



A Passionate Voice for Compassionate Care

October 13, 2015

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: REF CMS-3260-P

RE: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule (Federal Register Vol. 80, No. 136, July 16, 2015)

Dear Administrator Slavitt:

The Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,200 Catholic health care systems, hospitals, long-term care facilities, sponsors, and related organizations, appreciates the opportunity to comment on the referenced proposal by the Centers for Medicare and Medicaid Services (CMS) to revise the requirements applicable to long term care facilities for participation in the Medicare and Medicaid programs.

CHA strongly supports CMS' objective to encourage more person-centered nursing home care. We support the many efforts throughout this proposed rule to include residents and their representatives in care; to support more home-like environments; to provide care that is more culturally and trauma-informed; to expand the role of physician's assistants, nurse practitioners, clinical nurse specialists and other non-physician health providers as appropriate; and to make information about the facilities and residents' transitions more transparent.

While we applaud the overall objectives of this rule, we are also concerned that the proposed requirements lack clarity in many places. In addition, the costs and resources that would be required to implement the changes are far more extensive than CMS has estimated in its regulatory impact statement. We appreciate the 30 day extension of the formal comment period but we are still concerned that the breadth of the proposed rule could mean that facilities will not be able to adequately assess and prepare for the significant changes the proposal will bring. We urge CMS to consider appropriate ways to allow stakeholders as well as CMS to more fully assess the effect of the proposed rules on cost and access to nursing facility services, and to

evaluate the potential for unintended consequences. One option CMS could pursue is to move forward with those components that are non-controversial, time-sensitive, or not likely to be cost and resource intensive. Other components of the rule that raise serious concerns or require further analysis to understand their potential effects could be separated and moved forward once more careful deliberation has been conducted. CMS should also actively involve stakeholders in the development of necessary sub-regulatory guidance.

We agree with CMS that the implementation of the sweeping changes contemplated in this proposed regulation may take longer to implement than other more limited regulatory changes, and appreciate that CMS is seeking feedback from commenters on the implementation timeframes. In addition to the concerns CMS has raised regarding the time needed to develop revised interpretive guidance and survey processes, to conduct surveyor training and to implement software changes for QIS systems, we are concerned that the cost of implementing these provisions could be overwhelming, especially for smaller facilities. As a result, we recommend that CMS establish an extended timeline for implementation that takes place over a period of at least five years. A long phase-in would allow the cost and resource intensive provisions to be spread over multiple fiscal periods, thereby reducing the likelihood that the costs of the provisions will adversely affect access or quality of care for residents.

CMS describes one of its overall objectives for the revisions to the requirements of participation to be the reduction of unnecessary hospitalizations. We urge CMS to take this opportunity to consider the use of telemedicine services as having a potential role in helping many facilities, especially those located in rural areas, to achieve that objective. Research continues to accumulate about the benefits of telemedicine services in general. Nursing homes in particular that use telemedicine to provide after-hours care have been able to reduce hospitalization rates for residents and to reduce Medicare costs.¹ We urge CMS to incorporate and support the use of telemedicine services as a viable alternative to in-person physician meetings whenever telemedicine provides a safe and potentially effective alternative. We also recommend that CMS recognize the use of telemedicine by clinicians as an acceptable approach to assessing, evaluating and treating residents of nursing facilities. This can be particularly helpful for facilities that need support during off-hours, are in rural or remote locations, or that depend on a small number of physicians and other clinicians to provide care to residents.

In addition to those broader issues, CHA provides comments on specific provisions as follows:

Resident's Rights (§483.10)

CHA endorses the principle that residents should be able to choose their own doctors. However we recommend that CMS provide additional clarification on the right of residents to choose their own attending physicians. For example, how does this right apply to residents who are enrolled

¹ D. C. Grabowski and A. J. O'Malley, "Use of Telemedicine Can Reduce Hospitalizations of Nursing Home Residents and Generate Savings for Medicare," *Health Affairs*, Feb. 2014 33(2):244–50.

in a managed care plan or any plan with limited networks of providers? Could the beneficiary be limited to choosing only participating providers? Clarification is also needed concerning credentialing. Facilities would need to ensure (as further specified in Facility Responsibilities (§483.11)) that the chosen attending physicians are appropriately licensed and credentialed. Verification of professional credentialing requirements can take time. While that process is being completed with respect to the resident's chosen doctor, the resident may need to be attended by another credentialed physician. We also ask CMS to reconsider the application of this requirement in sub-acute settings where residents generally have shorter lengths of stay.

CHA agrees that facilities should provide residents with reasonable access to means of communication such as telephones, resident-owned cell phones and other forms of electronic communication. While cell phone coverage and internet access has expanded rapidly, there are still some areas of the country that have no or very poor access to these services. The proposed regulations note that the required access to electronic communications is subject to whether such access is available at the facility. CHA suggests that the final rule include a similar caveat with respect to the availability of cell phone coverage.

Facility Responsibilities (§483.11)

In new paragraph §483.11(d)(2) CMS proposes to support patient-centered care and to increase a resident's self-determination by requiring that facilities make visitation policies more open. Further, a facility would be required to provide "immediate access" to a resident by immediate family and other relatives, as well as to other visitors (see also proposed §483.10(e) to give residents the right to "[r]eceive visitors of his or her choosing at the time of his or her choosing"). The requirement with respect to other visitors is made "subject to reasonable clinical and safety restrictions." There are similar provisions in existing regulations. While CHA believes that every effort should be made to ensure that residents have access to family members and other visitors, the unqualified "immediate access" requirement raises safety concerns as many facilities do not have the security and other staff available to accommodate twenty-four hour visitation policies. In addition, this policy raises the issue of whether facilities would be allowed to restrict or bar family members or other visitors who become violent or may pose a threat to other residents and staff. Accordingly, we recommend that visitation by both family members and other visitors be subject to "reasonable clinical, safety and security restrictions." CHA asks CMS to clarify that a general restriction on visitation during the night would be reasonable. However failure to accommodate by family members who are only able to visit during those hours would not be deemed reasonable.

Proposed §483.11(e)(7)(i), appearing as §483.10(b)(11) in existing rules, requires facilities to immediately inform the resident, consult with the resident's physician and notify the resident's representative when there is an accident which results in injury and has the potential for requiring physician intervention. We have heard reports that the phrase "potential for requiring physician intervention" is unclear and results in physician notification when it is not necessary.

We suggest CMS consider clarifying this, perhaps by indicating that physicians should be notified only when the nursing staff believes there is a need for physician intervention.

Comprehensive Person-Centered Care Planning (§483.21)

CMS proposes to expand the membership of the interdisciplinary team responsible for preparing the comprehensive care plan and developing the discharge plan. A nurse aide with responsibility for the resident, a member of the food and nutrition services staff and a social worker would now be part of the team, which may also include other appropriate staff or professionals. CHA supports expanding the team in this way, but urges CMS to be mindful of placing additional demands on the time of those performing these functions. CMS should indicate that these positions can participate in the planning process in a way that does not require them to attend in-person meetings.

In §483.21(b)(3), CMS proposes to require that facilities ensure that services in a resident's comprehensive care plan are provided in a culturally-competent and trauma-informed manner. In §483.25(d), CMS further proposes to include trauma-informed care as a special care issue. As part of that, the facility also must ensure that residents who are trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice, and that the care provided to the residents accounts for their experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization. However, CMS does not provide definitions for the meaning of "culturally competent care" and "trauma-informed care." At this time, there is not a generally accepted understanding of what comprises care that minimizes triggers and re-traumatization or care that is culturally competent and trauma-informed. While CHA appreciates the references to SAMSHA principles for such care, we request that CMS provide additional non-regulatory guidance to facilities on what CMS expects facilities to do to meet these requirements.

Quality of Care and Quality of Life (§483.25)

Existing regulations identify care issues of special concern. For each of those special care areas, a facility must ensure that residents receive treatment and care in accordance with professional standards of practice. CHA supports CMS' proposed additions to the list of special care issues. In particular, we support the inclusion of bed rails as a special care area and the inclusion of several elements that facilities must ensure are taken into account in using bed rails: that facilities attempt to use alternatives prior to installing a side or bed rail and that facilities obtain informed consent prior to such installation.

Physician Services (§483.30)

CMS proposes to require that a physician, physician assistant, nurse practitioner or clinical nurse specialist provide orders for a resident's immediate care needs on admission and provide an "in-person" evaluation of a resident before a non-emergent transfer to a hospital occurs. For many

facilities, especially those in rural communities or small stand-alone facilities, it may not be possible to provide such in-person evaluations in a short time period. Thus, this provision may have the unintended consequence of delaying care for people in need of immediate or urgent care. It could also create a problem for facilities when a resident or family member demands that the patient be transferred to a hospital when the situation is non-emergent and there is no physician, physician assistant, nurse practitioner or clinical nurse specialist available to provide an in-person evaluation.

CHA recommends that CMS drop the proposal for an in-person evaluation and allow any pre-transfer evaluation to occur by telephone or through a form of safe and appropriate telemedicine. CMS should also consider the use of on-line and other tools that empower nurses to assess symptoms and communicate with physicians about a resident's condition. Should CMS decide to finalize the proposal it should include guidance for facilities on how to resolve the potential conflicts it could create with patients or family members.

We support the aspect of the proposal that would allow non-physician professional staff to conduct a pre-transfer evaluation. CHA also supports the additional flexibility that CMS is proposing in §483.30(f)(3) allowing physicians to delegate the writing of dietary orders to qualified dietitians or other clinically qualified nutrition professionals, and therapy orders to qualified therapists.

Nursing Services (§483.35)

Ensuring proper staffing of nursing facilities is of paramount importance to CHA and its members. We acknowledge, however, the complexity involved in setting specific staff ratio standards and share CMS' concerns regarding the complicated mix of factors that result in high quality care, including the skills and competencies of staff, as well as residents' needs and acuity. CMS carefully considered the possibility of setting minimum nurse staffing standards and declined to make such a proposal. We support CMS' decision not to create minimum nurse staffing standards and agree that facilities should examine their staffing needs.

CMS requests feedback on the recommendation offered by the Institute of Medicine (IOM) that a registered nurse (RN) be present within every facility at all times. Our members' experience suggests that such a requirement would be problematic for many facilities to meet, especially those in rural areas. Rural facilities are often in areas that have too few RNs and have a difficult time competing with other employers for the limited number in the community. CHA would oppose a proposal to require an RN to be present at all times.

Pharmacy Services (§483.45)

We have serious concerns about several of the changes proposed in §483.45. While we appreciate and share CMS' overall objective of reducing the inappropriate use of antipsychotic medications, we are concerned that the proposed changes in this section are overly broad; will

create barriers to good patient care; will undermine good pain management; and will cause unnecessary distress among residents, their families and nursing facility staff.

Under the proposal, CMS applies certain limitations to “psychotropic medications” that under existing rules only apply to antipsychotic medications. However, the proposed rule would define “psychotropic medications” very broadly, including all drugs that affect brain activities associated with mental processes and behavior. This sweeps in, for example, analgesics, antidepressants and anti-anxiety drugs as well as other drugs that have similar effects. CHA recommends that CMS narrow its definition to target the drugs that are truly of concern.

Further, CMS proposes to impose a limit on the use of PRN orders for all drugs falling into that broad group of psychotropic drugs. Specifically, CMS proposes that “PRN orders for psychotropic drugs are limited to 48 hours and cannot be continued beyond that time unless the resident’s physician or primary care provider documents the rationale for this continuation in the resident’s clinical record.” While CHA agrees it is wise to review PRN orders, we are concerned that the proposed language appears to require a facility to contact the attending physician every 48 hours to renew orders for patients who struggle with pain management, including those who have had recent surgery or suffer from many other painful conditions such as bone fractures, open wounds and ulcers. These provisions together would undermine CMS’ otherwise stated priority of pain management and would increase substantially the burden on staff and attending physicians. We strongly urge that CMS not finalize this proposal.

We are also concerned about the proposal to require pharmacy review of the medical charts of new patients and patients transferred to the facility. Such reviews likely would require an on-site visit by a pharmacist. In many facilities on-site pharmacists provide a medication review for new and readmitted patients. Some nursing homes have so many admissions that reviewing medical records of all admissions would necessitate the daily presence of a pharmacist, which would constitute a significant additional cost. CMS should drop this proposal or amend it to make clear that pharmacist review of the full medical chart could take place within a given time period following the admission or readmission.

Dental Services (§483.55)

CMS proposes that facilities must refer a resident for dental services within three business days or less from the time that a resident’s dentures are lost or damaged. We assume the word “refer” is used here in the sense of directing someone to a source of information, and that what is intended is that the facility provide residents with the information they need to set up an appointment with a dentist within three days. But if CMS intends to require that the resident actually see a dentist within three days we would be concerned that this timeline is unrealistic as it does not account for the usual wait times for dental appointments, nor would it allow the facility to accommodate residents who may prefer to wait longer in order to see a dentist of their choice. We recommend CMS clarify that this is not a requirement to have the appointment take

place within three days. If the intention is to provide a timeline for the occurrence of the appointment, we urge CMS not to finalize the proposal.

Food and Nutrition Services (§483.60)

CHA strongly supports CMS' proposed changes to increase the use of local food sources and to take into account resident preferences in food and nutrition policies, for example, by replacing the existing requirement that there be no more than 14 hours between evening meals and breakfast with the requirement to provide suitable nourishing alternative meals and snacks. Such flexibility would greatly improve a resident's quality of life by allowing for those who prefer eating at non-traditional times to be able to do so. We also support the flexibility in the proposed rule allowing attending physicians to delegate to dietitians or other qualified nutrition professionals the task of prescribing a patient's diet, to the extent it is allowed by state law. Dietitians and other non-physician professionals are often able to identify issues or areas of concern before attending physicians and, with the physician's permission, could act on those more quickly than attending physicians.

Administration (§483.70)

As noted above, we generally support CMS' proposal to require facilities to examine their staffing needs (proposed in §483.70(e)) and to establish competency-based workforce standards instead of setting specific minimum numbers of nursing staff per resident or numbers of hours of nursing care. We are concerned, however, that the comprehensive facility assessment for establishing staffing is not well defined. What would compliance with this requirement entail? How often would it have to be updated?

Further, competency-based standards are not clearly defined, and in most cases generally accepted and understood competency-based standards do not exist. Without guidance or additional clarity, our presumption is that the responsibility for determining "competency" falls to each individual facility. Specific areas for which competency-based requirements are added by this rule include:

- Nurse staffing (§483.35) would establish a competency requirement for determining sufficient nursing staff based on a facility assessment and would require that nurse aides and non-permanent caregivers meet competency knowledge and skill requirements to the same extent as permanent personnel; and
- Behavioral health (§483.40) would require that staff have appropriate competencies and skills to provide behavioral health services.

We are concerned about how these standards will be operationalized and what the implications of facility-specific standards will be for survey and certifications. Will surveyors automatically

accept whatever standards are established by each facility? Will additional guidance on setting such standards be provided?

CMS also proposes new criteria which must be met in order for facilities and residents to agree to use binding arbitration to resolve disputes. The proposal is intended to address CMS' stated concern that some residents may be, or may feel, coerced into agreeing to arbitration provisions. While we share CMS' aversion to resident coercion, we believe that existing state contract law provides adequate protection against unfair or unconscionable arbitration agreements. The question of whether a given agreement should be revoked on those grounds should be decided by state courts after consideration of the facts and in light of years of case law on the subject, not by surveyors. For example, determining whether an agreement was fully understood and entered into voluntarily requires a full examination of the facts and circumstances surrounding the agreement. This is a type of inquiry appropriate for courts, not surveyors. One of the proposed limitations on binding arbitration agreements provides that such agreements may not prohibit or discourage residents from communicating with federal, state or local officials, including surveyors and ombudsmen. We believe this issue is covered elsewhere in the rules covering residents' right to communicate with and access persons inside and outside the facility.

CMS also invites comments on whether arbitration agreements should be prohibited. The right of parties, including SNFs and their residents, to agree to binding arbitration under the Federal Arbitration Act is well-established and confirmed by the Supreme Court. (See , e.g., *Marmet Health Care Ctr., Inc. v. Brown*, 132 S. Ct. 1201 (2012)). As CMS notes in the preamble, banning such agreements would deprive the resident of the right to choose binding arbitration. Residents may prefer to submit disputes to arbitration rather than judicial review for many reasons, including to achieve a faster and less costly resolution. They should not be denied this option.

For these reasons, we believe CMS should not include in the final rule restrictions on the right of the parties to agree to binding arbitration.

Quality Assurance and Performance Improvement (QAPI) (§483.75)

The proposed provisions in §483.75((a)(2-4) require facilities to present their QAPI plan to the state agency surveyor at the first annual recertification survey that occurs after the effective date of the regulation and to a state agency or federal surveyor at each annual recertification survey. In addition, documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the requirement must be made available to a state agency, or federal surveyor or to CMS, upon request. Combined with §483.11(e)(3), which would require a facility to make available reports with respect to any surveys, certifications and complaint investigations during the three preceding years for any individual to review upon request, the two provisions raise serious confidentiality concerns for facilities. Such materials are currently internal documents that are not prepared for public purposes. We urge CMS to clarify that these

provisions as taken together are not intended to have the effect of making the results of facilities' QAPI programs available to surveyors and to the public.

Infection Control (§483.80)

CHA supports CMS' proposals to update and strengthen infection control policies by incorporating infection prevention, adding specific elements to infection control programs (for example, by requiring facilities to designate an infection prevention and control officer) and tying infection control into quality assessment activities. These changes, however, are a good example of the need to phase-in implementation of the proposed conditions. We expect that many facilities, particularly those that are small or in rural areas, will not be able to hire an Infection Prevention and Control Officer (IPCO) with specialized training whose infection control duties are their primary responsibility. Many of those facilities already struggle to keep staffing levels up and to compete for RNs.

We recommend that the IPCO have duties that are clearly delineated in a job description and that facilities have the flexibility to give these responsibilities to existing staff -- for example, to the staff education coordinator or the assistant director of nursing.

Training Requirements (§483.95)

CMS proposes to establish a new section for nursing home requirements that would pull together all standards related to an effective training program for staff, including volunteers and staff under contracts. In this new section, CMS proposes a number of new and more specific training and education requirements for staff. For example, facilities would be required to provide education on activities that constitute abuse, neglect, exploitation or misappropriation of resident property, and the procedures for reporting these incidents; on infection prevention and control programs; on Quality Assurance and Performance Improvement Programs; on behavioral health and, for nurse aides, dementia and resident abuse prevention. Considering the deluge of new training responsibilities, we urge CMS to assist facilities in these requirements by identifying training resources, and gathering and disseminating best practices and protocols.

Estimates of Burden Hours and Cost Estimates

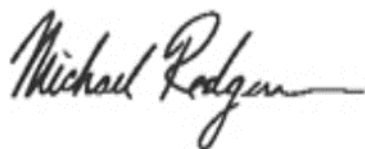
We believe CMS has underestimated the cost impact of the proposed changes and that if the rule is finalized the costs will likely exceed those estimates by a considerable amount. In many cases, the estimates presented seem to reflect the lowest possible cost outcome instead of the middle of the distribution of possible outcomes. They often incorporate the cost of the lowest paid staff to do activities that facilities would likely require more highly paid staff to do. Moreover, we believe that the costs of many of the proposed provisions would likely raise considerable difficulties for many nursing home providers, particularly small facilities or those in rural areas that will not have the resources to make the required facility or staff changes. Some specific examples of costs that we believe have been considerably underestimated include:

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- The right of a resident to sign their care plan (§483.10(B)(5)(v)). CMS estimates that it will take two minutes for a nurse to obtain a resident's signature on a patient's care plan. However, two minutes is likely to be a best case scenario only for the most highly-functioning residents who ask no questions. CMS does not account for the need to physically reposition a resident (which in many cases, can require additional staff); the time it would take for a nursing staff member to remind the resident of what a care plan is; to review what is in their care plan; to describe why the resident is being asked to sign the plan; and to answer any questions that are raised.
- Making the grievance policy available to residents upon request (§483.11(h)(1)). CMS estimates the cost of this requirement to be based on a clerk taking ten minutes to update the required notice describing the facility's grievance policy. CMS does not include the costs of providing the notices to residents; walking residents through the policy; and answering their questions – activities that a clerk would not be qualified to conduct. A more realistic estimate would include closer to 30 minutes for a nurse or grievance official to provide the notices to each of the residents requesting the information.
- Infection control program (§483.80). CMS does not include a number of components of the costs of establishing an infection control program including, for example, the cost of education, linens and the antibiotic stewardship programs.

In closing, thank you for the opportunity to provide comments to the revised requirements for long term care facility participation in the Medicare and Medicaid programs. If you have any questions about these comments or need more information, please do not hesitate to contact Julie Trocchio, Senior Director for Community Benefit and Continuing Care or Kathy Curran, Senior Director Public Policy at 202-296-3993.

Sincerely,



Michael Rodgers
Senior Vice President
Public Policy and Advocacy