



October 14, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244

Re: CMS 3260-P, Medicare and Medicaid Programs; Reform of Requirements for Long-term Care Facilities; Proposed Rule, July 16, 2015.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to revise the requirements for long-term care (LTC) facilities.

We appreciate that CMS is updating age-old requirements for health care providers to ensure that regulations are current, reflect the best and most recent knowledge about care delivery, and embody high expectations for quality of care. Overall, CMS has done a good job in proposing changes to bring the LTC facility standards up to date. The proposed rule incorporates important themes, such as resident-centeredness, competency-based approaches and behavioral health. In addition, it integrates many current best practices. At the same time, we have concerns about select proposed changes as well as the cost of implementing the new provisions.

Frequency of updates. We urge CMS to update its Medicare-related quality and safety standards more frequently. It is unclear why the LTC facility regulations have not been comprehensively reviewed since 1991, although there have been some updates to the interpretive guidance. However, we also have seen long delays in updates for other quality and safety regulations, such as the fire safety standards for health care facilities. Given that the science of medicine and the practice of safe care delivery evolve constantly, CMS should review quality and safety regulations every few years to keep pace with current knowledge and to ensure changes are more manageable. By routinely updating standards, comprehensive overhauls of regulations will be unnecessary.



<u>Timeframe for implementation</u>. We appreciate CMS's recognition that it may take longer than 12 months for facilities, as well as CMS, to implement the finalized provisions. **We recommend that CMS adopt a staggered implementation timeline that incorporates the release of subregulatory guidance.** Under this approach, CMS would develop sub-regulatory guidance and educational materials for specific sections of the rule *before* they take effect. Depending on how CMS finalizes its proposals and when interpretive guidance is available, we believe a five-year implementation period would be reasonable. A staggered implementation would require CMS to prioritize which provisions would take effect first based on criteria such as statutory deadlines, data demonstrating the areas in need of improvement, the complexity of the requirements, and the resources of LTC facilities and their communities.

Cost estimates. The AHA supports the proposed rule; however, we believe that CMS's economic impact analysis – of more than \$700 million in the first year alone – falls significantly short of what it will truly cost to implement the proposed changes, based on several observations. First, the burden estimates contained in the rule do not cover every proposed change. For example, although we support antibiotic stewardship, we do not see where the cost estimates take this new requirement into consideration. Although CMS estimates a first-year, per facility cost of \$46,491 to implement all changes in the proposed rule, our members have indicated that the proposed addition of an antibiotic stewardship program and other pharmacy requirements would cost that much alone. Second, some of the regulatory impact analyses are inadequate, such as the suggestion that it would take only eight hours to develop or update training programs covering eight separate subjects (and there is no accounting for the implementation of the full training requirements). Further, some of the proposals will require LTC facilities to make modifications to electronic health records (EHRs) and health information systems as well as paper documentation systems. CMS makes inadequate accounting for these kinds of facility costs.

The Office of Management and Budget should insist on a full and accurate cost accounting for this rule, and others, and should urge CMS to look for areas to minimize implementation costs. There may be ways for CMS to assist facilities, such as by providing templates or standard notices to help facilities meet the information requirements or by creating videos that can be part of a LTC facility's training program. In other words, CMS could look for ways to centralize implementation of select functions, rather than having each of the 15,000+ LTC facilities carry out those functions independently. For example, CMS could play a significant role in helping LTC facilities develop competencies for trauma-informed care and provide tools for conducting facility assessments that would determine staffing needs. In other areas, CMS may need to scale back its proposals, especially for smaller LTC facilities and those in rural areas.

Our detailed comments about selected proposed provisions follow.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)

The AHA supports CMS's proposal for LTC facilities to develop and implement QAPI programs. We agree that all LTC facilities should have ongoing, comprehensive, data-driven QAPI programs. We believe LTC facilities that are affiliated with hospitals will have expertise, based on hospital QAPI requirements, to implement effective QAPI programs if they have not done so already. We ask CMS to consider the following as it finalizes its QAPI proposal:

- Our members appreciate the QAPI educational materials that CMS has provided thus far.
 We ask CMS to provide additional resources, including examples of what the agency
 considers to be model QAPI programs for LTC facilities of different sizes and
 populations, before the final rule takes effect.
- We ask CMS to clarify that a LTC facility that is owned by a hospital or health system can fulfill at least some QAPI requirements by participating in a larger, system-based improvement program, as long as the facility meets the requirements of proposed § 483.75. For example, a system that aims to reduce hospitalizations for chronic obstructive pulmonary disease patients might have a cross-cutting performance improvement project that involves the LTC facility. These types of programs enable hospitals to share resources and expertise with LTC facilities and foster increased communication from LTC facilities back to hospitals.
- CMS specifically asks for comment on whether it should require a specific number of performance improvement projects (PIPs) or establish mandatory PIPs (and thus require facilities to implement at least one PIP selected from the mandatory PIPs). We do not believe CMS should approve a mandatory list of PIPs from which LTC facilities must choose. The number and type of PIPs conducted should be specific to the facility and should be responsive to the data generated through the QAPI program about priority areas.

The Affordable Care Act requires LTC facilities to submit their QAPI plans to the Department of Health and Human Services (HHS) Secretary, but the statutory language does not require LTC facilities to reveal detailed information resulting from the implementation of their QAPI programs. We are concerned about CMS's proposal to require access to information, such as investigative reports, by state or federal surveyors. Specifically, some of our members are concerned that sharing this information with state or federal surveyors may be viewed as waiving Quality Assessment and Assurance (QAA) committee privilege protections recognized by courts. We urge CMS not to finalize provisions that would have this effect.

INFECTION PREVENTION AND CONTROL

We support CMS's proposal to require LTC facilities to enhance their infection prevention and control programs (IPCPs), but we seek flexibility for specific provisions. CMS proposes to build upon current infection control regulations. Under the proposed rule, for instance, CMS

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would require LTC facilities to have antimicrobial stewardship programs and infection prevention and control officers (IPCOs). As with the QAPI program, we believe that LTC facilities connected in some way to hospitals or health systems will have organizational expertise and resources to meet the requirements.

We ask CMS to allow flexibility so that LTC facility IPCPs may be part of larger, system-wide programs, as long as the requirements of proposed § 483.80 are met. Some health care systems with multiple facilities may centralize some of their infection prevention and control work. While we recognize that these programs must be tailored to meet the needs of individual facilities, a centralized approach might be useful, for example, with the requirement for an antimicrobial stewardship program. Instead of each facility building its own program, a system could develop and monitor a centralized program that collects and analyzes data from each facility. This may provide the opportunity to build appropriate decision support into the EHR system, to benchmark where appropriate, and to improve quality across the system. At the same time, we believe that each LTC facility must have an antibiotic stewardship program that is tailored to its size, scope of services and the risks present.

CMS proposes that each facility must designate one individual as the IPCO and that the IPCP at that facility would need to be a major responsibility for that individual. The IPCO would need to 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. CMS does not define either "specialized training" or "part-time" but instead takes a competency-based approach so that facilities will have the flexibility to determine the appropriate training and time required based on the facility's assessment. We agree with this approach, as needs will vary by facility. In addition, it may be hard for LTC facilities to locate and hire practitioners with advanced *certification* in infection control, versus specialized training.

We anticipate that LTC facilities that are part of health systems will find it effective and efficient to have one IPCO oversee IPCPs at more than one facility. **CMS should allow a health care** system to run the infection control program as long as each facility has an IPCO who is clearly designated as having responsibility for the IPCP at that site, and the individual spends time at the facility overseeing, training and improving infection control practices.

RESIDENT RIGHTS

Resident Representatives. We ask for clarification regarding resident representatives. In the proposed rule, CMS states 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. Further, 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, but a resident could still exercise his or her rights to the extent not prohibited by court order.

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We agree that residents should retain their rights as much as possible. We also understand that the scopes of court orders, powers of attorney and health care proxies may not always be clearly defined. We ask CMS to clarify in the final rule that a resident retains any rights not specifically covered by a court order or other document.

CMS also recognizes that resident representatives may be designated informally or orally. We note that with informal designations of resident representatives, it can be even harder for a facility to define which rights specifically have been delegated. We have concerns about how surveyors will assess compliance with this standard as it pertains to informally designated representatives. We ask CMS to clarify in the final rule that, when no clear written instructions are available, surveyors will respect the good faith judgment of the LTC facility in managing the exercise of rights by informally designated representatives.

<u>Self-administered medications</u>. We ask CMS to modify a provision related to self-administered medications. In current requirements, an individual resident may self-administer drugs if the interdisciplinary team has determined that this practice is *safe*. In the proposed rule, residents would have the right to self-administer medications if the interdisciplinary team has determined that this practice is *clinically appropriate*. We recommend CMS use the words "clinically appropriate and safe" for this provision, to ensure that patients as well as others are protected.

Medical records. We ask CMS to create an exception to a policy related to medical records for long-term residents. The proposed rule 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.

We agree that residents should have access to their medical records as quickly as possible. However, long-term residents may have lengthy medical records, and it may be difficult to print and collate them within 24 hours. Therefore, we ask CMS to grant an exception to allow records for those long-term residents to be provided within three days.

Internet access. We support CMS's proposal that residents have the right to have reasonable access to and privacy in their use of electronic communications, such as email and video communications and Internet research. CMS clarifies at § 483.10(h)(2)(i) that residents should have such access *if the access is available to the facility*. We believe the language in § 483.10(h)(2)(i) is very important to include in the final rule, as some facilities in rural areas and inner cities may have limited broadband. We ask CMS to finalize this provision as proposed.

FACILITY RESPONSIBILITIES

We have concerns about CMS's proposal to require facilities to provide notice to residents when changes in coverage are made to items and services covered by Medicare. We understand the importance of ensuring that residents are equipped with the knowledge to make informed decisions, and recognize that LTC facilities are already responsible for informing patients about changes to items and services related to nursing care in the state plan.

We have two concerns regarding this proposal. First, changes in coverage for items and services in Medicare fee-for-service (FFS) occur often. For LTC facilities that do not already notify residents about coverage changes, this provision could add significant administrative burden. Second, we are unclear about how facilities would operationalize this provision as it pertains to patients enrolled in Medicare Advantage or those in dual-eligible demonstration programs. CMS has not articulated either in the preamble of the rule or its cost estimates how the agency expects LTC facilities to carry out such notifications for each patient. We are concerned that this provision, as proposed, could take time away from resident care.

As CMS finalizes the rule, we urge the agency to better understand the implications of this proposal for LTC facilities. We believe CMS and Medicare Advantage plans should have the primary responsibility for alerting residents about changes in their Medicare coverage. At the very least, if CMS finalizes this proposal, the agency should post timely and accessible information on its website about changes in coverage, to help facilities comply.

BEHAVIORAL HEALTH

Under the rule, LTC facilities would be required to provide the necessary behavioral health care and services for residents to attain or maintain the highest practicable mental and psychosocial well-being. We appreciate CMS's incorporation of behavioral health into the updated quality standards for LTC facilities. We agree that LTC facilities should understand the holistic needs of residents and provide or arrange behavioral health services so that residents can achieve their highest potential for health. Facilities also need flexibility to meet resident needs as they evolve over time.

However, CMS's proposal needs substantial clarification. It is unclear what level of behavioral health services LTC facilities would be required to provide. For example, CMS would require facilities to have staff with the appropriate competencies to care for residents with mental illnesses, psychosocial disorders and trauma. We do not interpret this to mean that all facilities would need to have the ability to care for residents requiring psychiatric care, because in the preamble of the rule CMS states it would require facilities to alert individuals prior to admission if it did not have such capability (see page 42189 of the rule). We ask CMS to clarify its expectations with regard to what an LTC facility providing basic nursing facility services would need to do to comply with the proposed behavioral health requirements, including how these expectations relate to Level 2 Pre-Admission Screening Resident Review (PASARR) evaluations. We note that there are some statutory limits to the admission of residents who are mentally ill.

In finalizing this section, we urge CMS to consider the shortages of mental health care providers in many communities. According to the Congressional Research Service, "[a]s of January 2015, HRSA had designated 4,071 Mental Health Professional Shortage Areas (MHPSAs), including one or more in each state, the District of Columbia, and each of the territories." CMS should explain how it envisions LTC facilities in shortage areas will comply with the proposed behavioral health requirements and to outline how HHS is working to address the mental health workforce shortages.

In addition, we ask CMS to clarify that there are enough social workers to meet both the proposed behavioral health care requirements as well as the proposed requirement that a social worker be part of the interdisciplinary care team. CMS explains in its Regulatory Impact Analysis that it has received input that some nursing homes already have difficulty in hiring qualified social workers. Therefore, it is unclear what data CMS has to indicate enough social workers are available to meet its proposed requirements. CMS should not finalize requirements unless it has assurances, through appropriate research and data as well as LTC facility feedback, that the proposed standards are actually achievable.

Finally, CMS proposes for facilities to ensure that, "[a] resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder 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 development of such a pattern was unavoidable." We ask CMS to modify this provision to say that LTC facilities would be required to detect and address the needs of residents who display such patterns. But to mandate that patients will never become angry or depressed may be outside the control of the facility. It is reasonable to expect that all individuals may go through periods of anger or depression. Nursing home residents may experience these emotions as the result of many different and normal life events, such as when a resident's loved one dies. It is reasonable to expect the facility to provide services to help residents manage their emotions, but it is not reasonable to expect that facilities can prevent residents from experiencing anger or depression.

PHYSICIAN SERVICES

We support CMS's proposal to allow a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist to provide orders for a resident's immediate care and needs after admission, until a comprehensive assessment and care planning is completed. Current requirements indicate that only physicians, and not other midlevel professionals, may provide such orders.

¹ Heisler, Elayne J. and Bagalman, Erin. *The Mental Health Workforce: A Primer*. Congressional Research Service. April 16, 2015. Accessed at https://www.fas.org/sgp/crs/misc/R43255.pdf on Aug. 31, 2015.

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We also support CMS's proposal to 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.

We do not support CMS's proposal to 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. We appreciate CMS's goal to reduce hospital readmissions, but we note that CMS has implemented a number of regulations, quality measures, and public reporting requirements that have already successfully created incentives to achieve that goal. Even though the evaluation would not be required in emergency situations, we are concerned that this proposed requirement could lead to delays in care that cause patient harm. In addition, it may be difficult for facilities to recruit on-call providers during non-business hours.

ADMISSIONS

<u>Personal property</u>. We ask CMS to change a provision at proposed § 483.15(a)(2)(iii) that would prohibit facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. CMS indicates that the goal of this proposed provision is to encourage facilities to develop policies and procedures to safeguard residents' personal possessions without effectively prohibiting a resident's use of personal possessions. Therefore, instead of finalizing the provision at proposed § 483.15(a)(2)(iii), CMS should require LTC facilities to have such policies in place and provide oversight of these policies through the annual survey process and by tracking resident complaints.

The AHA believes LTC facilities should have effective policies in place to protect resident property. LTC facilities typically do have systems for safeguarding personal property, such as using or providing safes, providing drawers that lock, or checking items with security. In addition, facilities cover or replace items if the loss is the fault of the facility.

However, LTC facilities do not have total control over a resident's personal property. In addition, many elderly residents have varying levels of memory loss, which can make it difficult to keep track of items. Further, it can be hard to substantiate claims of loss. We are concerned that, under CMS's proposal, facilities would feel compelled to replace any item reported as missing, regardless of whether the facility was responsible, to avoid the larger expense of being taken to court.

Facilities should be able to set reasonable expectations about what they can and cannot do to protect personal property, and they should be able to take preventive measures such as discouraging skilled nursing facility (SNF) residents from bringing in items of value that are not helpful in the recovery process but which create burdens for health care staff to safeguard. For

example, it is reasonable to encourage residents to safeguard items like expensive jewelry at home or with family members.

Contractors. We seek clarification about the use of contractors. 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 the final rule, we ask CMS to clarify whether these provisions apply to all contract arrangements or only those with unsupervised access to patients. We believe this provision would be very difficult to implement for all contracts. For example, LTC facilities may have service agreements with electrical or cable companies. LTC facilities may not have complete control over who the company sends to provide services. Other times, an individual might be hired on a contract basis to do marketing, chart review or other such administrative services and would have no direct access to patients or their belongings.

PHARMACY SERVICES

We ask for changes to and clarifications of several proposed pharmacy services requirements.

Records review. 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 QAA committee has requested be included in the pharmacist's monthly drug review.

CMS should outline exceptions to this policy when the resident returns from the hospital.

For example, sometimes a resident may be transferred to the hospital temporarily for a diagnostic procedure, medical test or minor medical procedure. In these instances, the patient's medications are not altered, and nothing has changed the patient's condition. When a resident returns from the hospital, an appropriate licensed physician or practitioner should review his or her record to understand what happened at the hospital, but the pharmacist should not have to review either the record or drug regimen unless there was a change in drug therapy.

<u>PRN orders</u>. We have concerns about the proposed requirement that PRN (or "as needed") orders for a psychotropic drug be limited to 48 hours unless the resident's physician or primary care provider documents justification for continuation. Given the proposed expanded definition of psychotropic drugs, this proposal is confusing and may be inconsistent

with clinical needs. For example, a clinician could prescribe an anti-anxiety medication for a resident to take as needed, when symptoms arise. Those symptoms may arise once every few weeks or months, and it would be important for the resident to have the medication on hand. We ask CMS to explicitly describe how it expects the physician or primary health care provider to document that justification in the medical record. Further, if CMS finalizes this provision, we ask CMS to clarify that the physician or health care provider *would not need to document the justification every 48 hours*, as some stakeholders have interpreted this proposed provision.

<u>Cost</u>. AHA is concerned about the cost of the proposed pharmacy changes. SNFs often rely on pharmacy vendors, and we understand that the vendor market has recently undergone significant consolidation. With this in mind, we are concerned about both the ability of vendors to provide the proposed services as well as the associated costs. We ask CMS to continue to work with stakeholders to develop true and accurate cost estimates for its proposed pharmacy services and antibiotic stewardship program requirements to ensure that the costs will be manageable.

COMPREHENSIVE PERSON-CENTERED CARE PLANNING

We ask CMS to clarify its proposals for discharge planning. In the proposed rule, CMS will require that facilities develop and implement an effective discharge planning process that will result in the development of a discharge plan for each resident. Based in part upon how the proposed regulatory language is worded, we ask CMS to clarify whether it intended for the discharge planning requirements to apply to *all* residents. We agree that LTC facilities should understand the discharge goals of each resident regardless of whether he or she expects to be in facility for a short time (such as those receiving temporary SNF services) or whether the nursing facility is his or her current home. However, it does not make sense to create a discharge plan for those residents who expect to remain in the nursing home permanently. We urge CMS to clarify that residents who are permanent placements would not need a discharge plan.

TRANSITIONS OF CARE

The AHA asks CMS to change a proposal related to transitions of care. In a newly titled "Transitions of Care" section, CMS 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 would need to address 18 elements, including data about unique device identifiers (UDI) for any implantable devices. While the AHA supports the use of the UDI to improve care and patient safety, we believe the inclusion of UDIs is premature. The Food and Drug Administration has not fully implemented its UDI program, and we do not believe it will be fully operational until 2020. Furthermore, current EHR technology does not yet permit electronic summary of care documents that will support inclusion of the UDI, or even consensus standards for including the UDI in electronic records. At a minimum, CMS should delay implementation of this data element until the UDI has been fully rolled out and EHRs certified through the federal certification program are able to support the UDI.

VISITATION

We agree that LTC facilities should have resident-centered visitation policies and are supportive of CMS's proposals. Under the proposed rule, 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. The proposed rule would further 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.

The proposed text of the regulation would allow reasonable limitations on visitation policies, which we support. Nevertheless, we have heard concerns that open visitation policies might be disruptive to roommates, such as if a resident received a visitor late in the evening. We ask CMS to clarify in the final rule its expectations that open visitation policies should be implemented in a way that maintains the privacy of and respect for roommates.

Further, we do not believe that the cost estimates take into account the true effort that some LTC facilities will need to undertake to comply with an open, 24-hour visitation policy. For example, some nursing homes may need to hire additional staff, such as a receptionist, who can sign visitors in after hours and verify that residents have consented to see them.

BED RAILS

We support, but ask for clarification about, proposed requirements pertaining to bed rails. The proposed rule would require bed rails to be correctly installed, used and maintained, and that facilities obtain informed consent prior to installation of bed rails. In the final rule, we ask CMS to clearly articulate all of the types of devices it considers to be "bed rails." For example, residents may have "assist bars" or "grab bars" that are not full bed rails, but which help prevent falls.

PHYSICAL ENVIRONMENT

We do not support the requirement that, for new construction or reconstruction projects, each resident room must have a bathroom equipped with a shower. This provision could prove cost prohibitive for some older buildings, given issues with access to plumbing. Especially for facilities whose payer mixes are predominantly comprised of Medicaid, such requirements may preclude facilities from upgrading. In addition, we ask for clarification about whether a shared Jack-and-Jill style bathroom arrangement would satisfy the requirement for each room to have its own bathroom.

ADMINISTRATION

We ask CMS to amend a proposal related to licensing of LTC facility administrators. Current regulations require that governing bodies of LTC facilities must appoint an administrator who is licensed by the state *where licensing is required*. CMS would delete the words "where licensing is required" because states participating in the Medicaid program are required by federal law to license nursing home administrators.

However, we are unclear how this provision would apply to distinct part units of hospitals, and we know that it would conflict with the requirements of at least one state — California — that make an exception for SNF distinct part units. The AHA does not believe that administrators of hospitals or critical access hospitals with SNF distinct part units should be required to be licensed as nursing facility administrators. We urge CMS to clarify in the final rule that a hospital administrator does not need to obtain such certification.

DEFINITIONS

We support the inclusion of a definition for "abuse," but we ask CMS to clarify its proposed language.

CMS proposes the following definition of abuse:

Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse 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, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful*, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

The AHA fully supports CMS's expanded emphasis on preventing abuse and its inclusion of a definition for "abuse" in the proposed rule. However, we believe the definition needs significant clarification with respect to the explanation of the term "willful." This explanation is vague, and we ask CMS to further define what types of actions the agency is trying to prevent. We are concerned that the proposed definition could capture many types of actions that should not be considered abuse.

For example, a nurse may provide medication to a patient not knowing that they are allergic to it, either because it is the first time the patient is given the mediation or because an adequate history is not available to the LTC facility. In that case, the nurse would certainly have acted deliberately, but he or she would not have intended harm. Nevertheless, his or her actions may be

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considered to be abuse under the proposed definition. We can think of many variations of this theme, involving the provision of medical treatment to residents or honest mistakes by well-meaning staff. Therefore, we urge CMS to revise its language to address our concerns and specifically to find a more precise term than "deliberately."

Thank you again for the opportunity to comment. If you have any questions, please contact me or Evelyn Knolle, senior associate director of policy, at eknolle@aha.org.

Sincerely,

/s/

Tom Nickels Executive Vice President