the amount of assistance needed to perform a task?

b. What did the facility do to decrease behavioral symptoms?

c. What did the facility do to improve gross and fine motor coordination?

d. What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?

e. What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

3. For speech-language pathology.

a. What did the facility do to improve auditory comprehension such as understanding common, functional words, concepts of time and place, and conversation?

b. What did the facility do to improve speech production?

c. What did the facility do to improve the expressive behavior such as the ability to name common, functional items?

d. What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received and audiologic evaluation? For example, did the facility instruct the resident how to effectively and independently use environmental controls to compensate for hearing loss such as eye contact, preferential seating, use of the better ear?

e. For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

4. For health rehabilitative services for MI and MR

    a. What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior?

    b. What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?

    c. What did the facility do to develop and maintain necessary daily living skills?

    d. How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR?

    e. Questions to ask individuals with MI or MR:

        (1) Who do you talk to when you have a problem or need something?

        (2) What do you do when you feel happy? Feel sad? Can't sleep at night?

        (3) In what activities are you involved, and how often?

F407

§483.45(b) Qualifications

Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

Intent §485.45(b)

The intent of this regulation is to assure that the rehabilitative services are medically necessary as prescribed by a physician and provided by qualified personnel to maximize potential outcomes.

Specialized rehabilitative services are provided for individual's under a physician's order by a qualified professional. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative sides will follow to maintain functional and physical status.

Interpretive Guidelines §483.45(b)

"**Qualified personnel**" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws.

Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only by licensed or credentialed personnel.

Procedures §483.45(b)

Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care providers qualification.

Probes: §483.45(b)

If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

F411

§483.55 Dental Services

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

§483.55(a) Skilled Nursing Facilities

A facility--

(1) Must provide or obtain from an outside resource, in accordance with <u>§483.75(h)</u> of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must if necessary assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

Intent §483.55

The intent of this regulation is to ensure that the facility be responsible for assisting the resident in obtaining needed dental services, including routine dental services.

Interpretive Guidelines §483.55

This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents, i.e., employ a staff dentist or have a contract (arrangement) with a dentist to provide services.

For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services.

For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find and alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well-being. (See §483.15(g).)

The facility is responsible for selecting a dentist who provides dental services in accordance with professional standards of quality and timeliness under §483.75(h)(2).

"**Routine dental services**" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures, e.g., taking impressions for dentures and fitting dentures.

"**Emergency dental services**" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity by a dentist that required immediate attention.

"**Prompt referral**" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

Probes: §483.55

Do residents selected for comprehensive or focused reviews, as appropriate, with dentures use them?

Are residents missing teeth and may be in need of dentures?

Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?

Are resident's dentures intact? Proper fit?

F412

§483.55(b) Nursing Facilities

The facility--

(1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident--

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

Interpretive Guidelines §483.55(b)(1)(i)

For Medicaid residents, the facility must provide the resident, without charge, all emergency dental services, as well as those routine dental services that are covered under the State plan.

F425

§483.60 Pharmacy Services

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

Interpretive Guidelines §483.60

The facility is responsible under §483.75(h) for the "timeliness of the services."

A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

Procedures §483.60

During the surveyor's observation of the drug pass, are all ordered medications available?

F426

§483.60(a) Procedures

A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

F427

§483.60(b) Service Consultation

The facility must employ or obtain the services of a licensed pharmacist who--

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

Interpretive Guidelines §483.60(b)(2) and (3)

A record of receipt and disposition of controlled drugs does not need to be proof of use sheets. The facility can use existing documentation such as the Medication Administration Record (MAR) to accomplish this record.

Periodic reconciliations should be monthly. If they reveal shortages, the pharmacist and the director of nursing may need to initiate more frequent reconciliations. In situations in which loss of controlled drugs is evident, the facility may have to utilize proof of use sheets on all controlled drugs for all shifts. However, when the source of shortage is located and remedied, the facility may go back to periodic reconciliation by the pharmacist.

Please note that the regulation does not prohibit shortages of controlled drugs - only that a record be kept and that it be periodically reconciled. If the survey reveals that all controlled drugs are not accounted for, refer the case to the State nursing home licensure authority, or to the State Board of Pharmacy.

F428

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

Interpretive Guidelines §483.60(c)(1)

It may be necessary to review more frequently (e.g., every week) depending on the residents' condition and the drugs they are taking.

F429

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.60(c)(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and

Interpretive Guidelines 483.60(c)(2)

The facility is encouraged to share the pharmacist's drug regimen review report with the medical director. The medical director is responsible for coordination of medical care in the facility (see §483.75(i)(2)(ii).)

Miscellaneous Drugs That Are Potentially Inappropriate in the Elderly

The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, MD. This paper was published in the "Archives of Internal Medicine," Volume 157, July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times:

1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit."

2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur."

These criteria are divided into two broad categories. Drug therapy that is classified as having "high severity" and therapy that is considered as not having "high severity." Severity is defined as: "a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur." The survey guidelines are located in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation.

1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with §483.25(l)(1), Unnecessary Drug (F329), and

2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with §483.60(c)(1), Drug Regimen Review Report (F429) which are located under guidance to surveyors for drug regimen review.

It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not

necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety.

List of Drug Combinations With High Potential for Less Severe Adverse Outcomes

1. Phenylbutazone (Butazolidin)

   Risk: "May produce serious hematological side effects (blood disorders) and should not be used in elderly patients."

   Blood disorders include bone marrow depression, aplastic anemia, agranulocytosis, leukopenia, pancytopenia, thrombocytopenia, macrocytic or megoblastic anemia.

2. Trimethobenzamide (Tigan)

   Risk: "Trimethobenzamide is one of the least effective antiemetics, yet it can cause extrapyramidal side effects."

   Extrapyramidal side effects may involve various combinations of tremors, postural unsteadiness, lack of or slowness of movement, cogwheel rigidity, expressionless face, drooling, infrequent blinking, shuffling gate, decreased arm swing, and rigidity of muscles in the limbs, neck, and trunk.

3. Indomethacin (Indocin, Indocin SR)

   Risk: "Of all the nonsteroidal anti-inflammatory drugs, indomethacin produces the most central nervous system side effects and should therefore be avoided in the elderly." The most common side effects (in order of frequency of occurrence) are headache (10%), dizziness (3-9%), and vertigo, somnolence, depression, and fatigue (1-3%).

   Exception: It is considered acceptable to use indomethacin for short term (e.g., 1 week) treatment of an acute episode of gouty arthritis.

4. Dipyridamole (Persantine)

   Risk: "Dipyridamole frequently cause orthostatic hypotension in the elderly. It has been proven beneficial only in patients with artificial heart valves. Whenever possible, its use in the elderly should be avoided**.**

5. Reserpine (Serpasil)

   Combination products such as Ser-Ap-Es, Serathide, Hydropses, Unipres, Uni-serp, Diutensen-R, Metatensin #2 & #4, Diupres, Hydroserpine, Hydromox-R, Regroton, Renese-R, Salutensin.

Risk: "Reserpine imposes unnecessary Risks in the elderly, inducing depression, impotence, sedation, and orthostatic hypotension. Safer alternatives exist."

6. Diphenhydramine (Benadryl)

Note: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for these drugs under: D. Drugs for Sleep Induction. The surveyor should use that guideline if diphenhydramine is being used as a hypnotic. If diphenhydramine is being used as an antihistamine, this guideline should be used.

Risk: "Diphenhydramine is potently anticholinergic and usually should not be used as a hypnotic in the elderly. When used to treat or prevent allergic reactions, it should be used in the smallest dose and with great caution." Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: For treatment of allergies, review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

7. Ergot Mesyloids (Hydergine), Cyclandelate (Cyclospasmol)

Risk: **"**Hydergine and the central vasodilators have not been shown to be effective, in the doses studied for treatment of dementia or any other condition."

8. Muscle Relaxants

Muscle Relaxants such as Methocarbamol (Robaxin), Carisoprodol (Soma), Chlorzoxazone (Paraflex) Metaxalone (Skelaxin), Cyclobenzaprine (Flexiril), Dantrolene (Dantrium), Orphenadrine (Norflex, Banflex, Myotrol).

Risk: "Most muscle relaxants are poorly tolerated by the elderly, leading to anticholinergic side effects, sedation, and weakness." Anticholinergic side effects include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

9. Antihistamines

Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril, Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripelennamine (PBZ), Dexchlorpheniramine (Polarmine).

Risk: "All nonprescription and many prescription antihistamines have a potent anticholinergic properties." Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. When used to treat or prevent allergic reactions, antihistamines should be used in the smallest possible dose, and for the shortest period of time, and with great caution.

Diagnosis/Drug Combinations With High Potential For Less Severe Outcomes

1. Diabetes

Drugs: Corticosteriods such as Beclomethasone (beclovent, Vanceril), Betamethasone (Celestone), Cortisone Acetate(Cortone Acetate), Dexamethasone (Decadron, Dexone), Hydrocortisone (Cortef), Methyl prednisone (medrol), Prednisolone (many brands), Prednisone (many brands).

Risk: "May worsen diabetic control, if recently started."

If Recently Started: The panelists for the Beers' study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should pay close attention to obtaining a rationale for its use during that time. The surveyor should be responsible for indepth investigation to determine when the drug was actually started. It should be noted that rapid withdrawal of these medicines in a steroid-dependent person can cause serious side effects.

2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease.

Drugs: Aspirin in excess of 325 mg. per day.

Risk: "May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD)."

Note: The panelists did not believe that enteric coated aspirin would be beneficial since aspirin exacerbates these conditions primarily through its systemic effects rather than its local effects.

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Drugs: Potassium supplements such as Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K or Ten K. This includes liquid oral dosage forms which, if used, should be administered after meals with an optimal amount of water or fruit juice (depending on the resident's fluid restrictions) to decrease the potential of gastric distress or bad taste as much as possible.

Risk: "May cause gastric irritation with symptoms similar to ulcer disease."

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Exception: Use of these medications to treat low potassium levels until they return to normal range if determined by the prescriber that use of fresh fruits and vegetables or other dietary supplementation is not adequate or possible.

3. Seizures or Epilepsy

Drugs: Clozapine (Clozaril), Chlorpromazine (Thorazine), Thioridazine (Mellaril), Chlorpropthixene (Taractan), Metoclopramide (Reglan), Fluphenazine (Prolixin, Permitil), Perphenazine (Trilafon), Mesoridazine (Serentil), Prochlorperazine (Compazine), Promazine (Sparine), Trifluoperazine (Stelazine), Triflupromazine (Vesprin), Haloperidol (Haldol), Loxapine (Loxitane), Molindone (Moban), Olanzapine (Zyprexa), Pimozide (Orap), Risperidone (Risperdal), Thiothixene (Navane), Quetiapine (Seroquel).

Risk: "May lower seizure threshold."

Potential Side Effect: Increased risk of seizure activity.

Exception: Use of these drugs within the already established CMS guidelines (483.25(l)) for a 72 hour period or less, when treating acute psychosis, such that the individual is a danger to self or others.

4. Benign Prostatic Hypertrophy (BPH)

Drugs: Narcotic drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Risk: "Anticholinergic drugs may impair micturition and cause obstruction in men with BPH."

Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, low back pain.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Drugs: Flavoxate (Urispas), Oxybutynin (Ditropan), Bethanechol (Urecholine, Duvoid).

Risk: "Bladder relaxants may cause obstruction in persons with BPH."

Potential Side Effects: Urinary retention, incontinence, hesitancy, reflux, hydronephrosis.

5. Constipation

Drugs: Anticholinergic antihistamines such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril & Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleennamine (PBZ), Dexchlorpheniramine (Polaramine).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anti-Parkinson medications such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemadren), Biperiden (Akineton).

GI Antispasmodics such as Dicyclomine (Bentyl), Hyoscyamine (Levsin & Levsinex), Propantheline (Pro-Banthine), Belladonna Alkaloids (Donnatal), Clidinium containing products such as Librax.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anticholinergic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

Narcotic Drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphen (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

6. Insomnia

Drugs:

- Decongestants such as Phenylephrine (Duo-Medihaler), Phenylpropanolamine (Genex), Pseudoephedrine (Novafed, Sudafed, Triaminic AM, Efidac/24);
- Theophylline (Elixophyllin Bronkodyl, Theo-Dur, Slo-Bid);
- Desipramine (Pertofrane, Norpramin);
- Selective Serotonin Reuptake Inhibitors such as Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft);
- Methylphenidate (Ritalin);
- Monamine Oxidase Inhibitors (MAOIs) such as Phenelzine (Nardil), Tranylcypromine (Parnate); and
- Beta Agonists such as Isoproterenol (Isuprel), Albuterol (Proventil), Bitolterol (Tornalate), Terbutaline (Brethine).

Risk: "May cause or worsen insomnia."

(The surveyor should consider that insomnia is often a symptom of untreated depression and Chronic Obstructive Pulmonary Disease (COPD.))

F430

§483.60(c)(2)

these reports must be acted upon.

Interpretive Guidelines §483.60(c)(2)

The director of nursing and the attending physicians are not required to agree with the pharmacist's report, nor are they required to provide a rationale for their "acceptance" or "rejection" of the report. They must, however, act upon the report. This may be accomplished by indicating acceptance or rejection of the report and signing their names. The facility is encouraged to provide the medical director with a copy of drug regimen review reports and to involve the medical director in reports that have not been acted upon.

F431

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

Interpretive Guidelines §483.60(d)

This section imposes currently accepted labeling requirements on **facilities**, even though the pharmacies will be immediately responsible for accomplishing the task.

The critical elements of the drug label in a long-term care facility are the name of the drug and its strength.

The names of the resident and the physician do not have to be on the label of the package, but they must be identified with the package in such a manner as to assure that the drug is administered to the right patient.

All drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container. "When applicable" means that expiration dates must be on the labels of drugs used in long term care facilities unless State law stipulates otherwise.

F432

§483.60(e) Storage of Drugs and Biologicals

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Interpretive Guidelines §483.60(e)

Compartments in the context of these regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for authorized personnel to have access to keys must be determined by the facility management in accordance with

Federal, State, and local laws and facility practices. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs.

Probes: §483.60(e)

Are all drugs and biologicals stored properly, locked and at proper temperature?

F441

§483.65 Infection Control

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an infection control program under which it--

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

Intent §483.65(a)

The intent of this regulation is to assure that the facility has an infection control program which is effective for investigating, controlling, and preventing infections. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

Interpretive Guidelines §483.65(a)

The facility's infection control program must have a system to monitor and investigate causes of infection (nosocomial and community acquired) and manner of spread. A facility should, for example, maintain a separate record on infection that identifies each resident with an infection, states the date of infection, the causative agent, the origin or site of infection, and describes what cautionary measures were taken to prevent the spread of the infection within the facility. The system must enable the facility to analyze clusters, changes in prevalent organisms, or increases in the rate of infection in a timely manner.

Surveillance data should be routinely reviewed and recommendations made for the prevention and control of additional cases.

The written infection control program should be periodically reviewed by the facility and revised as indicated.

Current standards for infection control program address the following. The following are not regulatory requirements but provide guidance for evaluating the facility's program.

- Definition of nosocomial/facility acquired infections and communicable diseases.

- Risk assessment of occurrence of communicable diseases for both residents and staff that is reviewed annually, or more frequently if indicated.

- Methods for identifying, documenting and investigating nosocomial infections and communicable diseases. The infection control program should be able to identify new infections quickly, paying particular attention to residents at high risk of infection of infection (e.g. residents who are immobilized, have invasive devices or procedures, have pressure sores, have been recently discharged from a hospital to the long term care facility, have MI or MR, have decreased mental status, are nutritionally compromised or have altered immune systems).

- Early detection of residents who have signs and symptoms of TB and a referral protocol to a facility where TB can be evaluated and managed appropriately.

- Measures for prevention of infections, especially those associated with intravascular therapy, indwelling urinary catheters, tracheostomy care, stoma care, respiratory care, immunosuppression, pressures sores, bladder and bowel incontinence and any other factors which compromise a resident's resistance to infections.

- Measures for the prevention of communicable disease outbreaks, including tuberculosis, flu, hepatitis, scabies, MRSA.

- Procedures to inform and involve a local or State epidemiologist, as required by the State for non-sporadic, facility-wide infections that are difficult to control.

- Isolation procedures and requirements for infected and at risk or immunosuppressed nursing home residents.

- Use of and inservice education regarding standard precautions, (e.g., universal precautions/body substance isolation).

- Handwashing, respiratory protection, linen handling, housekeeping, needle and hazardous waste disposal, as well as other means for limiting the spread of communicable organisms.

- Authority, indications, and procedures for obtaining and acting upon microbiological cultures from residents and for isolating residents.

- Proper use of disinfectants, antiseptics and germicides in accordance with the manufacturers' instructions and EPA of FDA label specifications to avoid harm to staff, residents and visitors and to ensure its effectiveness.

- Orientation of all new facility personnel to the infection control program and periodic updates for all staff.

- Measures for the screening of the health care workers for communicable diseases, and for the evaluation of workers exposed to residents with communicable diseases including TB and Blood Borne Pathogens.

- Work restriction guidelines for an employee that is infected or ill with a communicable disease.

- Measures which address prevention of infection common to nursing home residents (e.g., vaccination for influenza and pneumococcal pneumonia as appropriate) TB screening and testing.

- Sanitization of tubs, whirlpools and multiple use equipment to be performed according to manufacturer's recommendations.

Observe whether staff including direct care, housekeeping, kitchen staff, use gloves in accord with aseptic principles.

Determine if there is consistent use of aseptic technique for dressing changes.

If breaks in technique are observed, verify that the facility has a system in place for routine monitoring of staff infection control practices.

Ask direct care giver staff what do they do and who do they notify when an infection is noted.

Procedures §483.65(a)

Observe sanitation of tub, shower, multiple residents' whirlpool and care equipment, as necessary.

Identify all residents in the sample who are currently on antibiotic therapy and verify that these residents are reported on the facility's infection control logs/records to ensure that infections are being identified timely and that these residents are being adequately monitored for infection.

Review policies related to infection control if observation, record review, or staff interview indicate a problem with infection control.

Observe direct care staff routinely washing their hands according to facility written protocols.

Probes: §483.65(a)

- Are there unexplained and/or similar infections?
- For sampled residents at high risk of infection, what has staff done to reduce residents' risk of infection?
- Do surveillance data show a significant increase in the rate of infection from month to month? Over several months? How is this being addressed?
- What infection control policies does the facility use for persons with AIDS, TB, or hepatitis B? Do these policies conform with Occupational Safety and Health Administration's requirements for protecting employees and current accepted standards of practice recommended by Centers for Disease Control and Prevention (CDC)? Does the staff follow its own procedures?
- How does the facility define and dispose of its infectious waste?

F442

§483.65(b) Preventing Spread of Infection

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

Intent §483.65(b)

The intent of this regulation is to assure that the facility isolates residents appropriately to prevent the spread of infection. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

Interpretive Guidelines §483.65(b)

Procedures must be followed to prevent cross-contamination, including handwashing and/or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be available to staff. The facility should follow the CDC's "Guideline for Handwashing and Hospital Environmental Control," 1985 for handwashing.

The facility should isolate infected residents only to the degree needed to isolate the infecting organism. The method used should be the least restrictive possible, while maintaining the integrity of the process. For example, the HIV virus is present in blood and other body fluids. The facility should take universal or standard blood and body fluid precautions related to HIV contamination for the following:

- Blood;
- Semen;
- Vaginal secretions;
- Cerebrospinal fluid;
- Synovial fluid;
- Pleural fluid;
- Peritoneal fluid;
- Pericardial fluid;
- Amniotic fluid; and/or
- Fluids with visible blood.

Residents, visitors and employees should be protected from these fluids. Although the resident infected with HIV should not be isolated routinely, the resident should be isolated if he/she is in the communicable stages of an opportunistic infection, his/her body fluids cannot be contained or he/she has very poor hygiene and the likelihood of spillage is high.

NOTE: TB isolation rooms are not needed if the facility does not provide care to active TB patients/residents.

“Universal precautions” or “Standard blood and body fluid precautions” is an approach to infection control where all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Probes: §483.65(b)

- For isolated residents, does the facility need to segregate them to control the infectious agent?

- For residents who have been isolated appropriately, does staff use correct procedures consistently? For example, if isolation procedures require wearing gowns, do **all** staff put on and dispose of the gown in a way that lessens the spread of infection?

- How does the facility control the spread of infection by persons who visit infectious residents? Is there a written protocol?

- Do persons with a communicable disease or infected skin lesions provide care to residents?

- Have any residents developed a communicable disease as defined by State law while in the facility? If so, have appropriate barrier or isolation precautions been followed to control further spread of infection?

Procedures §483.65(b)(1)

Verify that all residents who require isolation as determined by the infection control program are isolated. Observe residents that have been isolated. Determine what level of isolation they are required to have. Evaluate isolation procedures utilized by staff members. Determine if the facility has isolated the resident in the least restrictive environment possible.

F443

§483.65(b)(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

Intent §483.65(b)(2)

The intent of this regulation is to prevent the spread of communicable diseases from employees to residents when the employee has a communicable disease or an infected skin lesion.

Skin lesions should be considered infected if they have purulent drainage, or are res, hot, indurated without purulent drainage.

Procedures §483.65(b)(2)

Determine if the facility prohibits employees with diseases communicable through direct contact or infected skin lesions from having direct contact with residents. To make this determination, observe residents' condition and treatments provided, interview facility staff, and review relevant facility policies and procedures for preventing the spread of infection.

F444

§483.65(b)(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

Intent §483.65(b)(3)

The intent of this regulation is to assure that staff use appropriate handwashing techniques to prevent the spread of infection from one resident to another

Interpretive Guidelines §483.65(b)(3)

Procedures must be followed to prevent cross-contamination, including handwashing or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be readily available to staff. The facility should follow the CDC's "Guideline for Handwashing and Hospital Environmental Control, 1985," for handwashing.

Procedures §483.65(b)(3)

Verify that the facility has policy that requires staff to wash their hands after each direct resident contact when indicated. Observe hand washing by staff after direct contact with residents.

It is important for the surveyor to begin a thorough investigation of the facility's infection control program when poor resident outcomes and poor practices are observed.

Probes: §483.65(b)(3)

- Does the facility have a written protocol describing handwashing practices and is it consistent with the latest published standards?

- Do staff follow the facility policy and protocol for handwashing?

F445

§483.65(c) Linens

Personnel must handle, store, process, and transport linens so as to prevent the spread of infection

Intent §483.65(c)

The intent of this regulation is to prevent the spread of infection through linens.

Interpretive Guidelines **§483.65(c)**

Soiled linens should be handled to contain and to minimize aerosolization and exposure to any waste products. Soiled linen storage areas should be well ventilated and maintained under a relative negative air pressure. The laundry should be designed to eliminate crossing of soiled and clean linen.

Probes: §483.65(c)

- Do staff handle linens on the resident care floors and in the laundry area to prevent the spread of infection?
- Do staff follow the facility's protocols for handling linens?
- Are linens processed, transported, stored, and handled properly?

F454

§483.70 Physical Environment

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.70(a) Life Safety From Fire

§483.70(a)(1) Except as otherwise provided in this section –

§483.70(a)(1)(i) the facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

§483.70(a)(1)(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

§483.70(a)(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

§483.70(a)(3) The provisions of the Life Safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

§483.70(a)(4) Beginning March 13, 2006, a long-term care facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

§483.70(a)(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to long-term care facilities.

§483.70(a)(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if -

§483.70(a)(6)(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

§483.70(a)(6)(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

§483.70(a)(6)(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

§483.70(a)(6)(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA temporary interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Battery March Partk, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the Federal Register to announce the changes.

§483.70(a)(7) A long-term care facility must:

§483.70(a)(7)(i) Install battery-operated smoke detectors in resident sleeping rooms and public areas by May 24, 2006.

§483.70(a)(7)(ii) Have a program for testing, maintenance, and battery replacement to insure the reliability of the smoke detectors.

§483.70(a)(7)(iii) Exception:

§483.70(a)(7)(iii)(A) The facility has a hard-wired AC smoke detection system in patient rooms and public areas that is installed, tested, and maintained in accordance with NFPA 72, National Fire Alarm Code, for hard-wired AC systems; or

§483.70(a)(7)(iii)(B) The facility has a sprinkler system throughout that is installed, tested, and maintained in accordance with NFPA 13, Automatic Sprinklers.

Interpretive Guidelines §483.70(a)

A waiver of specific provisions of the Life Safety Code is reviewed each time a facility is certified. The State fire authority will determine if the waiver continues to be justified, in that compliance with the requirement would result in an unreasonable hardship upon the facility and does not adversely affect the health and safety of residents or personnel. The State fire authority will forward its findings and recommendation as soon as possible to the State survey agency which will forward it to the CMS RO for a decision on granting a waiver.

Procedures §483.70(a)

The survey for safety from fire is normally conducted by the designated State fire authority. The State agency must establish a procedure for the State fire authority to notify them whether the facility is or is not in compliance with the requirement. If the survey team observes fire hazards or possible deficiencies in life safety from fire, they must notify the designated State fire authority or the RO.

F455

§483.70(b) Emergency Power

(1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

Interpretive Guidelines **§483.70(b)(1)**

"**Emergency electrical power system**" includes, at a minimum, battery-operated lighting for all entrances and exits, fire detection and alarm systems, and extinguishing systems.

An "**exit**" is defined as a means of egress which is lighted and has three components: an exit access (corridor leading to the exit), an exit (a door), and an exit discharge (door to the street or public way). We define an entrance as any door through which people enter the facility. Furthermore, when an entrance also serves as an exit, its components (exit access, exit, and exit discharge) must be lighted. A waiver of lighting required for both exits and entrances is not permitted.

Procedures §483.70(b)(1)

Review results of inspections by the designated State fire safety authority that the emergency power system has been tested periodically and is functioning in accordance with the Life Safety Code.

Check placement of lighting system to ensure proper coverage of the listed areas. Test all batteries to ensure they work.

Probes: §483.70(b)(1)

Is emergency electrical service adequate?

Additional guidance is available in the National Fire Protection Association's Life Safety Code 99 and 101 (NFPA 99 and NFPA 101), 12-5.1.3 which is surveyed in Tags K105 and K106 of the Life Safety code survey.

§483.70(b)(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises

Interpretive Guidelines §483.70(b)(2)

"**Life support systems**" is defined as one or more Electro-mechanical device(s) necessary to sustain life, without which the resident will have a likelihood of dying (e.g., ventilators suction machines if necessary to maintain an open airway). The determination of whether a piece of equipment is life support is a **medical determination** dependent upon the condition of the individual residents of the facility e.g. suction machine maybe required "life support equipment" in a facility, depending on the needs of its residents).

Procedures §483.70(b)(2)

If life support systems are used determine if there is a working emergency generator at the facility, A generator is not required if a facility does not use life support systems. Check that the emergency generator starts and transfers power under load conditions within 10 seconds after interruption of normal power. Where residents are on life support equipment, **do not test** transfer switches by shutting off the power unless there is an uninterruptible power supply available.

Probes §483.70(b)(2)

Is there a working generator if the facility is using life support systems?

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.70(c) Space and Equipment

The facility must--

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

Intent §483.70 (c)(1)

The intent of this regulation is to ensure that dining, health services, recreation, activities and programs areas are large enough to comfortably accommodate the needs of the residents who usually occupy this space.

Dining, health services, recreation, and program areas should be large enough to comfortably accommodate the persons who usually occupy that space, including the wheelchairs, walkers, and other ambulating aids used by the many residents who require more than standard movement spaces. "Sufficient space" means the resident can access the area, it is not functionally off-limits, and the resident's functioning is not restricted once access to the space is gained.

Program areas where resident groups engage in activities focused on manipulative skills and hand-eye coordination should have sufficient space for storage of their supplies and "works in progress."

Program areas where residents receive physical therapy should have sufficient space and equipment to meet the needs of the resident's therapy requirement.

Recreation/activities area means any area where residents can participate in those activities identified in their plan of care.

Procedures §483.70(c)(1)

In the use of space, consider if available space allows residents to pursue activities and receive health services and programs as identified in their care plan.

F456

§483.70(c)(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

Probes: §483.70(c)(2)

Is essential equipment (e.g., boiler room equipment, nursing unit/medication room refrigerators, kitchen refrigerator/freezer and laundry equipment) in safe operating condition?

Is equipment maintained according to manufacturers recommendations.

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.70(d) Resident Rooms

Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

F457

§483.70(d)(1) Bedrooms must--

§483.70(d)(1)(i) Accommodate no more than four residents;

Interpretive Guidelines **§483.70(d)(1)(i)**

See §483.70(d)(3) regarding variations.

Probes: §483.70(d)(1)(i)

Unless a variation has been applied for and approved under §483.70(d)(3), do the residents' bedrooms accommodate no more than four residents?

F458

§483.70(d)(1)(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

Interpretive Guidelines **§483.70(d)(1)(ii)**

See §483.70(d)(3) regarding variations.

The measurement of the square footage should be based upon the useable living space of the room. Therefore, the minimum square footage in resident rooms should be measured based upon the floor's measurements exclusive of toilets and bath areas, closets, lockers, wardrobes, alcoves, or vestibules. However, if the height of the alcoves or vestibules reasonably provides useful living area, then the corresponding floor area may be included in the calculation.

The space occupied by movable wardrobes should be excluded from the useable square footage in a room unless it is an item of the resident's own choice and it is in addition to the individual closet space in the resident's room. Non-permanent items of the resident's own choice should have no effect in the calculation of useable living space.

Protrusions such as columns, radiators, ventilation systems for heating and/or cooling should be ignored in computing the useable square footage of the room if the area involved is minimal (e.g., a baseboard heating or air conditioning system or ductwork that does not protrude more than 6 to 8 inches from the wall, or a column that is not more than 6 to 8 inches on each side) and does not have an adverse effect on the resident's health and safety or does not impede the ability of any resident in that room to attain his or her highest practicable well-being. If these protrusions are not minimal they would be deducted from useable square footage computed in determining compliance with this requirement.

The swing or arc of any door which opens directly into the resident's room should not be excluded from the calculations of useable square footage in a room.

Procedures §483.70(d)(1)(ii)

The facility layout may give square footage measurements. Carry a tape measure and take measurements if the room appears small.

Probes: §483.70(d)(1)(ii)

Unless a variation has been applied for and approved under §483.70(d)(3), are there at least 80 square feet per resident in multiple resident rooms and at least 100 square feet for single resident rooms?

F459

§483.70(d)(1)(iii) Have direct access to an exit corridor;

Interpretive Guidelines **§483.70(d)(1)(iii)**

There is no authority under current regulations to approve a variation to this requirement. Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 12-2.5.1, which is Tag K41 of the Life Safety Code Survey

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F460

§483.70(d)(1)(iv) Be designed or equipped to assure full visual privacy for each resident;

Interpretive Guidelines **§483.70(d)(1)(iv)**

"**Full visual privacy**" means that residents have a means of completely withdrawing from public view while occupying their bed (e.g., curtain, moveable screens, private room).

The guidelines do not intend to limit the provisions of privacy to solely one or more curtains, movable screens or a private room. Facility operators are free to use other means to provide full visual privacy, with those means varying according to the needs and requests of residents. However, the requirement explicitly states that bedrooms must "be designed or equipped to assure full visual privacy for each resident." For example, a resident with a bed by the window cannot be required to remain out of his or her room while his/her roommate is having a dressing change. Room design or equipment must provide privacy. Surveyors will assess whether the means the facility is using to assure full visual privacy meets this requirement without negatively affecting any other resident rights.

Procedures §483.70(d)(1)(iv)

There are no provisions for physician statements to be used as a basis for variation of the requirements for full visual privacy.

Probes: §483.70(d)(1)(iv)

Observe whether each resident selected for a comprehensive or focused review has a means to achieve full visual privacy.

> **§483.70(d)(1)(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;**

Interpretive Guidelines **§483.70(d)(1)(v)**

The term "**initially certified**" is defined as all newly certified nursing facilities (NFs) or SNFs as well as NFs and SNFs after March 31, 1992, which re-enter the Medicare or Medicaid programs, whether they voluntarily or involuntarily left the program.

It is not necessary for the bed to be accessible from both sides when the privacy curtain in pulled.

Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 31-1.4.1, 31-4.5, which is Tag K74 of the Life Safety Code Survey.

F461

> **§483.70(d)(1)(vi) Have at least one window to the outside; and**

Interpretive Guidelines **§483.70(d)(1)(vi)**

A facility with resident room windows, as defined by section 13-3.8.1 of the 1985 edition of the Life Safety Code, that open to an atrium in accordance with Life Safety Code 6-2.2.3.5 can meet this requirement for a window to the outside.

In addition to conforming with the Life Safety Code, this requirement was included to assist the resident's orientation to day and night, weather, and general awareness of space outside the facility. The facility is required to provide for a "safe, clean, comfortable and homelike environment" by deemphasizing the institutional character of the setting, to the extent possible. Windows are an important aspect in assuring the homelike environment of a facility.

Probes: §483.70(d)(1)(vi)

Is there at least one window to the outside?

§483.70(d)(1)(vii) Have a floor at or above grade level.

Interpretive Guidelines **§483.70(d)(1)(vii)**

"**At or above grade level**" is defined as a room in which the floor is at or above ground level.

Probes: §483.70(d)(1)(vii)

Are the bedrooms at or above ground level?

Additional guidance is available in the National Fire Protection Association's Life Safety Code 101 (NFPA 101), 12-2.5.1, 12-2.5.7, which is Tag K41 of the Life Safety Code survey.

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§483.70(d)(2) The facility must provide each resident with--

(i) A separate bed of proper size and height for the convenience of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

Probes: §483.70(d)(2)(i), (ii), and (iii)

Are mattresses clean and comfortable?

Is bedding appropriate to weather and climate?

§483.70(d)(2)(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

Interpretive Guidelines §483.70(d)(2)(iv)

"Functional furniture appropriate to the residents' needs" means that the furniture in each resident's room contributes to the resident attaining or maintaining his or her highest practicable level of independence and well-being. In general, furnishings include a place to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the resident while protecting it from casual access by others; a place to put personal effects such as pictures and a bedside clock, and furniture suitable for the comfort of the resident and visitors (e.g., a chair).

There may be instances in which individual residents determine that certain items are not necessary or will impede their ability to maintain or attain their highest practicable well-being (e.g., Both the resident and spouse use wheelchairs. They visit more easily without another chair in the room.) In this case, the resident's wishes should determine the furniture needs.

"Shelves accessible to the resident" means that the resident, if able, or a staff person at the direction of the resident, can get to their clothes whenever they choose.

Probes: §483.70(d)(2)(iv)

Functional furniture: Is there functional furniture, appropriate to residents' needs?

Closet space: Is there individual closet space with accessible clothes racks and shelves?

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§483.70(d)(3) CMS, or in the case of a nursing facility the survey agency, may permit variations in requirements specified in paragraphs (d)(1)(i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations--

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

Interpretive Guidelines **§483.70(d)(3)**

A variation must be in accordance with the special needs of the residents and must not adversely affect the health or safety of residents. Facility hardship is not part of the basis for granting a variation. Since the special needs of residents may change periodically, or

different residents may be transferred into a room that has been granted a variation, variations must be reviewed and considered for renewal whenever the facility is certified. If the needs of the residents within the room have not changed since the last annual inspection, the variance should continue if the facility so desires.

Interpretive Guidelines **§483.70(d)(1)(i):**

As residents are transferred or discharged from rooms with more than four residents, beds should be removed from the variance until the number of residents occupying the room does not exceed four.

F462

§483.70(e) Toilet Facilities

Each resident room must be equipped with or located near toilet facilities.

Interpretive Guidelines **§483.70(e)**

"**Toilet facilities**" is defined as a space that contains a lavatory and a toilet. If the resident's room is not equipped with an adjoining toilet facility, then "located near" means residents who are independent in the use of a toilet, including chairbound residents, can routinely use a toilet in the unit.

Probes: §483.70(e)

Are resident rooms equipped with or located near toilet and bathing facilities?

F463

§483.70(f) Resident Call System

The nurses' station must be equipped to receive resident calls through a communication system from--

(1) Resident rooms; and

(2) Toilet and bathing facilities.

Intent §483.70(f)

The intent of this requirement is that residents, when in their rooms and toilet and bathing areas, have a means of directly contacting staff at the nurse's station. This

communication may be through audible or visual signals and may include “wireless systems.”

Interpretive Guidelines **§483.70(f)**

This requirement is met only if all portions of the system are functioning (e.g., system is not turned off at the nurses’ station, the volume too low to be heard, the light above a room or rooms is not working).

Probes: §483.70(f)

Is there a functioning communication system from rooms, toilets, and bathing facilities?

F464

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.70(g) Dining and Resident Activities

The facility must provide one or more rooms designated for resident dining and activities.

These rooms must--

§483.70(g)(1) Be well lighted;

Interpretive Guidelines §483.70(g)(1)

“**Well lighted**” is defined as levels of illumination that are suitable to tasks performed by a resident.

Probes: §483.70(g)(1)

Are there adequate and comfortable lighting levels?

Are illumination levels appropriate to tasks with little glare?

Does lighting support maintenance of independent functioning and task performance?

§483.70(g)(2) Be well ventilated, with nonsmoking areas identified;

Interpretive Guidelines §483.70(g)(2)

“**Well ventilated**” is defined as good air circulation, avoidance of drafts at floor level, and adequate smoke exhaust removal.

"**Nonsmoking areas identified**" is defined as signs posted in accordance with State law regulating indoor smoking policy and facility policy.

Probes: §483.70(g)(2)

How well is the space ventilated?

Is there good air movement?

Are temperature, humidity, and odor levels all acceptable?

Are non-smoking areas identified?

§483.70(g)(3) Be adequately furnished; and

Interpretive Guidelines §483.70(g)(3)

An "**adequately furnished**" dining area accommodates different residents' physical and social needs. An adequately furnished organized activities area accommodates the specific activities offered by the facility.

Probes: §483.70(g)(3)

How adequate are furnishings?

Are furnishings structurally sound and functional (e.g., chairs of varying sizes to meet varying needs of residents, wheelchairs can fit under the dining room table)?

§483.70(g)(4) Have sufficient space to accommodate all activities.

Interpretive Guidelines §483.70(g)(4)

"**Sufficient space to accommodate all activities**" means that the space available is adaptable to a variety of uses and residents' needs.

Probes: §483.70(g)(4)

How sufficient is space in dining, health services, recreation and program areas to accommodate all activities?

Are spaces adaptable for all intended uses?

Is resident access to space limited?

Do residents and staff have maximum flexibility in arranging furniture to accommodate residents who use walkers, wheelchairs, and other mobility aids?

Is there resident crowding?

F465

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

§483.70(h) Other Environmental Conditions

The facility must provide a safe, functional, sanitary, and comfortable environment for residents, staff and the public.

F466

(Rev. 12, Issued: 10-14-05, Effective: 10-14-05, Implementation: 10-14-05)

The facility must--

§483.70(h)(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

Interpretive Guidelines **§483.70(h)(1)**

The facility should have a written protocol which defines the source of water, provisions for storing the water, both potable and non-potable, a method for distributing water, and a method for estimating the volume of water required.

Procedures §483.70(h)(1)

During the entrance conference, ask the administrator the facility's procedure to ensure water availability.

F467

§483.70(h)(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

Probes: §483.70(h)(2)

How well is the space ventilated?

Is there good air movement?

Are temperature, humidity, and odor levels all acceptable?

F468

§483.70(h)(3) Equip corridors with firmly secured handrails on each side; and

Interpretive Guidelines **§483.70(h)(3)**

"**Secured handrails**" means handrails that are firmly affixed to the wall.

Probes: §483.70(h)(3)

Are handrails secure?

F469

§483.70(h)(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

Interpretive Guidelines **§483.70(h)(4)**

An "**effective pest control progra**m" is defined as measures to eradicate and contain common household pests (e.g., roaches, ants, mosquitoes, flies, mice, and rats).

Procedures §483.70(h)(4)

As part of the overall review of the facility, look for signs of vermin. Evidence of pest infestation in a particular space is an indicator of noncompliance.

Probes: §483.70(h)(4)

Is area pest free?

F490

§483.75 Administration

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

Procedures §483.75

If there is a deficiency in §483.13, Resident behavior and facility practices; §483.15, Quality of life; or §483.25, Quality of care, which has the scope and/or severity to be defined as substandard quality of care, fully review for compliance all the tags within this section (§483.75).

F491

§483.75(a) Licensure

A facility must be licensed under applicable State and local law.

Interpretive Guidelines **§483.75(a)**

Applicable licenses, permits, and approvals must be available to you for inspection upon request.

Procedures §483.75(a)

If there are problems with care provided or supervised by licensed personnel, verify applicable licenses, permits and approvals.

F492

§483.75(b) Compliance With Federal, State, and Local Laws and Professional Standards

The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

Intent §483.75(b)

The intent of this regulation is to ensure that a facility is in compliance with Federal, State, and local laws, regulations, and codes relating to health, safety, and sanitation.

Interpretive Guidelines **§483.75(b)**

The State is responsible for making decisions about whether there are violations of State laws and regulations. Licenses, permits and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

§483.75(c) Relationship to Other HHS Regulations

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

Procedures §483.75(b)

If resident/family interviews reveal possible problems with admission contracts, review these contracts for violations of requirements at §§483.10 and 483.12. As appropriate, refer problems to an ombudsman or other agencies, e.g., Office for Civil Rights.

Some State or local laws are more stringent than the Federal requirement on the same issue. Failure of the facility to meet a Federal, State or local law may be cited at this tag only when the authority having jurisdiction has **both** made a determination of noncompliance and has taken a final adverse action as a result.

Accepted professional standards and principles include the various practice acts and scope of practice regulations in each State, and current, commonly accepted health standards established by national organizations, boards and councils.

If interviews with residents suggest that the facility may have required deposits from Medicare residents at admission, review the facility's admissions documents.

Procedures §483.75(c)

If during the survey you identify problems relating to one or more of these requirements, which are under the purview of another Federal agency, forward the information to the RO, who will forward it to the appropriate Federal agency.

F493

§483.75(d) Governing Body

(1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is--

(i) Licensed by the State where licensing is required; and

(ii) Responsible for the management of the facility.

Interpretive Guidelines **§483.75(d)(2)(1)**

The administrator must be licensed where required by the State.

§483.75(e) Required Training of Nursing Aides

(1) Definitions

"Licensed health professional" means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

"Nurse aide" means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay.

Interpretive Guidelines **§483.75(e)**

Volunteers are not nurse aides and do not come under the nurse aide training provisions of these requirements. Unpaid students in nursing education programs who use facilities as clinical practice sites under the direct supervision of an RN are considered volunteers.

Private duty nurse aides who are not employed or utilized by the facility on a contract, per diem, leased or other basis, do not come under the nurse aide training provisions

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F494

§483.75(e)(2) General rule

A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§483.151-483.154 of this part; or

(B) That individual has been deemed or determined competent as provided in §483.150(a) and (b).

§483.75(e)(3) Non-permanent employees

A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2)(i) and (ii) of this section.

(See tag F495 for guidelines, probes, and procedures for §483.75(e)(2-4))

F495

(4) Competency

A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual--

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in §483.150(a) and (b).

Interpretive Guidelines **§483.75(e)(2 - 4)**

Facilities may use, as nurse aides, any individuals who have successfully completed either a nurse aide training and competency evaluation program or a competency evaluation program. However, if an individual has not completed a program at the time of employment, a facility may **only** use that individual as a nurse aide if the individual is in a nurse aide training and competency evaluation program (**not a competency evaluation program alone**) and that individual is a permanent employee in his or her first four months of employment in the facility.

Facilities may not use non-permanent employees as nurse aides unless they have either completed a training and competency evaluation program, or a competency evaluation program.

Probes: §483.75(e)(2 - 4)

During an extended or partial extended survey:

- Have all nurse aides completed a nurse aide training and competency evaluation program or a competency evaluation program? If not, are those nurse aides permanent employees enrolled in a training and competency evaluation program who have worked in the facility for 4 months or less?

- Ask nurse aides where they received their training, how long the training was and how long they have worked in the facility as a nurse aide.

During all surveys:

- If incorrect nurse aide work performance is observed during the survey, check to see if the nurse aide received training and licensed nurse supervision to correctly carry out the task.

A "**permanent employee**" is defined as any employee you expect to continue working on an ongoing basis.

Procedures §483.75(e)(2-4)

Review competency requirements for nurse aides if you identify potential deficient care practices in quality of care, resident rights, resident behavior and facility practice or quality of life which may be related to nurse aide competency. Is there evidence that the nurse aide has successfully completed the competency evaluation program, or has the individual been grandfathered in by the State?

If you identify deficient care practices by nurse aides who do not have evidence of having successfully completed a competency evaluation program, determine:

- If the aide is currently receiving training an a State approved Nurse Aide Training Program;

- If the aide is under the supervision of a licensed nurse; and

- If the aide has been trained and determined to be proficient for the tasks to which he or she is assigned. See §483.152 for specific training that the aide is to receive. This training includes:

- At least 16 hours of training in the following subjects **before** any direct contact with the resident:

    - Communication and interpersonal skills;
    - Infection control;
    - Safety and emergency procedures, including the Heimlich Maneuver;
    - Promoting resident's independence; and
    - Respecting resident's rights.
- Basic nursing skills;
- Personal care skills;
- Mental health and social services of residents;
- Care of cognitively impaired residents;
- Basic restorative services; and
- Resident's rights.

F496

§483.75(e)(5) Registry verification

Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless--

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii)The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

§483.75(e)(6) Multi-State registry verification

Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual.

§483.75(e)(7) Required retraining

If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

Interpretive Guidelines **§483.75(e)(7)**

If an individual does not wish to be retrained, the individual must establish that he or she performed nursing or nursing-related services for monetary compensation for at least one documented day (i.e., 8 consecutive hours) during the previous 24 months. The State is required to remove the individual's name from the registry if the services are not provided for monetary compensation during the 24-month period. Thus, in the absence of any evidence to the contrary, you can assume that the retraining requirement does not apply to an individual whose name appears on the registry.

F497

§483.75(e)(8) Regular In-Service Education

The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must--

(i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;

(ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and

(iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

Interpretive Guidelines **§483.75(e)(8)**

The adequacy of the in-service education program is measured not only by documentation of hours of completed in-service education, but also by demonstrated competencies of nurse aide staff in consistently applying the interventions necessary to meet residents' needs.

If there has been deficient care practices identified during Phase 1 of the survey, review as appropriate training received by nurse aides in that corresponding subject area. For example, if the facility has deficiencies in infection control, review the infection control unit in the facility's inservice nurse aide training program.

Each nurse aide must have no less than twelve hours of in-service education per year. Calculate the date by which a nurse aide must receive annual in-service education by the employment date rather than the calendar year.

Probes: §483.75(e)(8)

During an extended or partial extended survey, or during any survey in which nurse aide performance is questioned. (See §483.75(f).)

- Does the facility review the performance of its nurse aides?
- How has in-service education addressed areas of weakness identified in performance reviews, special resident needs, and needs of residents with cognitive impairments?
- How has in-service education addressed quality of care problems including those of special care needs and resident rights?

F498

§483.75(f) Proficiency of Nurse Aides

The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

Interpretive Guidelines **§483.75(f)**

"Competency in skills and techniques necessary to care for residents' needs" includes competencies in areas such as communication and personal skills, basic nursing skills, personal care skills, mental health and social service needs, basic restorative services and resident rights.

Procedures §483.75(f)

During the Resident Review, observe nurse aides.

Probes: §483.75(f)

Do nurse aides show competency in skills necessary to:

Maintain or improve the resident's independent functioning, e.g.:

Performing range of motion exercises,

Assisting the resident to transfer from the bed to a wheelchair,

Reinforcing appropriate developmental behavior for persons with MR, or

Psychotherapeutic behavior for persons with MI;

Observe and describe resident behavior and status and report to charge nurse;

Follow instructions; and

Carry out appropriate infection control precautions and safety procedures.

F499

§483.75(g) Staff Qualifications

(1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

Procedures §483.75(g)

If there is reason to doubt the qualifications of temporary agency personnel working in the facility, check with the appropriate registry or professional licensing board.

F500

§483.75(h) Use of Outside Resources

(1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or an agreement described in paragraph (h)(2) of this section.

(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for--

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

F501

(Rev. 15, Issued: 11-28-05; Effective/Implementation: 11-25-05)

§483.75(i) Medical Director

(1) The facility must designate a physician to serve as medical director.

(2) The medical director is responsible for –

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

INTENT:

The intent of this requirement is that:

- *The facility has a licensed physician who serves as the medical director to coordinate medical care in the facility and provide clinical guidance and oversight regarding the implementation of resident care policies;*
- *The medical director collaborates with the facility leadership, staff, and other practitioners and consultants to help develop, implement and evaluate resident care policies and procedures that reflect current standards of practice; and*

- *The medical director helps the facility identify, evaluate, and address/resolve medical and clinical concerns and issues that:*
    - *Affect resident care, medical care or quality of life; or*
    - *Are related to the provision of services by physicians and other licensed health care practitioners.*

NOTE: *While many medical directors also serve as attending physicians, the roles and functions of a medical director are separate from those of an attending physician. The medical director's role involves the coordination of facility-wide medical care while the attending physician's role involves primary responsibility for the medical care of individual residents.*[1]

DEFINITIONS

Definitions are provided to clarify terms related to the provision of medical director services.

- *"Attending Physician" refers to the physician who has the primary responsibility for the medical care of a resident.*
- *"Current standards of practice" refers to approaches to care, procedures, techniques, treatments, etc., that are based on research and/or expert consensus and that are contained in current manuals, textbooks, or publications, or that are accepted, adopted or promulgated by recognized professional organizations or national accrediting bodies.*
- *"Medical care" refers to the practice of medicine as consistent with State laws and regulations.*
- *"Medical director" refers to a physician who oversees the medical care and other designated care and services in a health care organization or facility. Under these regulations, the medical director is responsible for coordinating medical care and helping to develop, implement and evaluate resident care policies and procedures that reflect current standards of practice.*
- *"Resident care policies and procedures" – Resident care policies are the facility's overall goals, directives, and governing Statements that direct the delivery of care and services to residents. Resident care procedures describe the processes by which the facility provides care to residents that is consistent with current standards of practice and facility policies.*

OVERVIEW

The medical director has an important leadership role in actively helping long term care facilities provide quality care. The regulation requires each facility to have a medical director who is responsible for the implementation of resident care policies and the coordination of medical care. These two roles provide the basis for the functions and tasks discussed in this guidance. The medical director's roles and functions require the physician serving in that capacity to be knowledgeable about current standards of practice in caring for long term care residents, and about how to coordinate and oversee related practitioners. As a clinician, the medical director plays a pivotal role in providing clinical leadership regarding application of current standards of practice for resident care and new or proposed treatments, practices, and approaches to care. The medical director's input promotes the attainment of optimal resident outcomes which may also be influenced by many other factors, such as resident characteristics and preferences, individual attending physician actions, and facility support. The 2001 Institute of Medicine report, "Improving the Quality of Long Term Care," urged facilities to give medical directors greater authority for medical services and care. The report states, "nursing homes should develop structures and processes that enable and require a more focused and dedicated medical staff responsible for patient care."[2]

The medical director is in a position, because of his/her roles and functions, to provide input to surveyors on physician issues, individual resident's clinical issues, and the facility's clinical practices. The text "Medical Direction in Long Term Care"[3] asserts that:

> *"The Medical Director has an important role in helping the facility deal with regulatory and survey issues…the medical director can help ensure that appropriate systems exist to facilitate good medical care, establish and apply good monitoring systems and effective documentation and follow up of findings, and help improve physician compliance with regulations, including required visits. During and after the survey process, the medical director can clarify for the surveyors clinical questions or information about the care of specific residents, request surveyor clarification of citations on clinical care, attend the exit conference to demonstrate physician interest and help in understanding the nature and scope of the facility's deficiencies, and help the facility draft corrective actions."*

Nationally accepted statements concerning the roles, responsibilities and functions of a medical director can be found at the American Medical Directors Association Web site at www.amda.com.

NOTE: *References to non-CMS sources or sites on the Internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.*

MEDICAL DIRECTION

The facility is responsible for designating a medical director, who is currently licensed as a physician in the State(s) in which the facility(ies) he/she serves is (are) located. The facility may provide for this service through any of several methods, such as direct employment, contractual arrangements, or another type of agreement. Whatever the arrangement or method employed, the facility and the medical director should identify the expectations for how the medical director will work with the facility to effectively implement resident care policies and coordinate medical care.

> ***NOTE:*** *While the roles of medical directors who work for multi-facility organizations with corporate or regional offices may vary for policy development, the medical directors, nonetheless, should be involved in facility level issues such as application of those policies to the care of the facility's residents.*

Implementation of Resident Care Policies and Procedures

The facility is responsible for obtaining the medical director's ongoing guidance in the development and implementation of resident care policies, including review and revision of existing policies. The medical director's role involves collaborating with the facility regarding the policies and protocols that guide clinical decision making (for example, interpretation of clinical information, treatment selection, and monitoring of risks and benefits of interventions) by any of the following: facility staff; licensed physicians; nurse practitioners; physician assistants; clinical nurse specialists; licensed, certified, or registered health care professionals such as nurses, therapists, dieticians, pharmacists, social workers, and other health care workers.

The medical director has a key role in helping the facility to incorporate current standards of practice into resident care policies and procedures/guidelines to help assure that they address the needs of the residents. Although regulations do not require the medical director to sign the policies or procedures, the facility should be able to show that its development, review, and approval of resident care policies included the medical director's input.

This requirement does not imply that the medical director must carry out the policies and procedures or supervise staff performance directly, but rather must guide, approve, and help oversee the implementation of the policies and procedures. Examples of resident care policies include, but are not limited to:

- *Admission policies and care practices that address the types of residents that may be admitted and retained based upon the ability of the facility to provide the services and care to meet their needs;*

- *The integrated delivery of care and services, such as medical, nursing, pharmacy, social, rehabilitative and dietary services, which includes clinical assessments,*

analysis of assessment findings, care planning including preventive care, care plan monitoring and modification, infection control (including isolation or special care), transfers to other settings, and discharge planning;

- *The use and availability of ancillary services such as x-ray and laboratory;*
- *The availability, qualifications, and clinical functions of staff necessary to meet resident care needs;*
- *Resident formulation and facility implementation of advance directives (in accordance with State law) and end-of-life care;*
- *Provisions that enhance resident decision making, including choice regarding medical care options;*
- *Mechanisms for communicating and resolving issues related to medical care;*
- *Conduct of research, if allowed, within the facility;*
- *Provision of physician services, including (but not limited to):*
    - *Availability of physician services 24 hours a day in case of emergency;*
    - *Review of the resident's overall condition and program of care at each visit, including medications and treatments;*
    - *Documentation of progress notes with signatures;*
    - *Frequency of visits, as required;*
    - *Signing and dating all orders, such as medications, admission orders, and re-admission orders; and*
    - *Review of and response to consultant recommendations.*
- *Systems to ensure that other licensed practitioners (e.g., nurse practitioners) who may perform physician-delegated tasks act within the regulatory requirements and within the scope of practice as defined by State law; and*
- *Procedures and general clinical guidance for facility staff regarding when to contact a practitioner, including information that should be gathered prior to contacting the practitioner regarding a clinical issue/question or change in condition.*

Coordination of Medical Care

The medical director is responsible for the coordination of medical care in the facility. The coordination of medical care means that the medical director helps the facility obtain and maintain timely and appropriate medical care that supports the healthcare needs of the residents, is consistent with current standards of practice, and helps the facility meet its regulatory requirements. In light of the extensive medical needs of the long term care population, physicians have an important role both in providing direct care and in influencing care quality. The medical director helps coordinate and evaluate the medical care within the facility by reviewing and evaluating aspects of physician care and practitioner services, and helping the facility identify, evaluate, and address health care issues related to the quality of care and quality of life of residents. "A medical director should establish a framework for physician participation, and physicians should believe that they are accountable for their actions and their care."[4]

The medical director addresses issues related to the coordination of medical care identified through the facility's quality assessment and assurance committee and quality assurance program, and other activities related to the coordination of care. This includes, but is not limited to, helping the facility:

- *Ensure that residents have primary attending and backup physician coverage;*
- *Ensure that physician and health care practitioner services are available to help residents attain and maintain their highest practicable level of functioning, consistent with regulatory requirements;*
- *Develop a process to review basic physician and health care practitioner credentials (e.g., licensure and pertinent background);*
- *Address and resolve concerns and issues between the physicians, health care practitioners and facility staff; and*
- *Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings.*

Throughout this guidance, a response from a physician implies appropriate communication, review, and resident management, but does not imply that the physician must necessarily order tests or treatments recommended or requested by the staff, unless the physician agrees that those are medically valid and indicated.

In addition, other areas for medical director input to the facility may include:

- *Facilitating feedback to physicians and other health care practitioners about their performance and practices;*
- *Reviewing individual resident cases as requested or as indicated;*
- *Reviewing consultant recommendations;*

- *Discussing and intervening (as appropriate) with a health care practitioner about medical care that is inconsistent with applicable current standards of care;*

- *Assuring that a system exists to monitor the performance of the health care practitioners;*

- *Guiding physicians regarding specific performance expectations;*

- *Identifying facility or practitioner educational and informational needs;*

- *Providing information to the facility practitioners from sources such as nationally recognized medical care societies and organizations where current clinical information can be obtained; and*

- *Helping educate and provide information to staff, practitioners, residents, families and others.*

NOTE: *This does not imply that the medical director must personally present educational programs.*

REFERENCES

[1] *Pattee JJ, Otteson OJ. (1991). Medical direction in the nursing home (p.5). Minneapolis, MN: Northridge Press.*

[2] *Institute of Medicine (2001). Improving The Quality Of Long-Term Care (pp. 201). Washington, DC: National Academy Press.*

[3] *Levenson, S. A. (1993). Medical Direction In Long-Term Care. A Guidebook For The Future (2nd ed., pp. 135). Durham, NC: Carolina Academic Press.*

[4] *Levenson, SA. Medical Director and Attending Physicians Policy and Procedure Manual for Long-term Care. Dayton, Ohio: MedPass. 2005.*

INVESTIGATIVE PROTOCOL

MEDICAL DIRECTOR

Objective

- *To determine whether the facility has designated a licensed physician to serve as medical director; and*

- *To determine whether the medical director, in collaboration with the facility, coordinates medical care and the implementation of resident care policies.*

Use

Use this protocol for all initial and extended surveys or, as indicated, during any other type of survey. Use this protocol if the survey team has identified:

- *That the facility does not have a licensed physician serving as medical director; and/or*

- *That the facility has designated a licensed physician to serve as medical director; however, concerns or noncompliance identified indicate that:*

    - *The facility has failed to involve the medical director in his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies; and/or*

    - *The medical director may not have performed his/her roles and functions related to coordination of medical care and/or the implementation of resident care policies.*

Procedures

The investigation involves interviews, review of pertinent policies and procedures, and may involve additional review of resident care.

Provision of a Medical Director

Determine whether the medical director is available during the survey to respond to surveyor questions about resident care policies, medical care, and physician issues.

Interview the facility leadership (e.g., Administrator, Director of Nursing [DON], others as appropriate) about how it has identified and reviewed with the medical director his/her roles and functions as a medical director, including those related to coordination of medical care and the facility's clinical practices and care.

Interview the medical director about his/her understanding and performance of the medical director roles and functions, and about the extent of facility support for performing his/her roles and functions.

If the survey team has identified that the facility lacks a medical director, collect information from the facility administrator to:

- *Determine the duration and possible reasons for this problem; and*
- *Identify what the facility has been doing to try to retain a medical director.*

Facility/Medical Director Responsibility for Resident Care Policies

After identifying actual or potential noncompliance with the provision of resident care or medical care:

- *Review related policies/procedures;*
- *Interview facility leadership (e.g., Administrator, DON) to determine how or if they involved the medical director in developing, reviewing, and implementing policies and procedures regarding clinical care of residents (especially where these involve medical and clinical issues; for example, management of causes of delirium, falling, and weight loss) to ensure that they are clinically valid and consistent with current standards of care;*
- *Interview the medical director regarding his/her input into:*
    - *Scope of services the facility has chosen to provide;*
    - *The facility's capacity to care for its residents with complex or special care needs, such as dialysis, hospice or end-of-life care, respiratory support with ventilators, intravenous medications/fluids, dementia and/or related conditions, or problematic behaviors or complex mood disorders;*
    - *The following areas of concern:*
        - *Appropriateness of care as it relates to clinical services (for example, following orders correctly, communicating important information to physicians in a timely fashion, etc.);*
        - *Processes for accurate assessment, care planning, treatment implementation, and monitoring of care and services to meet resident needs; and*
        - *The review and update of policies and procedures to reflect current standards of practice for resident care (e.g., pressure ulcer*

prevention and treatment and management of incontinence, pain, fall risk, restraint reduction, and hydration risks) and quality of life.

Coordination of Medical Care/Physician Leadership

If the survey team has identified issues or concerns related to the provision of medical care:

- *Interview appropriate facility staff and management as well as the medical director to determine what happens when a physician (or other healthcare practitioner) has a pattern of inadequate or inappropriate performance or acts contrary to established rules and procedures of the facility; for example, repeatedly late in making visits, fails to take time to discuss resident problems with staff, does not adequately address or document key medical issues when making resident visits, etc;*

- *If concerns are identified for any of the following physician services, determine how the facility obtained the medical director's input in evaluating and coordinating the provision of medical care:*

    - *Assuring that provisions are in place for physician services 24 hours a day and in case of emergency (§483.40(b));*

    - *Assuring that physicians visit residents, provide medical orders, and review a resident's medical condition as required (§483.40(b)&(c));*

    - *Assuring that other practitioners who may perform physician delegated tasks, act within the regulatory requirements and within their scope of practice as defined by State law (§483.40(e)&(f));*

    - *Clarifying that staff know when to contact the medical director; for example, if an attending or covering physician fails to respond to a facility's request to evaluate or discuss a resident with an acute change of condition;*

    - *Clarifying how the medical director is expected to respond when informed that the staff is having difficulty obtaining needed consultations or other medical services; or*

    - *Addressing other concerns between the attending physician and the facility, such as issues identified on medication regimen review, or the problematic use of restraints.*

In addition, determine how the facility and medical director assure that physicians are informed of expectations and facility policies, and how the medical director reviews the

medical care and provides guidance and feedback regarding practitioner performance, as necessary.

Regardless of whether the medical director is the physician member of the quality assurance committee, determine how the facility and medical director exchange information regarding the quality of resident care, medical care, and how the facility disseminates information from the committee to the medical director and attending physicians regarding clinical aspects of care and quality such as infection control, medication and pharmacy issues, incidents and accidents, and other emergency medical issues (§483.75(o)).

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F501)

This requirement has 3 aspects: Having a physician to serve as medical director, implementing resident care policies, and coordinating medical care. As with all other long term care requirements, the citation of a deficiency at F501, Medical Director, is a deficiency regarding the facility's failure to comply with this regulation. The facility is responsible for designating a physician to serve as medical director and is responsible for oversight of, and collaboration with, the medical director to implement resident care policies and to coordinate medical care.

Criteria for Compliance

The facility is in compliance if:

- *They have designated a medical director who is a licensed physician;*
- *The physician is performing the functions of the position;*
- *The medical director provides input and helps the facility develop, review and implement resident care policies, based on current clinical standards; and*
- *The medical director assists the facility in the coordination of medical care and services in the facility.*

If not, cite F501.

Noncompliance for F501

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. The survey team must identify whether the noncompliance cited at other tags relates to the medical director's roles and responsibilities. In order to cite at F501 when noncompliance has been identified at another tag, the team must demonstrate an association between the identified deficiency

*and a failure of medical direction. Noncompliance for F501 may include (but is not limited to) the **facility's** failure to:*

- *Designate a licensed physician to serve as medical director; or*
- *Obtain the medical director's input for timely and ongoing development, review and approval of resident care policies;*

*Noncompliance for F501 may also include (but is not limited to) the **facility** and **medical director** failure to:*

- *Coordinate and evaluate the medical care within the facility, including the review and evaluation of aspects of physician care and practitioner services;*
- *Identify, evaluate, and address health care issues related to the quality of care and quality of life of residents;*
- *Assure that residents have primary attending and backup physician coverage;*
- *Assure that physician and health care practitioner services reflect current standards of care and are consistent with regulatory requirements;*
- *Address and resolve concerns and issues between the physicians, health care practitioners and facility staff;*
- *Resolve issues related to continuity of care and transfer of medical information between the facility and other care settings;*
- *Review individual resident cases, as warranted, to evaluate quality of care or quality of life concerns or other problematic situations and take appropriate steps to resolve the situation as necessary and as requested;*
- *Review, consider and/or act upon consultant recommendations that affect the facility's resident care policies and procedures or the care of an individual resident, when appropriate;*
- *Discuss and intervene (as appropriate) with the health care practitioner about medical care that is inconsistent with applicable current standards of care; or*
- *Assure that a system exists to monitor the performance and practices of the health care practitioners.*

This does not presume that a facility's noncompliance with the requirements for the delivery of care necessarily reflects on the performance of the medical director.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F501 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of resident care policies and/or medical care.

Deficient practices related to actual or potential harm/negative outcome for F501 may include but are not limited to:

- *Lack of medical director involvement in the development, review and/or implementation of resident care policies that address the types of residents receiving care and services, such as a resident with end-stage renal disease, pressure ulcers, dementia, or that address practices such as restraint use;*

- *Lack of medical director involvement in coordinating medical care regarding problems with physician coverage or availability; or*

- *Lack of medical director response when the facility requests intervention with an attending physician regarding medical care of a resident.*

2. Degree of harm (actual or potential) related to the noncompliance.

Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

- *If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and*

- *If harm has not yet occurred, determine the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.*

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for F501. First, the team must rule out whether Severity Level 4, Immediate Jeopardy, to a resident's health or safety exists by evaluating the deficient

practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- *Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and*

- *Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.*

NOTE: *The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the immediate jeopardy.*

In order to cite immediate jeopardy at this tag, the surveyor must be able to identify the relationship between noncompliance cited as immediate jeopardy at other regulatory tags, and the failure of the medical care and systems associated with the roles and responsibilities of the medical director. ***In order to select severity level 4 at F501, both of the following must be present:***

1. Findings of noncompliance at Severity Level 4 at another tag:

- *Must have allowed, caused or resulted in, or is likely to allow, cause or result in serious injury, harm, impairment or death and require immediate correction. The findings of noncompliance associated with immediate jeopardy are written at tags that also show evidence of process failures with respect to the medical director's responsibilities; and*

2. There is no medical director or the facility failed to involve the medical director in resident care policies or resident care or medical care as appropriate, or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:

- *To get involved or to intercede with the attending physician in order to facilitate and/or coordinate medical care; and/or*

- *To provide guidance and/or oversight for relevant resident care policies.*

NOTE: *If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.*

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being.

In order to cite actual harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and failure of medical care or processes and practices associated with roles and responsibilities of the medical director, such as:

1. *Findings of noncompliance at Severity Level 3 at another tag must have caused actual harm:*

    - *The findings of noncompliance associated with actual harm are written at tags that show evidence of process failures with respect to the medical director's responsibilities; and*

2. *There is no medical director or the facility failed to involve the medical director in resident care policies or resident care or medical care as appropriate or the medical director had knowledge of a problem with care, or physician services, or lack of resident care policies and practices that meet current standards of practice and failed:*

    - *To get involved or intercede with the attending physician in order to facilitate and/or coordinate medical care (medical care and systems associated with roles and responsibilities of the medical director show evidence of breakdown); or*

    - *To provide guidance and/or oversight for resident care policies.*

NOTE: *If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.*

Severity Level 2 Considerations: No Actual Harm with Potential for More than Minimal Harm that is not Immediate Jeopardy

In order to cite no actual harm with potential for more than minimal harm at this tag, the surveyor must be able to identify a relationship between noncompliance cited at other regulatory tags and the failure of medical care, processes and practices associated with roles and responsibilities of the medical director, such as:

1. *Findings of noncompliance at Severity Level 2 at another tag:*

    - *Must have caused no actual harm with potential for more than minimal harm (Level 2). Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided; and*

2. *There is no medical director or the facility failed to involve the medical director in resident care policies or resident care as appropriate or the medical director had knowledge of an issue with care or physician services, and failed:*

    - *To get involved with or intercede with attending physicians in order to facilitate and/or coordinate medical care; or*

    - *To provide guidance and/or oversight for resident care policies.*

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

In order to cite no actual harm with potential for minimal harm at this tag, the survey team must have identified that:

- *There is no medical director; and*

    - *There are no negative resident outcomes that are the result of deficient practice; and*

    - *Medical care and systems associated with roles and responsibilities of the medical director are in place; and*

    - *There has been a relatively short duration of time without a medical director; and*

    - *The facility is actively seeking a new medical director.*

F502

§483.75(j) Laboratory Services

(1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

Intent §483.75(j)(1)

The intent of this regulation is to assure that laboratory services are accurate and timely so that the utility of laboratory testing for diagnosis, treatment, prevention or assessment is maximized. The facility is responsible for quality and timely laboratory services whether or not services are provided by the facility or an outside agency.

Interpretive Guidelines **§483.75(j)(1)**

A "**laboratory service or test**" is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

Services provided must be both accurate and timely. Timely means that laboratory tests are completed and results are provided to the facility (or resident's physician) within timeframes normal for appropriate intervention. All laboratories providing services for facility residents must meet applicable requirements of 42 CFR Part 493. The purpose of this requirement is to assist in assuring quality of laboratory services.

Procedures §483.75(j)(1)

Verify that laboratory services are provided to meet the needs of the residents. If a problem in quality of care leads you to suspect a problem in laboratory services, timeliness or quality, refer to the interpretive guidelines for laboratory testing found in Appendix C.

Probes: §483.75(j)(1)

Are problems attributable to:

- An inability to order laboratory tests in a timely manner, including delays in transporting the resident to and from the source of service, if needed?
- A delay of treatment due to untimely receipt of lab results?
- A large lag time between an order for a test and the recording of the results that may have resulted in poor care?

F503

§483.75(j)(1)(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

§483.75(j)(1)(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in Part 493 of this chapter.

§483.75(j)(1)(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

§483.75(j)(1)(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

Intent §483.75(j)(1)(i) - (iv)

The intent of this regulation is to assure that laboratory services, blood bank and transfusion services are obtained from an entity that meets the requirements of 42 CFR Part 493 in order to provide a standard of quality for laboratory and transfusion services. If the long term care facility does not provide laboratory services on site, there must be an agreement to obtain these services from a laboratory that meets the same requirements.

Interpretive Guidelines **§483.75(j)(1)(i) - (iv)**

If a facility provides its own laboratory services, the provisions of 42 CFR Part 493 apply.

The facility must have a Clinical Laboratory Improvement Amendments (CLIA) certificate appropriate for the level of testing performed. An application for a certificate of waiver may be made if the facility performs only those tests categorized as waived under CLIA.

Direct questions concerning the application of these requirements to your State laboratory consultant or the CMS RO.

Procedures §483.75(j)(1)(i) - (iv)

Determine if all laboratory services provided for the facility are provided by a laboratory that meets the requirements of 42 CFR Part 493.

The surveyor should determine if the facility has an arrangement in writing to assume responsibility for (a) obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and (b) the timeliness of the services.

Probes: §483.75(j)(1)(i) - (iv)

Are problems attributable to:

- Lack of an arrangement to provide or obtain clinical laboratory services from a source that meets the applicable conditions for coverage of the services?
- Delays in interpreting the results of laboratory tests?

F504

§483.75(j)(2) The facility must--

§483.75(j)(2)(i) Provide or obtain laboratory services only when ordered by the attending physician;

Intent §483.75(j)(2)(i)

The intent of this regulation is to assure that only medically necessary laboratory services are ordered.

Procedures §483.75(j)(2)(i)

Verify that all laboratory services received were ordered by the attending physician.

F505

§483.75(j)(2)(ii) Promptly notify the attending physician of the findings;

Intent §483.75(j)(2)(ii)

The intent of this regulation is to assure that the physician is notified of all lab results so that prompt, appropriate action may be taken if indicated for the resident's care.

Procedures §483.75(j)(2)(ii)

If you have reason to believe that a physician(s) may not have been notified of laboratory results in a timely manner, determine if the facility has a policy/procedure for routine notification of physician and if the procedure is implemented.

Probes: §483.75(j)(2)(ii)

- Are any problems identified as relating to lack of prompt notification of the attending physician, contributing to delays in changing the course of treatment or care plan?

F506

§483.75(j)(2)(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

Intent §483.75(j)(2)(iii)

The intent of this regulation is to assure that residents are able to get to and receive necessary laboratory testing when the testing is conducted outside of the facility.

Probes: §483.75(j)(2)(iii)

- Does the resident ever have to cancel lab service appointments due to difficulties with transportation?

F507

§483.75(j)(2)(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

Intent §483.75(j)(2)(iv)

The intent of this regulation is to assure that the laboratory performing the tests is Medicare approved, and that test results are accurate and are available for clinical management.

F508

§483.75(k) Radiology and Other Diagnostic Services

(1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

Intent §483.75(k)(1)

The intent of this regulation is to assure that the resident receives quality radiologic and diagnostic services in a timely manner to meet his/her needs for diagnosis, treatment, and prevention.

Probes: §483.75(k)(1)

If problems are identified in radiology or other diagnostic services, are problems attributable to:

- An inability to order radiological and diagnostic services in a timely manner, including delays in transporting the resident for these services?
- Delays in interpreting the results of x-rays and other tests?
- Lack of prompt notification, in writing, of test results to the attending physician, contributing to delays in changing care plans or the course of treatment?

F509

§483.75(k)(1)(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in §482.26 of this subchapter.

§483.75(k)(1)(ii) If the facility does not provide it's own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

F510

§483.75(k)(2) The Facility must---

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

F511

§483.75(k)(2)(ii) Promptly notify the attending physician of the findings;

F512

§483.75(k)(2)(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

F513

§483.75(k)(2)(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

F514

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.75(l) Clinical Records

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines **§483.75(l)(1)**

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress

information to work with the resident and less with how often that information is gathered.

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up:

- There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility.
- The computer has built-in safeguards to minimize the possibility of fraud.
- Each person responsible for an attestation has an individualized identifier.
- The date and time is recorded from the computer's internal clock at the time of entry
- An entry is not to be changed after it has been recorded.
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

Procedures §483.75(l)(1)

In reviewing sampled residents' clinical records:

- Is there enough record documentation for staff to conduct care programs and to revise the program, as necessary, to respond to the changing status of the resident as a result of interventions?
- How is the clinical record used in managing the resident's progress in maintaining or improving functional abilities and mental and psychosocial status?

§483.75(l)(5) the clinical record must contain--

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) the plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) progress notes.

F515

§483.75(l)(2) Clinical records must be retained for--

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or,

(iii) For a minor, three years after a resident reaches legal age under State law.

F516

(Rev. 5, Issued: 11-19-04, Effective: 11-19-04, Implementation: 11-19-04)

§483.20(f)(5)

(5) Resident-identifiable information.

(i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

Interpretive Guidelines §483.20(f)(5):

Automated RAI data are part of a resident's clinical record and as such are protected from improper disclosure by facilities under current law. Facilities are required by §§1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act and 42 CFR Part 483.75(l)(3) and (l)(4), to keep confidential all information contained in the resident's record and to maintain safeguards against the unauthorized use of a resident's clinical record information, regardless of the storage method of the records.

§483.75(l) (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

Intent §483.75(l)(3)

To maintain the safety and confidentiality of the resident's record.

Procedures §483.75(l)(3)

Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.

Probes: §483.75(1)(3)

- How does the facility ensure confidentiality of resident records/
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?

Intent §483.75(l)(3)

To maintain the safety and confidentiality of the resident's record.

Procedures §483.75(l)(3)

Determine through observations and interviews with staff, the policy and implementation of that policy, for maintaining confidentiality of residents' records.

Probes: §483.75(1)(3)

- How does the facility ensure confidentiality of resident records/
- If there is a problem with confidentiality, is it systematic, that is, does the problem lie in the recordkeeping system, or with a staff person's use of records, e.g., leaving records in a place easily accessible to residents, visitors, or other unauthorized persons?

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§483.75(m) Disaster and Emergency Preparedness

F517

§483.75(m)(1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

F518

§483.75(m)(2) The facilities must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

Interpretive Guidelines §483.75(m)

The facility should tailor its disaster plan to its geographic location and the types of residents it serves. "Periodic review" is a judgment made by the facility based on its unique circumstances changes in physical plant or changes external to the facility can cause a review of the disaster review plan

The purpose of a "staff drill" is to test the efficiency, knowledge, and response of institutional personnel in the event of an emergency. Unannounced staff drills are directed at the responsiveness of staff, and care should be taken not to disturb or excite residents.

Procedures; §483.75(m)

Review and disaster and emergence preparedness plan, including plans for natural or man made disasters

Probes: §483.75(m)

Ask two staff persons separately (e.g., nurse aide, housekeeper, maintenance person) and the charge nurse:

- If the fire alarm goes off, what do you do?
- If you discover that a resident missing, what do you do?
- What would you do if you discovered a fire in a resident's room?
- Where are fire alarms and fire extinguisher(s) located on this unit?
- How do you use the fire extinguisher?

NOTE: Also, construct probes relevant to a geographically specific natural emergencies (e.g., for areas prone to hurricanes, tornadoes, earthquakes, or floods, each of which may require a different response).

Are the answers to these questions correct (staff answers predict competency in assuring resident safety)?

F519

§483.75(n) Transfer Agreement

(1) In accordance with section 1861(1) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate, as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents, and , when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

F520

§483.75(o) Quality Assessment and Assurance

(1) A facility must maintain a quality assessment and assurance committee consisting of--

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(ii) At least 3 other members of the facility's staff.

Intent §483.75(o)

The intent of this regulation is to ensure the facility has an established quality assurance committee in the facility which identifies and addresses quality issues, and implements corrective action plans as necessary.

Interpretive Guidelines §483.75(o)

The quality assessment and assurance committee is responsible for identifying issues that necessitate action of the committee, such as issues which negatively affect quality of care ands services provided to residents. In addition, the committee develops and implements plans of action to correct identified quality deficiencies. The medical director may be the designated physician who serves on this committee pursuant to §483.75(o)(1)(ii).

Procedures §483.75(o)

This requirement is reviewed only after completion of phase 2 sampling. There are two phases to the quality assurance review. During phase 1 for all facilities:

- The survey team should review how the quality assurance committee functions. Determine through interviews with administrative staff and Quality Assessment and Assurance Committee members if the facility has a Quality Assurance Committee which meets the requirements in §483.75(o).

- Determine if the committee has a formal method to identify issues in the facility which require quality assessment and assurance activities. The facility should also have a method to respond to identified issues and a means to evaluate the response to these issues.

Phase 2 of the review should be conducted if the survey team has identified quality issues. During Phase 2:

- Verify, through interviews with committee members and, as necessary, direct care staff that the committee has established a protocol or method for addressing specific quality problems in the facility that the facility believes have now been resolved.

Do not review committee records identifying details of the specific quality deficiencies. Surveyors should not focus on if the quality assurance committee has identified and addressed deficiencies which the survey team identifies. Concentrate on verifying that the facility has a quality assurance committee which addresses quality concerns and that staff know how to access that process.

Probes: §483.75(o)

When conducting interviews:

- How are facility policies and clinical policies revised based on quality assurance findings?

See Task 5F, Appendix P, for detailed information concerning survey procedures

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F521

(2) The quality assessment and assurance committee--

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

F522

§483.75(p) Disclosure of Ownership

(1) The facility must comply with the disclosure requirements of §§420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in--

(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility's administrator or director of nursing.

(3) The notice specified in the paragraph (p)(2) of this section must include the identity of each new individual or company.