Andy Slavitt

Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Room 445-G, Hubert H. Humphrey Building

200 Independence Ave., S.W.

Washington, D.C. 20201

**Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities**

**MCS-3260-P**

**Submitted electronically:** [**http://www.regulations.gov**](http://www.regulations.gov)

Dear Acting Administrator Slavitt:

 [Brief introduction of organization submitting comments, with explanation of why your organization is interested in the federal nursing home regulations.]

[Name of organization] thanks CMS for its work in revising the Requirements of Participation (RoPs) and appreciates the time and effort necessary for such a major overhaul. In general, we support the overall focus on person-centered care that is found throughout the proposed regulations and believe this will enhance residents’ quality of care and quality of life. There are other aspects of the proposed requirements that we support as well, including a greater focus on resident choice and preferences; more robust protections against abuse and neglect; and enhancements to the care planning process, such as a greater emphasis on resident participation. We are also pleased that residents’ rights have been strengthened in certain provisions.

CMS, however, has failed to address the greatest problem in nursing homes today ––inadequate staffing. Good staffing practices are necessary for facilities to deliver preventive, quality person-centered care. They start with adequate numbers of nurses and nurse aides. Building on that foundation, good practices include competent staff, as well as systems that promote individualized care, consistency, communication, and continuity.

We hear from our network many concerns about insufficient nursing staff. The absence of a minimum staffing standard and a registered nurse round the clock can and does harm nursing home residents. The proposed language of “sufficient nursing staff” with “competencies” based on a facility assessment does not adequately protect residents when nursing homes owned by corporations or private equity firms are incentivized in many ways to reduce staffing to dangerously low levels. The proposed regulations must explicitly establish a level below which staffing cannot be cut. Without detailed, explicit staffing standards, many nursing homes will not meet the needs of the frail elders and individuals with disabilities who reside there, nor will they comply with many of the proposed regulations.

We believe that the following issues deserve particular consideration. In some instances we have recommended revisions to the proposed regulations; in others, we indicate our support of the approach taken in the proposed regulations.

**Staffing - Nursing services**

CMS Should Require a Minimum Staffing Standard of at Least 4.1 Hours of Direct Care Nursing Per Resident Day and 24-hour Registered Nurse Coverage (§483.35)

We are deeply concerned that CMS has chosen to not mandate a specific minimum staffing standard or 24-hour registered nurse coverage. The lack of these provisions has been a major obstacle to quality care since the Nursing Home Reform Law was passed in 1987 and will continue to be until these standards are adopted.

**Minimum staffing standard of 4.1 hours per resident day (HPRD)**

Why a minimum is needed

The proposed requirement calls for “sufficient nursing staff with the appropriate competencies and skills sets.” This fails to address the long-standing problem that “sufficient” is vague and ambiguous. In addition, the “appropriate competencies and skills sets” do not take into consideration the number of staff and are to be determined by a facility assessment that CMS states is already an industry practice. We are deeply concerned that this will not result in increased staffing and even worse, that the growth of multistate for-profit corporations, the emergence of private equity firms in the nursing home market and the trend toward managed long-term care will create strong incentives for facilities to reduce costs by cutting staff.

Why the minimum should be 4.1 hours of direct care nursing per resident day (at least 2.8 hours from certified nursing assistants, 0.55 from licensed practical/vocational nurses; 0.75 from registered nurses)

There are several studies that support a minimum staffing standard of at least 4.1 hours per resident day. One of those studies is CMS’s own report, “Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes.” CMS discounts the findings of its study by stating that the HHS Secretary rejected the threshold of 4.1 due to concerns the data were not reliable at the facility level. However, additional studies, reports and articles support the 4.1 HPRD staffing level. These are listed in the comments submitted by the Consumer Voice.

**Twenty-four hour registered nurse**

Why a registered nurse is needed 24 hours a day

The current RoPs only mandate that facilities use a registered nurse (RN) eight continuous hours each day, seven days a week. These eight hours do not have to be spent providing care; they can be used to carry out any type of administrative tasks. Registered nurses by training and licensure have skills that are essential for timely assessment, intervention, and treatment.

Three Institute of Medicine studies[[1]](#endnote-1) have recommended that at least one RN be on duty at all times. Twenty-four hour RN coverage is essential because:

* The acuity level of nursing home residents has increased dramatically since the federal law was passed.[[2]](#endnote-2) Expert nursing skills are required to anticipate, identify and respond to changes in condition, ensure appropriate rehabilitation, and maximize the chances for a safe and timely discharge home.
* A resident’s condition can destabilize or deteriorate at any time. When that occurs, the individual must be immediately assessed and a determination made about whether the resident needs to go to the hospital for treatment or whether he or she can be properly cared for in the nursing home. Because physicians do not have to be on-site, registered nurses are often the only medical personnel in a nursing home with the education and licensure to conduct the assessment required for diagnosis and treatment.
* Higher RN levels result in lower antipsychotic use, fewer pressure ulcers, less restraint use and cognitive decline[[3]](#endnote-3) Of particular relevance to today’s health care improvement initiatives is the decrease in unnecessary hospitalizations of nursing home residents.[[4]](#endnote-4) Finally, we note that only 11% of nursing facilities nationwide report to CMS that they do not have enough RNs on staff for 24-hour RN coverage (see comments submitted by Consumer Voice for more information about this percentage) and a number of states already require some version of 24-hour RN coverage. Round-the-clock RN coverage is becoming the standard of care, and this standard should be reflected in the federal regulations.

**Arbitration**

Nursing Facilities Should Not Be Allowed to Obtain Blanket Arbitration Agreements Prior to a Dispute Arising (42 C.F.R. § 483.70(n))

CMS has asked for comments on “whether agreements for binding arbitration should be prohibited.” Our answer is an emphatic “yes.” More precisely, we recommend that agreements for arbitration not be allowed during admission or at any time prior to a dispute arising. It is unfair for nursing facilities to bind residents to arbitration at the time of admission. As a practical matter, residents (or resident representatives) sign arbitration agreements at admission not because they think arbitration is a good choice, but because they are routinely signing everything put in front of them.

Unlike other types of pre-dispute arbitration agreements, which may cover a single transaction or a specific type of dispute, arbitration agreements in nursing facilities cover every single aspect of a resident’s life, and may apply through weeks, months or years that the resident lives in the facility. Also, nursing facility arbitration agreements often involve claims involving (for example) pressure sores, infections, malnutrition, dehydration, asphyxiation, sexual assault, and death. It is unreasonable to expect residents and their representatives to make decisions regarding such catastrophic events during admission, long before the events have occurred.

Furthermore, the arbitration process tends to be slanted against consumers such as nursing facility residents. Arbitration companies have a financial incentive to side with the nursing facilities who are responsible for sending them cases on an ongoing basis. Also, discovery is limited in arbitration, hindering plaintiffs from developing their cases. Arbitration proceedings are secretive, often protected by confidentiality rules. And, while court filing fees are relatively nominal, arbitrators charge by the hour, with the extensive costs generally split between the parties.

As part of the proposed regulations, CMS rightly recognizes the significant negative impact of pre-dispute arbitration agreements, proposing regulatory language that would set various procedural protections. CMS’s proposed language, however well-intentioned, would make matters worse. No amount of procedural protections can change the basic power dynamic of the admissions process — incoming residents and their families are generally in a time of great stress, and the terms of the admission agreement are drafted exclusively by the facility. Worse, if CMS’s proposed language were to become law, nursing facilities would cite the regulatory language to courts as evidence that CMS approves nursing facility arbitration, and would argue that compliance with the regulation was proof that the arbitration agreement and the circumstances surrounding its signing were fair.

We emphasize that our recommendation would not prohibit a resident or resident’s representative from choosing arbitration after a dispute has arisen, if the resident or representative at that time concludes (likely through legal counsel) that arbitration is the best option. Any pre-dispute arbitration agreement, however — particularly if it is signed during the admission process — is unfair to residents and should not be allowed.

**Resident rights**

All Resident Rights Should be listed in the Resident Rights Section (§483.10)We are very concerned about the way in which CMS is proposing to restructure the section on Resident Rights. There are many important resident rights that have been moved from the current Resident Rights section and relocated in Facility Responsibilities. At the same time, many rights now found under “Facility Responsibilities” are not listed at all under Resident Rights. Since residents, their families and advocates look at the resident rights language to know what residents’ rights are (and they may be given copies of the federal rights), it is important that the statement of resident rights be thorough, comprehensive, and accurate. We recommend that the section on Resident Rights be rewritten to also include rights currently found under Facility Responsibilities.

Visitation Should not be Restricted for Clinical or Safety Reasons (§483.10(e)(3); §483.11(d)(1))

We strongly support the visitation rights provision and agree with CMS that being able to receive visitors of the resident’s choosing, at the time of the resident’s choosing, is an essential element of self-determination. Since the facility is the resident’s home, residents should have the same 24 hour access to visitors as those of us who live in the community.

However, we believe that this language is eroded by placing restrictions on visits that go beyond what is permitted under the Nursing Home Reform Law. The proposed changes would make visits from other visitors subject to reasonable “clinical and safety restrictions” and allow the facility to create written policies and procedures restricting resident access to visitors for clinical or safety reasons. Such restrictions are not consistent with federal law. We recommend that all references to clinically necessary or reasonable restriction or limitation or safety restriction or limitation be deleted and that the facility policies and procedures clearly state that residents have the right to 24-hour visitation.

All Admission Contacts Should Comply with the Federal Regulations (§ 483.11(e)(11))

We thank CMS for the provision that specifies that an admission contract must not conflict with the federal regulations. We request one small revision. The regulation’s current language applies only when the facility “requires” execution of an admission contract. The language should be changed to refer to all admission contracts, whether or not “required.” Nursing facilities often attempt to avoid contract-related laws by claiming that a resident or resident representative was not required to agree to a contract or provision, but purportedly “volunteered” to do so.

Access to Records Should Not Be Limited to Medical Records and Should Be Made Easier (§483(f)(3))

The proposed regulations would weaken residents’ rights to access their records. Current requirements give residents access to **all** their records. The new rule would change “all records” to “medical records,” giving residents access to less information than before. This is a step in the wrong direction. Moreover, the “cost-based fee” for the provision of copies that includes labor could easily become prohibitively expensive, further limiting a resident’s right to their records. We recommend restoring the current rule language of “all records” and eliminating any fees for labor costs.

Two additional and long-standing concerns with resident access to records have been the requirements that 1) the 24 hour time frame for accessing current records excludes weekends and holidays; and 2) the resident must inspect the record before purchasing it. Because the facility is the resident’s home, access to his or her records should be 24/7 and not contingent upon weekday staffing. Furthermore, the resident may wish to review his/her records with family members, whose visits may occur more frequently on the weekend and holidays. Additionally, we can see no valid reason for making residents inspect their records prior to purchasing copies except to delay resident access. There is no such requirement for individuals who wish to obtain copies of their records in settings outside of nursing homes. We urge CMS to remove both these requirements.

**“Transitions of Care”**

Resident Rights Should Continue To Be Described as “Rights,” Rather than Provisions Relating to “Transitions” (§ 483.15) Proposed section 483.15 uses the title “Transitions of Care,” although it contains many provisions that are denominated as “Admission, transfer and discharge rights” in current 42 C.F.R. § 483.12. The proposed loss of the term “rights” is troubling, for two reasons.

First, the term “rights” emphasizes the fact that a nursing facility is home to its residents, and they should not be deprived of that home except in rare circumstances. The term “transitions,” by contrast, suggests that a resident’s place of residence is of relatively little import as the resident “transitions” through levels of care.

Second, state nursing facility laws often incorporate the federal resident’s rights. If the federal rights in section 483.15 are no longer denominated as rights, they may not be incorporated by these state law provisions, which would lessen the protection extended to nursing facility residents.

Facilities Should Not Be Allowed to “Request” Improper Contractual Provisions (§ 483.15(a)(2), (3)) We strongly support the addition of the word “request” in subsections (2)(i), (ii), (iii), and (3). Sometimes facilities attempt to evade current law by using contracts that “request” but purportedly do not “require” residents to take on certain unfair obligations. From a consumer’s perspective, these provisions are objectionable whether the provision is phrased as a request or requirement. In either case, the facility is drafting the contract, and the resident (or resident representative) is signing the contract with little understanding of its contents, and little or no ability to negotiate terms.

Waivers of Liability Should Not Be Allowed (§ 483.15(a)(2)(iii)) We support the proposed provision that prohibits waivers of a facility’s liability for loss of personal property, but do not understand why this provision should be limited to personal property. All waivers of liability should be prohibited, whether they relate to (for example) the loss of a resident’s clothing, or negligent care by facility staff.

Admission Agreements Should Not Authorize the Nursing Facility to Sue a Resident’s Family Member or Friend for a Resident’s Unpaid Facility Bills (§ 483.15(a)(3)) Federal law prohibits a nursing facility from requiring a resident’s family member or friend to sign a financial guarantee to become financially responsible for the resident’s nursing facility expenses. Many facilities today are evading the no-financial-guarantee rule by using contracts that commit a resident representative to pay facility charges from the resident’s income or resources, and to take all necessary steps to submit a Medicaid application on the resident’s behalf. If the resident’s bill is unpaid, the facility then sues the representative on the contract, arguing that the representative has breached his or her contractual duties, and also arguing that this contractual obligation does not violate the no-financial-guarantee rule.

We ask CMS to revise the regulation to prohibit this evasion of current law. A resident’s family member should not face potentially enormous financial liability because a resident’s bill is (allegedly) not paid in full, or a Medicaid application is denied due to insufficient information. Such contractual provisions are just as unfair and coercive as the financial guarantees that explicitly are prohibited by current federal law.

We note that existing law has other tools for a nursing facility to use if a resident representative has misappropriated a resident’s money, rather than paying a facility. For example, courts have found family members liable to nursing facilities for fraudulent conveyance when they have used the resident’s money for themselves, rather than paying nursing facility bills.

Disclosure of “Special Characteristics or Service Limitations” Would Authorize Improper Transfers and Discharges (§ 483.15(a)(6))

We urge complete deletion of proposed section 483.15(a)(6), which obligates a nursing facility at admission to give “notice of special characteristics or service limitations.” The proposed subsection implies that a facility could use this notice to diminish the standard of care otherwise established by federal and state law, and to justify involuntary transfers and discharges for a purported inability to meet a resident’s needs.

The preamble discussion refers to a “more predictable” transfer if “the need for specific types of care or services later become necessary,” and gives the example of notice that a facility could not care for residents needing “psychiatric care.” In fact, many persons, both inside and outside of nursing facilities, have psychiatric diagnoses, and the nursing facility regulations explicitly establish a nursing facility’s duty to provide specialized services for residents with mental illness. Under the proposed subsection, a facility might well attempt to engineer the involuntary transfer or discharge of a “heavy care” resident with mental health issues, rather than providing the care otherwise required under the federal nursing facility law.

The preamble discussion also suggests that a facility’s “religious affiliation” might lead to a facility giving notice of “any special characteristics, requirements, or limitations.” This is a slippery slope, threatening a situation where a facility might cite its religious affiliation to justify various limitations on care.

For all these reasons, we urge the deletion of subsection (a)(6). If it were to go into effect, its primary effect would be to encourage facility discrimination against residents with higher care needs.

Facilities Should Not Be Allowed to Transfer or Discharge a Resident During an Appeal of an Involuntary Transfer/Discharge (§ 483.15(b)(1)(iii)) We support CMS’s common-sense protection to prohibit an involuntary transfer or discharge while the resident’s appeal is pending.

The Local Ombudsman Program Should Receive Copies of Notices of Proposed Transfer/Discharge (§ 483.15(b)(3)(i)) We support the proposed provision requiring copies of transfer/discharge notices be sent to the Long-Term Care Ombudsman Program. We ask CMS to consider deleting the language requiring resident consent since it seems an inherent conflict to have facility staff ask residents if they want a notice sent to the ombudsman in order to challenge the facility’s decision. We also suggest that the language be revised to specify that notice be sent to the local ombudsman office (rather than to the state ombudsman office, for example).

Facilities Should Not Feel an Obligation to Give Reduced Notice (§ 483.15(b)(4)(ii) Current law says that under certain circumstances a facility “may” give reduced notice of proposed transfer/discharge. In the proposed regulations, however, “may” has been changed to “must.”

We strongly recommend that the relevant language be changed back to “may.” Otherwise, a facility would feel an obligation to always give the most limited notice period possible, which would greatly disadvantage residents.

Readmission Should Be Made to the Same Room, If Possible (§ 483.15(c)(3)(i)) We support the proposed requirement that, in readmitting a hospitalized resident to the next available nursing facility bed, the resident should be readmitted to the previous room, if that room is available

Residents Should Have a Right to Appeal When Bed Hold or Readmission Request Is Denied (§ 483.15(c)(3)(ii) We are both encouraged and troubled by subsection (c)(3)(ii) which, in our reading, authorizes an administrative hearing for residents who have been denied readmission. The troubling aspects of the subsection are its limited scope and vague language. The subsection relates only to readmissions, but should also include instances when a facility refuses to honor a bed hold. Our biggest concern is the subsection’s failure to clearly state that a resident has an appeal right when he or she is not allowed to return to a facility after a hospitalization or other therapeutic leave. Given the importance of appeal rights, and the many instances in which nursing facilities essentially dump residents in hospitals, the final regulations should be much more explicit in stating that a resident has a right to appeal when denied his or her rights under a bed hold or under the provision that provides readmission to the next available room.

We also recommend that the regulation be revised to specify that a facility can only refuse a bed hold or a readmission right if 1) the resident’s needs cannot be met in the facility, or the resident’s presence in the facility would endanger others’ safety or health, and 2) the resident’s condition does not allow for the facility to follow the standard notice procedures for involuntary transfers and discharges. In general, a hospitalization should not be a means for a facility to evade the normal procedural requirements applicable to involuntary transfers and discharges.

**Assessment and care planning**

Requirement to Assess A Resident’s Strengths, Goals, Life History and Preferences Promotes Person-Centered Care (§483.20(b)(1))

We are pleased that a facility would be required to assess a resident’s strengths, goals, life history and preferences since this would help staff know more about the resident as a person. Involving direct access staff would provide additional valuable information. These employees have contact and interaction with residents and often know a great deal about the resident, how he or she is doing and his or her needs and preferences. We recommend that direct access staff be defined in order to provide more clarity.

Developing Baseline Care Plan Would Benefit Residents and Should Include Additional information (§483.21(a)(1)(i))

We strongly support requiring the facility to develop a baseline care plan. Staff need to have relevant information about the resident and instructions for care immediately upon admission in order to support the resident in an individualized and person-centered manner and prevent decline and injury. CMS should also require the facility to obtain information about the resident’s customary routines and preferences, as well as medication orders.

Inclusion of a Nurse Aide, Social Worker, Food and Nutrition Services Staff Would Strengthen Interdisciplinary Team and Pharmacist Should Be Added in Certain Cases (§483.21(b)((2)(ii))

We commend CMS for proposing that the interdisciplinary team include a nurse aide with responsibility for the resident, a member of the food and nutrition services staff and a social worker. We urge CMS to also mandate the participation of a pharmacist if a resident is prescribed psychotropic drugs. A pharmacist has the professional background to advise the interdisciplinary team (IDT) about drug interactions and the inappropriateness of antipsychotic drugs for individuals who do not have a diagnosis of psychosis, among other issues.

Facilities Should Do More to Facilitate and Promote Resident and Resident Representative Involvement in Care Planning Process (§483.21(b)((2)(ii))(F))

Including the resident and the resident’s representative(s) in the IDT is essential, and the proposed requirement that the facility would have to provide an explanation if such participation is found not practicable would better ensure resident involvement in decision making. However, we believe that CMS has not gone far enough and recommend the facility facilitate and promote resident and resident representative involvement. Facilitation would entail advance written notice of the date and time of the care plan meeting and reasonable accommodation of the schedules of the resident, resident representative or others invited at the resident’s request. Additionally, the facility should also arrange for conference calls or electronic tools for video conferencing if necessary to permit participation.

Discharge Planning and Summary Requirements Would Involve Residents More, Provide Better Information ((§483.21(c))

We applaud CMS for putting forth comprehensive and meaningful requirements for discharge planning. For too long, facilities have not sufficiently involved residents and their representatives in discharge planning, and residents have left the facility with inadequate preparation and too little information for the receiving providers.

Facilities Should Do More to Assess Caregiver/Support People and Help Residents Who Are Leaving (§483.21(c)(1)(iv))

We recommend that capacity, capability and willingness of a caregiver/support person to perform required care must not only be considered, but also assessed, because some may think they can do more than they really can and others may not want to perform care at all.

While individuals transitioning out of a nursing home or moving to another healthcare facility often have family or friends to help them, this is not always the case. If requested, the facility should be required to assist with the tasks necessary for relocation, such as making phone calls, packing, and obtaining prescriptions needed post-discharge.

**Quality of Life**

Quality of Life Should Be Restored to Its Own Section

We strongly oppose combining the Quality of Care and Quality of Life sections. One of the groundbreaking and revolutionary aspects of the Nursing Home Reform Law (NHRL) has always been that it entitles nursing home residents to quality of life as well as quality of care. Never before - either in the pre-1987 nursing home regulations or in other health care settings - had quality of life featured so prominently in a law and been elevated to the same level of importance as quality of care.

Deleting the Quality of Life Requirement of Participation undoes that by sending a strong message that Quality of Life is not essential. In the preamble, CMS argues that making care planning a stand- alone section raises its importance: “we believe that relocating the requirements to a new section dedicated solely to care planning would emphasize the importance of care planning….” It follows that the reverse is true – eliminating the section on Quality of Life reduces its importance. This seems contrary to CMS’ stated intent to promote person-centered care.

Also troubling is that CMS has scattered the provisions currently under Quality of Life through the proposed regulations. The requirement that a facility must maintain or enhance each resident’s quality of life is under Facility Responsibilities, while most of the other provisions are under Resident’s Rights. They no longer come together to form a coherent whole that gives a comprehensive sense of what the components are of quality of life. Just one provision remains in the proposed Quality of Care and Quality of Life section – activities. We recommend that Quality of Life be restored as its own section that includes language from self-determination (proposed rule 483.11(e); social services (proposed rule 483.40(d); and safe environment (proposed rule 483.11(g), in addition to the language in the proposed rule about activities.

**Training**

Requirements Would Be Increased, But More Needs to Be Done (§483.95)

We are pleased to see that CMS proposes training requirements for all staff, contractual employees, and volunteers on a number of important topics, including communication, residents’ rights, and abuse, neglect and exploitation. Ensuring that everyone who works or volunteers in a nursing home is knowledgeable in these areas will improve both quality of care and quality of life. We urge CMS to expand these required topics to also cover the aging process; appropriate dementia care (we believe this is a much more person-centered term than “dementia management”); and resident abuse prevention.

We believe that all operating organizations should be required to provide training on compliance and ethics annually, not just those that operate five or more facilities. We see no reason why the number of facilities should be a factor.

We support including dementia management and resident abuse prevention in in-service trainings for nurse aides. As noted above, we hope CMS will change the name of this topic to “appropriate dementia care” since “management” of residents has a negative connotation and is not person-centered. We urge CMS to also require that in-service training include end-of-life care, teamwork, and problem-solving.

Finally, we are concerned that the minimum number of hour per year of in-service training has not been increased. Given that there are new required topics for in-service training, facilities may choose to drop other important training topics. We encourage CMS to study this issue in order to determine what this minimum requirement should be in order to make in-service training as comprehensive as possible to enhance staff continued competency.

**Person-centered care**

Person-centeredness Would Be Emphasized

We are pleased to see that the concept of person-centeredness is incorporated into many aspects of the new rule. The rule would require that facilities learn more about who the resident is as a person, provide greater support for resident preferences and give residents increased control and choice. This focus on person-centered care and culture change would improve both the resident’s quality of life and quality of care.

**Physician services**

Resident Right to Choose a Physician Should Not Be Restricted by Credentialing (§483.10(c)(2))

The rule proposes to limit a resident’s right to choose his or her attending physician by requiring that the resident’s physician meet the credentialing requirements of the facility. CMS does not provide any reasons why such credentialing is necessary, nor does it propose any restrictions on what those credentialing requirements could be. Consequently, facilities could choose to write these in arbitrary ways that restrict a resident’s choice of physician.

The proposed new regulation is contrary to the Nursing Home Reform Law, which gives residents an unfettered right to choose their physician. We oppose the proposed requirement as it is currently written and recommends it be deleted.

Physicians Should be Permitted to Delegate Writing Orders (§483.30; §483.30(f))

We support the provision that allows delegation of orders to physician assistants, nurse practitioners, or clinical nurse specialists (for orders for immediate care); dietitians (for dietary orders), and therapists (for therapy orders). These professionals often know the residents’ well and have a solid understanding of the resident’s strengthens, weaknesses, and needs. Furthermore, the health care professional receiving the authority remains under the physician’ supervision, providing oversight and accountability.

In-Person Evaluation by a Physician Should Not Be Required Prior to Transfer to a Hospital, Because Necessary Hospitalizations Would Be Delayed Inappropriately (§483.30(e))

We oppose the proposal to require in-person examination by a physician prior to transfer to a hospital. While we understand and agree with the need to reduce unnecessary hospitalizations, particularly when a facility might be attempting to “dump” a resident in a hospital, we believe that this requirement could have negative consequences for residents, leading in some cases to injury or even death. We are aware of situations where families have advocated for a resident to be transferred to the hospital, but the facility has refused. In many of these situations, families called an ambulance out of desperation and later learned that the resident would have died had they not done so. Requiring an on-site evaluation would make it even more difficult than it currently is for a resident to be sent to the hospital.

In addition, under the proposed rule, the dividing line between whether an in-person evaluation of a resident must be made is whether the transfer to the hospital is emergent or non-emergent. Registered nurses are the only nursing personnel with the education and licensure to conduct the assessment necessary for such a determination, yet facilities are only required to have a registered nurse 8 hours a day, 7 days a week.

**Physical Restraints (including Bed Rails)**

More Detailed Language and Protections Should Be Added to the Language about Physical Restraints (§483.25(d)(1)

The proposed language adds a sentence about using the least restrictive alternative for the least amount of time and documenting ongoing evaluation of the need for the physical and chemical restraints. Although this new language is helpful, the proposed regulation does not adequately protect residents. The section does not call for an environmental assessment, informed consent, an in-person evaluation by the resident’s physician, or release and monitoring.

Bed Rail Requirements Would Include Important Protections But Need to Be Further Strengthened CMS currently defines bed rails as physical restraints when they prevent a resident from voluntarily getting out of bed. While some residents use bed rails to reposition themselves in bed or assist them when getting out of bed, for physically frail residents – especially those with dementia, delirium, or confusion – the risks of serious injuries and death from falls or entrapment, entanglement, and asphyxiation contradict claims that bed rails make patients safer. Alternatives, such as lowered beds and padding on the floor, provide better protection from fall-related injuries. Between 1985 and 2013, 531 bed rail deaths, 151 nonfatal injuries, and 220 interventions that prevented injuries were reported to the FDA under a voluntary system.

 We support CMS’s proposed language to improve protection of residents from bed rail injuries through measures such as trying alternatives, assessing residents for entrapment risks, and regularly inspecting bed rail systems. We urge CMS to further strengthen the proposed regulations by specifying residents' right to be free of bed rails used as restraints; mandating that bed rails can only be used  if the resident requests them for mobility or other assistance; and requiring that any time a bed rail is considered, a safety assessment be conducted using protocols that require an evaluation of residents and bed systems by an interdisciplinary team that includes professional staff, such as a registered nurse, physician, and licensed therapist.

**Dementia Care**

Regulations Should Establish a New Standard for Dementia Care The proposed regulations are virtually silent on dementia care. However, they include a proposed new section on “Behavioral health services” that is not well designed to guide care of residents who have dementia.

Nothing is more central to the purpose of nursing homes than providing good care to people with dementia. As HHS points out in the preamble to the proposed regulations, about half of all nursing home residents have some type of dementia, dementia among nursing home residents is increasing, and two-thirds of those dying with dementia die in nursing homes. Setting standards for dementia care in nursing homes is a common-sense necessity.

The quality of care for persons who have dementia is often poor. Too often, residents who have dementia are chemically restrained, deprived of needed care and treated without dignity.

To improve the quality of dementia care, we strongly recommend that HHS codify key provisions of CMS S&C Letter 13-35-NH on Dementia Care in Nursing Homes that it published on May 24, 2013. This CMS guidance presents a standard of care that is consistent with the Reform Law and should be in the Requirements of Participation so that the dementia care standards are known and enforced.

Rules Need to Strengthen Protections against Chemical Restraints and Antipsychotic Use ((§483.10)d)(1); (§483.45(d))

We are deeply concerned that the proposed regulations do not meaningfully address the pervasive use of antipsychotic drugs and other types of psychotropic drugs as chemical restraints. The proposed regulations would re-designate and restate the current right to be free from chemical restraint that is routinely violated by nursing homes throughout the nation. The proposed modifications to the unnecessary drug requirements are terribly inadequate to address this crisis.

There are epidemic levels of chemical restraint in nursing homes today. Nursing homes report they are currently giving antipsychotic drugs to over 281,000 residents. Even without taking into account the likely underreporting, this is a staggeringly high number of people being drugged. Nearly all of them have dementia – 88 percent according to Inspector General Daniel Levinson ­– a population the FDA has warned faces a significantly increased risk of death from these drugs. The misuse of these drugs is elder abuse on a massive scale.

The right to be free from chemical restraints is a central tenant of the Reform Law and its importance must be recognized and restored in the final regulations. We recommend a new section on chemical restraints and unnecessary use of psychotropic drugs that is based on regulations HHS proposed in 1992. The final regulation should establish a presumption that chemical restraint is harmful to residents, require written informed consent before use of psychotropic drugs, strengthen rather than diminish focus on misuse of antipsychotic drugs, require physicians to examine residents before prescribing antipsychotic drugs and justify that the potential benefits clearly outweigh the potential harmful effects, and require consultant pharmacists to be free of conflicts that compromise their independence.

Thank you for the opportunity to comment and for your consideration of our comments.

Sincerely,

Your Name Your Title

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