

August 10, 2015

CMS PROPOSES TO OVERHAUL REQUIREMENTS FOR LONG-TERM CARE FACILITIES

AT A GLANCE

At Issue:

On July 16, the Centers for Medicare & Medicaid Services (CMS) published a [proposed rule](#) to overhaul the requirements that long-term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. In the rule, CMS proposes substantial and comprehensive changes to the quality and safety standards for LTC facilities. CMS states that the proposals build upon improvements nursing homes have made, reflect current professional standards, implement new safeguards and incorporate provisions of the Affordable Care Act (ACA). When finalized, CMS's revisions will mark the first comprehensive update of these quality and safety requirements since 1991.

Our Take:

The AHA appreciates that CMS is proposing updates to ensure its regulations reflect current knowledge about safe care delivery and embody high expectations for quality of care. At the same time, we recognize that a rule encompassing such a broad set of revisions may be challenging and costly to implement. In the coming weeks, we will seek member feedback about CMS's proposals to better understand their impacts and to inform AHA's comments to CMS.

What You Can Do:

- ✓ Share this advisory with your leaders involved in the LTC facility services you provide, including any LTC facility administrators, physician and nursing leaders, quality and compliance managers and risk managers.
- ✓ **Ask relevant staff to participate in an AHA members-only call on Tuesday, Aug. 18 at 3 p.m. ET to provide input on the proposed changes.** Click [here](#) to register for the call.
- ✓ Alternatively, share your feedback about this proposed rule with AHA at ltcfeedback@aha.org.
- ✓ Submit comments directly to CMS on the proposed rule, describing how the proposed changes would affect your organization's ability to provide high-quality care to residents. **Public comments are due to CMS Sept. 14 by 5 p.m. ET.**

Further Questions:

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BACKGROUND

On July 16, the Centers for Medicare & Medicaid Services (CMS) published a [proposed rule](#) to overhaul the requirements that long-term care (LTC) facilities must meet to participate in Medicare and Medicaid. In the rule, CMS proposes substantial and comprehensive changes to the quality and safety standards for LTC facilities, with the intent of modernizing the regulations.

CMS states that the proposals build upon improvements nursing homes have made in recent years, reflect current professional standards, implement new safeguards suggested by stakeholders and fulfill requirements of the Affordable Care Act (ACA). In addition, the agency recognizes that there have been significant innovations in resident care and that the nursing home population has become more diverse and clinically complex over time. When finalized, CMS's revisions will mark the first comprehensive update of these quality and safety requirements since 1991.

The changes would affect facilities that participate as skilled nursing facilities (SNFs) in the Medicare program and as nursing facilities (NFs) in the Medicaid program, including SNF and NF distinct part units of larger organizations. Further, hospital and critical access hospital (CAH) providers with "swing beds" must substantially comply with select LTC facility requirements, as outlined in 42 CFR § 482.58 and 42 CFR § 485.645. (See pages 42246 and 42269 of the rule for the hospital and CAH-related lists of the new or revised LTC facility requirements that apply for swing beds.)

CMS estimates that implementation of this proposed rule would cost about \$729 million in the first year. The total cost in the second year and thereafter is estimated at \$638 million. CMS believes the rule will result in an estimated first-year cost of approximately \$46,491 per facility and a subsequent-year cost of \$40,685 per facility.

Note that, in addition to feedback about the proposed changes to LTC facility requirements, CMS asks for stakeholder suggestions regarding the appropriate timeframe for implementation of its proposed revisions. The agency anticipates that it may take longer than 12 months for facilities, as well as CMS, to implement the provisions once the rule is finalized.

AT ISSUE

This advisory summarizes many of CMS's proposed changes for LTC facility requirements. While the length of the proposed rule precludes a discussion of every revision, we provide references to numbered pages in the rule where the changes are described in full detail.

We urge LTC facility leaders and staff to review the proposed rule for a full understanding of all of CMS's proposals.

Definitions. CMS proposes to add and amend a number of definitions. For example, CMS would add definitions for "abuse," "adverse event," "exploitation," "misappropriation of resident property," "neglect," "person-centered care," "resident representative," and "sexual abuse." CMS proposes to modify other definitions, such as clarifying that composite distinct parts may not be used to separate residents by payment status.

[For more information about changes to this section, see pages 42180-81 and 42246-47.]

Resident Rights and Facility Responsibilities. CMS would expand current resident rights and delineate facility responsibilities pertaining to resident rights separately. Highlights of changes to resident rights include the following:

Resident representative. CMS recognizes that resident representatives may be designated several ways: informally (or orally), through advanced directives, and through court orders or otherwise under applicable law. (See also the proposed definition of "resident representative" on page 42247.)

In the proposed rule, CMS would clarify that a resident may designate a representative in accordance with state law, and that the representative may exercise the resident's rights. However, the resident would retain the ability to exercise those rights not delegated to the representative. In addition, the proposed rule states that a resident can revoke a delegation of rights unless limited by state law. For residents not adjudged incompetent, any legal surrogate designated in accordance with state law also may exercise the resident's rights, to the extent provided by state law. Further, the rule states that a same-sex spouse of a resident must be treated equally to an opposite-sex spouse.

If a resident is adjudged incompetent under state law by a court of competent jurisdiction, the resident's rights would be exercised by a representative appointed under state law. The representative would exercise the resident's rights to the extent deemed necessary by the court. However, CMS would clarify that a resident could still exercise his or her rights to the extent not prohibited by court order. For cases in which the resident is deemed incompetent, the proposed regulations state that "[t]he resident's wishes and preferences must be considered in the exercise of rights by the representative." In addition, and to the extent practicable, the resident must be allowed to participate in the care planning process.

Care planning. CMS would maintain residents' rights to be fully informed about their health status in languages they understand. The agency also would require that residents be informed in advance about care to be furnished and the disciplines involved, as well as the risks and benefits of proposed care and alternative treatment options. Further, under the provisions of the proposed rule, the resident also would have the right to participate in the establishment and implementation of a person-centered plan of care. This would include, for example, the right to help establish goals and outcomes; to identify individuals to be

included in the planning process; and to be informed of changes to the plan of care in advance.

Attending physician. CMS would maintain the right of the resident to choose an attending physician, but CMS would require the facility to ensure that the attending physician is licensed and meets the credentialing requirements of the facility. If the physician chosen by the resident does not meet such requirements, the facility may seek alternative physician participation to ensure the resident receives adequate care. However, it must discuss alternative physicians with the resident and honor the resident's wishes with regard to options.

Respect and dignity. CMS maintains without revision many of the resident rights related to respect and dignity, including the right to share a room with a spouse. CMS would additionally provide residents with the right to share a room with his or her roommate of choice when practicable, if both residents live in the facility and consent. Further, residents would have the right to receive visitors of their choosing at the time of their choosing, subject to a resident's right to deny visitation, and in a manner that does not impose on the rights of another resident. A facility's responsibilities for visitation are described further below in this advisory.

Access to information. CMS clarifies in the rule that residents have the right to receive notices verbally and in writing (including Braille) in a format they understand. Such notices include information about state and local advocacy organizations, Medicare and Medicaid eligibility, filing grievances, and more.

The proposed rule also reiterates that residents have the right to access their medical records. It specifies that, upon oral or written request, the resident has the right to access the records in the format requested, if records are readily producible in such form (including electronic format when records are kept electronically). Otherwise, the facility must grant access through a readable hard copy or other form as mutually agreed to by the resident and facility. As in current regulation, such access must be provided within 24 hours, excluding weekends and holidays. Further, the rule clarifies the right of the resident to purchase a copy of medical records (including in an electronic form when records are kept electronically) with two working days advance notice to the facility.

Privacy and confidentiality. CMS would enhance privacy and confidentiality requirements pertaining to personal and medical records. In the rule, residents would have the right to privacy in verbal, written and electronic communications, including the right to send and promptly receive unopened mail, packages and materials.

Communication. The rule would expand and modernize the rights related to communications. Specifically, CMS would amend the existing right that the resident must have reasonable access to the use of a telephone to explicitly include TTY and TDD services. The facility also must facilitate residents' rights to communicate with people and entities internally and outside the facility. Thus, facilities must provide reasonable access to a telephone, the Internet (if available to the facility) and items needed for regular (or "snail") mail.

The rule also would include for the first time the right to have and use a cell phone at the resident's expense. Further, the rule would establish the right to have reasonable access to

and privacy in the use of electronic communications such as email, video communications and Internet research. This provision would apply if access to electronic communications is available to the facility, and at the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

[For more information about changes to this section, see pages 42181-84 and 42247-49.]

Highlights of facility responsibilities pertaining to resident rights are below:

Exercise of rights. CMS proposes that facilities must: ensure that residents can exercise their rights without interference from the facility; provide equal access to quality care regardless of diagnosis, severity of condition or payment source; and respect the decisions of the resident representative to the extent required or delegated. However, the facility must not extend greater authority to representatives beyond their scope. If a facility believes a representative is acting contrary to the best interests of a resident, then “the facility may report such concerns as permitted and shall report such concerns when and in the manner required under State law.”

Planning and implementing care. Facilities must inform residents about the right to participate in their treatment and help them do so. This includes, for example, facilitating resident or representative inclusion in the planning process and incorporating residents' personal and cultural preferences in setting goals of care.

Self-determination. Similar to current regulation, the proposed rule would require facilities to respect and promote self-determination. Among the revisions to these requirements are the following:

Access to the resident. The facility must provide immediate access to the resident:

- by individuals specified in the rule, such as certain federal and state government representatives, the resident's individual physician, and the resident's representative;
- by family, subject to the resident's right to deny or withdraw consent at any time; and
- by others, with the consent of the resident, and subject to reasonable clinical and safety restrictions.

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

Visitation. The proposed rule would require facilities to: (1) have written visitation policies and procedures, including any necessary or reasonable limitations; (2) inform residents/representatives of their visitation rights (and any limitations); (3) inform residents they have the right to receive visitors of their choosing; and (4) ensure visitors have full and equal visitation privileges consistent with resident preferences. A facility cannot restrict or deny visitation privileges based on race, color, national origin, religion, sex, gender identity, sexual orientation or disability.

The rule also would make a few revisions to how resident and family groups are treated. In addition to providing private space for groups, the facility would need to provide a mutually agreed upon staff person to provide assistance and respond to written requests resulting from group meetings. In addition, the facility must consider the views of groups and act upon grievances and recommendations about resident care and life in the facility, but it would not be expected to fulfill every request.

Personal funds. CMS would update current provisions that apply when residents choose to deposit personal funds with the facility. The proposed changes aim to align the regulations with statutory provisions that require facilities to deposit residents' personal funds into interest bearing accounts if those funds reach certain thresholds. For patients whose care is funded through Medicaid, the threshold would be \$50 under the proposed rule. For all other residents, the threshold would be \$100. The proposed rule also prohibits a facility from charging a resident for hospice services elected by a resident and paid for by the Medicare hospice benefit or Medicaid under a state plan and charging residents for special foods and meals ordered by a resident's health care provider.

Information and communications. The rule clarifies that LTC facilities must provide information to residents in a form and manner they understand, including in an alternative format or language, with an exception for medical records.

The rule would require facilities to make available, to any individual, reports pertaining to federal and state surveys, certifications and complaint investigations within the last three years, as well as plans of correction in effect.

Facilities also would be required to provide notice to residents as soon as reasonably possible when changes in coverage are made to items and services covered by Medicare and/or the Medicaid state plan. In addition, residents must be informed at least 60 days prior to changes in charges for other items and services offered by the facility.

Further, the regulations would require that if a resident dies or is transferred and does not return to the facility, the facility must refund any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements. Facilities must make refunds within 30 days of discharge.

Currently, facilities must provide residents a written description of legal rights, such as how to establish eligibility for Medicaid, the contact information for pertinent government agencies, and a statement that residents may file complaints with the state. CMS would clarify these rights. For example, facilities would need to provide residents a statement that the resident may file a complaint with the state survey and certification agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

Safe environment. The rule would expand upon current provisions requiring the facility to provide a safe, clean, comfortable and homelike environment. Specifically, the proposed regulatory language describes the need to ensure that residents can receive care and

services safely and that the physical layout of the facility maximizes independence and does not pose a safety risk.

Grievances. Under the rule, facilities would need to (1) make information available about how to file a grievance or complaint, (2) make prompt efforts to resolve grievances, and (3) establish a grievance policy to be provided to residents upon request. The grievance policy must include numerous specific elements outlined in the proposed regulation. (See page 42253 for the proposed grievance policy components.)

Contact with external entities. CMS would clarify that a facility may not prevent or discourage a resident from communicating with federal, state or local officials, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

[For more information about changes to this section, see pages 42184-89 and 42249-53.]

Freedom from Abuse, Neglect and Exploitation. CMS would retain, clarify and expand upon residents' rights to be free from abuse, neglect, misappropriation of resident property and exploitation. The term "exploitation" would be included for the first time, and that concept would need to be incorporated into written policies and procedures.

Under the provisions of the rule, a facility would not be allowed to employ or otherwise engage (for example, as a contractor or volunteer) individuals who:

- have been found guilty of abuse, neglect, misappropriation of property or mistreatment by a court of law;
- have had a finding entered into the state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; or
- have had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.

In addition, the facility would need to establish policies and procedures to investigate any allegations of abuse, neglect, exploitation or misappropriation of resident property. CMS also would require training about residents' rights, facility responsibilities, and recognizing and reporting neglect, abuse and exploitation. Further, CMS would require facilities have policies and procedures to ensure the reporting of crimes in accordance with section 1150B of the Social Security Act (SSA), among other changes.

[For more information about changes to this section, see pages 42188 and 42253-54.]

Transitions of Care. In a newly titled "Transitions of Care" section, CMS would require facilities to establish admissions policies. The proposed revisions would prohibit facilities from requesting or requiring residents to waive Medicare or Medicaid benefits or their rights under federal, state and local licensing or certification laws. In addition, facilities could not ask or require residents (or potential residents) to waive any potential facility liability for losses of personal property. Further, nursing facilities would be required to advise residents and potential residents about any special characteristics or service limitations, such as

whether the facility has a religious affiliation that would result in special characteristics or limitations or if the facility lacks the capacity to care for residents needing psychiatric care.

CMS also would make an important change related to transfers and discharges. The agency would require facilities to ensure that transfers and discharges are documented in the resident's clinical record and that appropriate information is communicated to the receiving health care institution or provider. Information provided to the receiving provider must address 18 elements, such as demographic information, diagnoses, past medical history, lab tests, psychosocial assessment, medications, allergies, immunizations and unique device identifiers for any implantable devices. (See page 42255 of the rule for the complete list.) CMS does not propose a specific form or format for this communication and recognizes that limited information may initially be sent in an emergency. (This requirement may be satisfied by the discharge summary discussed in another section of the rule, as long as it contains the required elements.)

CMS would make additional changes related to discharging residents for non-payment, discharging residents for the safety of other individuals, and bed-hold policies.

[For more information about changes to this section, see pages 42189-91 and 42254-56.]

Resident Assessments. Among other changes, CMS would clarify that the resident assessment should include not only resident needs, but also resident strengths, goals, life history and preferences. In addition, current regulations require facilities to coordinate resident assessments with the Preadmission Screening and Resident Reviews (PASARR) program under Medicaid to the maximum extent practicable. CMS would clarify what it means to coordinate resident assessments with PASARR. Specifically, coordination with PASARR would include incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning and transitions of care. It also would include referring all level II residents and all residents with newly evident or possible serious mental illness, intellectual disability, or related conditions for level II resident review upon a significant change in status assessment.

[For more information about changes to this section, see pages 42191 and 42256.]

Comprehensive Person-centered Care Planning. Under current requirements, facilities must create a comprehensive care plan for residents within 21 days of admission. In the proposed rule, CMS would require that facilities also complete a baseline interim care plan for each resident within 48 hours of admission. The baseline care plan would need to include, at a minimum, initial goals, physician orders, dietary orders, therapy services, social services and PASARR recommendations, if applicable.

CMS also would modify regulations pertaining to the development of the comprehensive care plan, such as requiring discharge assessment and planning to be part of that process and specifying additional mandatory members of the interdisciplinary team (IDT). CMS would require a nurse aide with responsibility for the resident, a member of the food and nutrition services staff, a social worker and "other appropriate staff" (such as a mental health professional or chaplain) to be part of the IDT. In addition, CMS would expect the resident/resident representative to participate, to the extent practicable, in the development of the plan.

CMS would require that facilities develop and implement an effective discharge planning process that will:

- identify the discharge needs and goals for each resident;
- result in the development of a discharge plan for each resident that includes all relevant resident information;
- include regular re-evaluation of residents and updating of discharge plans as needed;
- involve the IDT in developing discharge plans as well as residents and their representatives;
- consider caregiver/support person availability and capacity;
- address residents' care goals and treatment preferences; and
- document that residents have been asked about their interest in receiving information about returning to the community. If discharge to the community is deemed unfeasible, the facility must document who made the determination and why.

The AHA will seek clarification from CMS as to whether these discharge planning requirements apply to all residents or only those receiving SNF care.

IMPACT Act provisions. The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) requires SNFs to take into account certain quality, resource use, and other data mandated by the law in their discharge planning processes. In the rule, CMS would require LTC facilities to consider standardized patient assessment data, quality measures and resource use measures that pertain to the IMPACT Act domains, as well as other measures specified by the Secretary.

CMS specifically proposes that, for residents who are transferred to another SNF or who are discharged to a home health agency (HHA), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH), facilities would need to assist residents and their resident representatives in choosing post-acute care providers by using data that includes, but is not limited to standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available. CMS would expect facilities to “compile the relevant data and present it to the resident and his or her resident representative in an accessible and understandable format and with useful content.”

[For more information about changes to this section, see pages 42192-96 and 42256-58.]

Quality of Care and Quality of Life. CMS would revise regulations currently organized under the heading, “Quality of Care.” Under the new heading, “Quality of Care and Quality of Life,” CMS would require that:

- care needed to maintain or improve, as practicable, a resident’s abilities to perform his or her activities of daily living, is provided. The facility must ensure that those abilities do not diminish for avoidable reasons (other than individual’s clinical condition);

- staff can provide basic life support (including cardiopulmonary resuscitation) to residents who require it before the arrival of emergency medical personnel;
- residents are free from restraints imposed for discipline or convenience. Further, restraints used must be the least restrictive alternative for the least amount of time. CMS notes that many facilities have achieved a rate of zero percent restraint use;
- bed rails are correctly installed, used and maintained. This includes attempting to use alternatives prior to installing a side or bed rail, assessing residents for risk of entrapment, reviewing the risks and benefits of bed rails with the resident/representative and obtaining informed consent prior to installation, ensuring that the resident's size and weight are appropriate for the bed's dimensions, and following the manufacturers' recommendations and specifications.
- trauma survivors, including Holocaust survivors, survivors of abuse, military veterans with post-traumatic stress disorder, and survivors of other trauma, receive culturally competent, trauma-informed care to eliminate or mitigate triggers that may re-traumatize the resident.

CMS also makes revisions and additions related to indwelling urinary catheters, fecal incontinence, foot care, assisted nutrition and hydration, therapeutic diets, pain management, dialysis, activities programs and more.

[For more information about changes to this section, see pages 42196-99 and 42258-59.]

Physician Services. CMS proposes a number of changes to the physician services requirements. First, CMS would allow a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist to provide orders for the resident's immediate care and needs after admission, until a comprehensive assessment and care planning is completed. Current requirements only refer to physician orders.

Second, CMS would require that before an unscheduled transfer of a resident to a hospital, a physician, physician assistant, nurse practitioner or clinical nurse specialist must conduct an in-person evaluation shortly after the potential need for a transfer is identified. However, the evaluation would not be required in emergency situations where the health or safety of the resident would be endangered.

Further, the proposed rule would allow a physician to: (1) delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, to the extent the dietitian or other clinically qualified nutrition professional is permitted to do so under state law, and (2) delegate to a qualified therapist, consistent with proposed § 483.65 (the revised section on "Specialized Rehabilitative Services"), the task of writing therapy orders, to the extent that the therapist is permitted to do so under state law.

[For more information about changes to this section, see pages 42199 and 42259.]

Nursing Services. In the preamble of the rule, CMS discusses nurse staffing requirements. CMS draws a distinction between staffing “to the number” and staffing to the needs of the resident population. The agency takes a competency-based staffing approach. That is, CMS believes that the focus should be on the skill sets and competencies that staff need to provide sufficient care. Therefore, CMS proposes that “facilities must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.” Staffing decisions would need to be based on resident assessments and individual plans of care and would consider the number, acuity and diagnoses of the facility’s resident population in accordance with a facility assessment described below.

However, CMS welcomes comments about: (1) establishing minimum nurse hours per resident day, (2) establishing minimum registered nurse (RN)-to-resident ratios, (3) requiring that an RN be present in every facility either 24 hours a day or 16 hours a day, and (4) requiring that an RN be on-call whenever an RN was not present in the facility.

[For more information about changes to this section, see pages 42199-42202 and 42260.]

Behavioral Health Services. CMS proposes to add a new section focusing on behavioral health care. Under the provisions of the rule, the facility must provide each resident the necessary behavioral health 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. Facilities would be required to have sufficient direct care/direct access staff who are competent to care for residents with mental illness, psychosocial disorders or a history of trauma and/or post-traumatic stress disorder, and staff who can implement non-pharmacological interventions.

Among other provisions, residents with mental or psychosocial adjustment difficulties or who have a history of trauma and/or post-traumatic stress disorder must receive appropriate treatment. In addition, the facility must ensure that residents without mental or psychosocial adjustment difficulties or documented histories of trauma and/or post-traumatic stress disorder do not display “a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident’s clinical condition demonstrates that development of such a pattern was unavoidable.”

[For more information about changes to this section, see pages 42202-03 and 42260-61]

Pharmacy Services. Currently, each resident’s drug regimen must be reviewed by a pharmacist at least once a month. CMS believes the pharmacist should review the resident’s medical record concurrently with the drug regimen review in some circumstances. Therefore, CMS proposes that a pharmacist be required to review the resident’s medical chart along with the drug regimen review at least every six months and when: (1) the resident is new to the facility; (2) the resident returns or is transferred from a hospital or other facility; and (3) during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic or any drug the quality assessment and assurance (QAA) committee has requested be included in the pharmacist’s monthly drug review.

In addition, current regulations include safeguards for the use of antipsychotic medications. CMS proposes to expand these protections to include all psychotropic medications. CMS would define psychotropic as any drug that affects brain activities associated with mental processes and behavior, including but not limited to the following: antipsychotic, anti-depressant, antianxiety, hypnotic, opioid analgesic, or any other drug with similar effects. In addition to the current protections, CMS would prohibit facilities from providing these drugs based on a PRN order, unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record. Further, PRN orders for a psychotropic drug would be limited to 48 hours unless the resident's physician or primary care provider documents justification for continuation.

[For more information about changes to this section, see pages 42203 and 42261.]

Laboratory, Radiology and Other Diagnostic Services. The proposed rule would create a new section to house requirements related to laboratories, radiology and other diagnostic services. Current requirements state that facilities must provide or obtain laboratory and radiology and other diagnostic services “only when ordered by the attending physician.” CMS would change this requirement to include a physician, physician assistant, nurse practitioner or clinical nurse specialist, when such practitioners are acting in accordance with state law and facility policy.

The rule also would expand the types of practitioners who can receive laboratory, radiology and other diagnostic results so that an ordering physician, physician assistant, nurse practitioner or clinical nurse specialist can be notified of laboratory results. Further, a lab would need to promptly notify an ordering professional if results fall outside of clinical reference or expected “normal” ranges, unless the orders for the test or the facility's policies and procedures require otherwise.

[For more information about changes to this section, see pages 42205 and 42261-62.]

Dental Services. CMS would clarify that a facility may not charge a resident for the loss of or damage to dentures when that loss or damage is determined to be (based on facility policy) the facility's responsibility. CMS also would revise language to ensure that facilities must, if necessary *or requested*, help residents make appointments and arrange transportation to dental services locations. Further, facilities would need to refer residents with lost or damaged dentures to dental services within three days, unless the facility provides documentation of extenuating circumstances. (Note: only the preamble references three “business” days.) For nursing facility residents, facilities would need to help eligible residents apply for reimbursement of dental services under the state plan.

[For more information about changes to this section, see pages 42205-06 and 42262.]

Food and Nutrition Services. CMS redefines the existing “Dietary Services” section as “Food and Nutrition Services” and makes numerous revisions to current requirements.

For example, CMS would enhance regulatory language pertaining to staff. The proposed regulations specify that facilities must employ sufficient staff with the appropriate competencies and skill sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the resident population (per the facility assessment described

below). This would include having a qualified dietitian or other clinically qualified nutrition professional either full-time, part-time or on a consultant basis.

The rule defines a qualified dietitian or other clinically qualified nutrition professional as one who is qualified based on state requirements to practice dietetics, including licensure/certification. If the state does not have requirements, the dietitian or professional could qualify based on registration by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics. Dietitians hired or contracted with before the effective date of the final rule must meet these requirements no later than five years after the effective date or as required by state law.

Similar to current regulations, if a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services. This person would need to receive frequently scheduled consultation from a qualified dietitian or other clinically qualified nutrition professional.

CMS also would establish qualification standards for a director of food and nutrition services. Specifically, CMS proposes that the director of food and nutrition services, *if hired or designated after the effective date of the final rule*, must be a certified dietary manager or certified food service manager or have similar national certification for food service management and safety from a national certifying body. If a director of food and nutrition service does not have one of these certifications on the effective date of the rule, he or she would have five years to obtain such certification. Alternatively, the director of food and nutrition services could meet the proposed requirement by having an associate's or higher degree in hospitality or food service management from an accredited institution of higher learning. Finally, the director of food and nutrition services would meet the proposed standards if he or she meets applicable state requirements for food service managers or dietary managers.

In addition, the rule would require that menus reflect the religious, cultural and ethnic needs of the residents, as well as input received from residents and resident groups, be updated periodically, and be reviewed by the dietitian or clinically qualified nutrition professional for nutritional adequacy. Facilities would need to provide food that accommodates resident allergies, intolerances and preferences. Revisions to current rules also would emphasize dietary fluids and hydration, such as providing drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.

Currently, therapeutic diets must be prescribed by the attending physician. CMS proposes to allow attending physicians to delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by state law.

Among other provisions, CMS also would:

- enhance the requirements for frequency of meals and snacks to make them more aligned with resident preferences or needs. However, the agency clarifies that it does not expect "a 24-hour-a-day full service food operation or an on-site chef."

- expand the requirements for assistive devices to ensure facilities provide appropriate assistance so that residents can use the assistive devices when consuming meals and snacks;
- clarify that facilities may procure food directly from local producers, in accordance with state and local laws or regulations and may use produce grown in facility gardens, in accordance with applicable safe growing and handling practices; and
- add a requirement for facilities to have policies regarding the use and storage of foods brought to residents by visitors to ensure safe and sanitary storage, handling and consumption.

[For more information about changes to this section, see pages 42206-09 and 42262-63.]

Specialized Rehabilitative Services and Outpatient Rehabilitative Services. Currently, facilities must provide or obtain specialized rehabilitative services for residents if required by their comprehensive care plans. These services include physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and intellectual disability. CMS would add respiratory therapy to this list. If rehabilitative services are obtained from an outside resource rather than provided directly, CMS would clarify that the services must be obtained from a Medicare or Medicaid provider of specialized rehabilitative services. CMS also proposes to require facilities that provide outpatient rehabilitative therapy services meet requirements similar to those established for hospitals.

[For more information about changes to this section, see pages 42209-10 and 42263.]

Administration. We highlight two changes added to the section on administration.

Facility assessments. CMS would establish a new requirement for an annual facility assessment that would be used to inform a number of activities, such as staffing decisions, emergency planning and the development of a quality assurance and performance improvement (QAPI) program. Specifically, LTC facilities would conduct and document facility-wide assessments to determine the resources needed to care for residents competently in both day-to-day operations and emergencies. Facilities would be expected to update their assessments annually and as necessary, and whenever there are changes that would require a substantial modification to any part of this assessment. Assessments would need to address the following:

- the number of residents and the facility's resident capacity; the care required by the resident population; the staff competencies necessary to provide that care; the physical environment, equipment, services and other physical plant considerations that are necessary; and any ethnic, cultural or religious factors that may potentially affect the care provided by the facility.
- the facility's resources, including but not limited to all buildings and/or other physical structures and vehicles; equipment (medical and nonmedical); services provided; all personnel, including managers, staff (both employees and those who provide services under contract) and volunteers, as well as their education and/or training;

contracts, memorandums of understanding or other agreements with third parties; and health information technology resources; and

- a facility-based and community-based risk assessment, utilizing an all-hazards approach.

Binding arbitration agreements. CMS also addresses binding arbitration agreements, which require parties to waive judicial review rights. The agency is concerned that residents may feel coerced into signing such agreements and/or may not fully understand them. Further, CMS is troubled by the idea that the agreements may have confidentiality clauses that could prevent residents from discussing incidents with government representatives. CMS proposes several restrictions on binding arbitration agreements and asks for comments on whether they should be prohibited altogether.

Under the proposed rule, if facilities enter into binding arbitration agreements with residents, they must ensure that the agreements are explained to residents in a form and manner they understand and that residents acknowledge that they understand the agreements. CMS emphasizes that “[t]he explanation must state, at a minimum, that the resident is waiving his or her right to judicial relief for any potential cause of action covered by the agreement.”

Further, the agreement:

- must be separate from other paperwork;
- must be entered into by the resident voluntarily, provide for the selection of a neutral arbiter, and provide for selection of a venue convenient to both parties; and
- cannot include language that prohibits or discourages the resident or anyone else from communicating with federal, state or local officials.

A facility cannot make admission to the facility contingent upon signing the agreement. The agreement may be signed by another individual if allowed by state law, if all of the requirements in this section are met, and if that individual has no interest in the facility.

[For more information about changes to this section, see pages 42210-12 and 42264-65.]

Quality Assurance and Performance Improvement (QAPI). The ACA mandates that the Secretary establish a QAPI program requirement for SNFs and NFs. CMS proposes that each LTC facility must develop, implement and maintain an effective, ongoing, comprehensive, data-driven and well-documented QAPI program. The specifics outlined in the proposed rule are very detailed. In a nutshell, the agency envisions that facilities will adopt a systematic approach to quality improvement, using data to study and continually make improvements to operations and services. A facility’s QAPI program would need to address its full range of care and services (including those under contract) and reflect its complexities and the unique care it provides. Facilities also must use the best available evidence to develop quality indicators and facility goals that incorporate processes known to promote good outcomes.

Under the specific provisions of the proposed rule, facilities must have policies and procedures to obtain feedback from staff and residents that identify problems that are high-risk, high-volume or problem-prone; collect and use data from all departments; develop

and monitor performance indicators; systematically track, investigate and analyze adverse events and implement preventive actions; and engage in performance improvement activities and monitor success. Performance improvement activities would need to focus on areas that are high-risk, high-volume or problem-prone and affect health outcomes, resident safety, resident autonomy, resident choice and quality of care.

The facility also must conduct distinct performance improvement projects (PIPs). The number and frequency of PIPs conducted by the facility would be expected to reflect the scope and complexity of the facility's services and available resources, as represented in the facility assessment. At least annually, however, the facility must undertake a project that focuses on high-volume, high-risk or problem-prone areas identified through the data collection and analysis. CMS specifically asks for comment on whether it should require a specific number of PIPS or establish mandatory PIPs (and thus require facilities to implement at least one PIP selected from the mandatory PIPs.)

The proposed rule tasks the governing body and/or executive leadership with QAPI program oversight and holds the governing body accountable for ensuring that the QAPI program is effectively implemented, maintained during transitions in leadership and staffing, and adequately resourced, among other requirements.

Further, facilities would be required to present the QAPI program to the state agency surveyor at the first annual recertification survey that occurs after the effective date of the regulation. Thereafter, facilities must present their QAPI plans to state or federal surveyors at annual recertification surveys or upon request during other surveys, or to CMS upon request. Further, they must provide evidence of the program's implementation to a state agency, federal surveyor or CMS upon request.

CMS would keep the current requirements for a QAA committee but expand its composition and responsibilities. In the rule, the QAA committee would consist at a minimum of the director of nursing services; the medical director or his/her designee; at least three other members of the facility's staff (at least one of whom must be the administrator, owner, a board member or other individual in a leadership role); and the infection control and prevention officer.

Under the provisions of the proposed rule, the QAA committee would:

- report to the governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program;
- meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program;
- develop and implement appropriate plans of action to correct identified quality deficiencies; and
- regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

CMS specifies that neither a state nor the Secretary may require disclosure of the records of the committee unless the disclosure is related to the committee's compliance with the

requirements of this section. However, CMS states that demonstrating compliance may require surveyor access to:

- systems and reports demonstrating systematic identification, reporting, investigation, analysis and prevention of adverse events;
- documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; and
- other documentation considered necessary by a state or federal surveyor in assessing compliance.

CMS emphasizes that good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

[For more information about changes to this section, see pages 42212-15 and 42265-66.]

Infection Control. The proposed rule updates and strengthens the infection control requirements for LTC facilities and emphasizes infection prevention as well as control. In the rule, facilities must establish and annually update infection prevention and control programs (IPCPs) that include a system for preventing, identifying, reporting, investigating and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement. This system must be based upon the facility assessment and follow accepted national standards.

Specifically, IPCPs would need to have:

- written standards, policies and procedures that address: communicable disease/infection surveillance, reporting procedures for incidents of communicable disease, standard and transmission-based precautions; isolation; hand hygiene; and limitations for employees with communicable diseases/infected skin lesions;
- an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use; and
- a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

Further, each facility must designate one individual as the infection prevention and control officer (IPCO) for whom the IPCP at that facility is a major responsibility. The IPCO must be a clinician who works at least part-time at the facility, and have specialized training in infection prevention and control beyond his or her initial professional degree.

[For more information about changes to this section, see pages 42215-16 and 42266.]

Compliance Programs. The ACA requires operating organizations of SNFs and NFs to have compliance and ethics programs to prevent and detect criminal, civil and administrative violations under the SSA.

Therefore, CMS proposes that operating organizations be required to develop, implement and maintain effective compliance and ethics programs that contain specific components

outlined in the rule, and that these programs be reviewed annually. For example, operating organizations would need written compliance and ethics standards, policies and procedures “that are reasonably capable of reducing the prospect of criminal, civil and administrative violations” under the SSA. The written policies should:

- designate a compliance and ethics program contact to whom individuals may report suspected violations, and an alternate way to anonymously report suspected violations; and
- describe disciplinary standards for staff, contractors and volunteers for violations.

CMS expects that policies and procedures would address, among other things, financial disclosure obligations, conflicts of interest standards and requirements for promptly reporting any abuse or neglect of a resident. The proposed rule also would require that operating organizations:

- assign “high-level personnel” (as defined in the rule) with the responsibility for oversight of the compliance program, and provide those individuals with adequate human and financial resources and authority;
- carefully select individuals to whom they delegate substantial discretionary authority. For example, CMS expects that “the level of scrutiny applied to the compliance officer should be much higher than the level given to an employee who has minimal discretionary authority over the residents’ activities.”
- effectively communicate standards, policies and procedures to the operating organization’s entire staff including individuals providing services under a contractual arrangement and volunteers, consistent with volunteers’ expected roles. Specific requirements would include mandatory participation training or orientation programs, and/or dissemination of information.
- ensure programs employ reasonable measures to achieve compliance with standards, policies and procedures. These measures include, for example, monitoring and auditing systems, anonymous reporting systems and processes for ensuring the integrity of reported data;
- consistently enforce standards, policies and procedures and have appropriate disciplinary mechanisms; and
- appropriately address detected violations, as described in the rule.

CMS proposes additional requirements for operating organizations that operate five or more facilities. These operating organizations would need to:

- provide a mandatory annual training program about the operating organization’s compliance and ethics program;
- designate a compliance officer for whom the operating organization’s compliance and ethics program is a major responsibility. The compliance officer must report directly to the operating organization’s governing body and cannot be subordinate to the general counsel, chief financial officer or chief operating officer; and
- designate compliance liaisons at each facility.

[For more information about changes to this section, see pages, 42217-21 and 42267.]

Physical Environment. CMS would make a number of changes to the physical environment requirements. Among the changes, CMS proposes to require that:

- facilities conduct regular inspections of all bed frames, mattresses and bed rails to identify risks of possible entrapment;
- bedrooms in facilities accommodate not more than two residents, **unless** the facility is currently certified to participate in Medicare and/or Medicaid or has received approval of construction or reconstruction plans by state and local authorities prior to the effective date of this regulation;
- for facilities that receive approval of construction or reconstruction plans or are newly certified after the effective date of the rule, each resident room would need to have its own bathroom equipped with at least a toilet, sink and shower;
- the facility must be adequately equipped to allow residents to call for staff assistance through a communication system that relays the call directly to a staff member or to a centralized staff work area from the resident's bedside, toilet and bathing facilities; and
- facilities must establish policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety.

[For more information about changes to this section, see pages 42221-22 and 42268.]

Training Requirements. Under the provisions of the proposed rule, facilities must develop, implement and maintain effective training programs for all new and existing staff; individuals providing services under contractual arrangements; and volunteers, consistent with their expected roles. Each facility would determine the amount and types of training necessary based on the facility assessment. However, training topics must include the following: communications (for direct care/direct access personnel); residents' rights; the prevention of abuse, neglect and exploitation; QAPI; infection control; compliance and ethics; required in-service training for nurse aides; and behavioral health. The rule also retains a requirement that paid feeding assistants must successfully complete a state-approved training program for feeding assistants.

[For more information about changes to this section, see pages 42222-23 and 42268.]

NEXT STEPS

The AHA will host a member call Tuesday, Aug. 18 at 3 p.m. ET to discuss this proposed rule and to gather input from the field for AHA's comment letter to CMS. Click [here](#) to register for the call. In addition, the AHA urges members with LTC facilities or distinct parts to submit feedback to the AHA at lctfeedback@aha.org. Specific questions include:

- Are there proposed revisions in the rule that you believe will be difficult to adopt?
- Are there specific changes AHA should support?
- How long would your facility need to implement the changes, and which revisions will take the longest? Please provide a description of the steps necessary to adopt the most challenging proposed changes.

The AHA will submit comments to CMS and encourages members to submit their own letters to CMS. Comments are due Sept. 14 by 5 p.m. ET and may be submitted electronically at <http://www.regulations.gov>. **Please refer to file code CMS-3260-P.**

For questions, contact Evelyn Knolle, senior associate director of policy, at (202) 626-2963 or eknolle@aha.org.