CANHR *Long Term Care Justice and Advocacy*
CALIFORNIA ADVOCATES FOR NURSING HOME REFORM

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October 13, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Attention: CMS–3260-P – Reform of Requirements for Long-Term Care Facilities
Submitted Electronically

Dear Mr. Slavitt:

We are writing on behalf of California Advocates for Nursing Home Reform (CANHR) to comment on the proposed regulations to reform the Requirements of Participation for Long-Term Care Facilities that were published in the Federal Register on July 16, 2015. CANHR is a statewide, nonprofit advocacy organization dedicated to improving the choices, care and quality of life for California's long term care consumers, their families and loved ones.

We have separately submitted a September 9, 2015 comment letter concerning dementia care and chemical restraint provisions of the proposed rules.

This letter addresses other aspects of the proposed rules. CANHR has several overarching concerns about the proposed rules, which we address first, followed by comments on specific provisions of the proposal.

Our central concerns are that the proposed rules:

- Fail to set specific staffing requirements;
- Diminish the quality of life, quality of care and residents' rights requirements; and
- Would institutionalize arbitration agreements that directly undermine resident protections in the Nursing Home Reform Law of 1987 (Reform Law).

We oppose the proposed reorganization of the Requirements of Participation and disagree with the assertion that the extensive reorganization improves the logical flow of the regulations. In most respects, the scattering of the current requirements diminishes their value, especially the quality of life requirements. CANHR recommends that CMS retain the current structure of the requirements. However, we support the establishment of the proposed new section on Comprehensive Resident-Centered Care Plans to emphasize the importance of care planning.

Staffing Requirements, Section 483.35

We are deeply concerned by CMS's plan not to adopt specific staffing requirements. After making a good case in the preamble for minimum staffing requirements, CMS opts instead for a "competency based" approach that would perpetuate understaffing and neglect of nursing home residents. We urge CMS to set specific nurse staffing requirements in the final regulations.

CANHR strongly endorses the September 2, 2015 comments and recommendations on staffing requirements submitted by Charlene Harrington, Ph.D., and other current and former members of the CMS TEP 5-Star Nursing Home Compare Committee.

Inadequate staffing is the single most important cause of the neglect and human suffering that is so commonplace in many nursing homes today. We hear daily from residents, their families and friends, and others about the impact of understaffing. They tell us that insufficient staff is at the root of poor care that has caused bedsores, avoidable falls, infections, dehydration, chemical restraints, repeated hospitalizations and preventable deaths. Too often, they say the institutionalized nature of understaffing makes them feel hopeless about their lives.

Consumers' experiences are borne out by decades of research, both private and government. In 2004, for example, the prestigious Institute of Medicine issued a report – *Keeping Patients Safe: Transforming the Work Environment of Nurses* – stating that inadequate nurse staffing is "associated with malnutrition, starvation and dehydration in nursing homes."[1] In calling for the same staffing standards we recommend here, the IoM report described dangerous conditions in nursing homes and noted that many studies show the relationship between nurse staffing levels and patient outcomes in nursing homes.

Entire nursing home chains are understaffed. A groundbreaking November 2014 series by the Sacramento Bee that examined the quality of care in each of California's 25 largest nursing home chains found that nursing homes owned by Shlomo Rechnitz, California's largest nursing home operator, fell below state averages on all five staffing measures reporters investigated.[2] Two other chains performed just as poorly.

The February 2014 OIG report, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, examined the toll from this neglect on Medicare beneficiaries. It found that one-third of residents who were in a skilled nursing facility (SNF) for short-term care were harmed, and that almost 60 percent of the injuries were preventable and attributable to poor care.[3] As a result, six percent of those who were harmed died, and more than half were re-hospitalized at an annualized cost of $2.8 billion in 2011.

This is not news to CMS. The preamble acknowledges the OIG findings and acknowledges that "CMS's own study reported that facilities with staffing levels below 4.1 hours per resident day (HRPD) for long stay residents may provide care that results in harm and jeopardy to residents (*Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II Final Report, 2001*, Abt Associates)."

The failure of HHS to act on its own report's findings more than a dozen years ago has fostered a system that allows nursing home owners to understaff their facilities without consequences. Beyond death and harm, this system routinely causes misery and humiliation to residents. Consider the plight of a Paradise, California nursing home resident that was captured in an inspection report.

> *On 9/30/14 at 3:40 pm, an additional confidential resident interview took place with a resident who had no memory impairment and was completely dependent on staff for all care needs, that included incontinence care. The resident explained that the staff in general are wonderful, but are too busy to meet her care needs. The resident explained that when staff are extremely busy they get frustrated with everything they have to do. Then when she needs help, they can't always get to her in time. The resident explained that the problem is the worst at night and explained that she has been left in a wet brief all night. She thinks the problem is not enough staff. The resident stated that staff would answer her light, but tell her that they are busy but will be there as soon as they can, but then they don't come back, and she is left laying in a wet brief. The resident explained that when she gets tired of waiting, she will put her call light on again. The resident stated staff have responded to her call light being on again with comments that include, "I heard you, I told you I'd be back, I have lots of lights on, you're not the only one here." The resident stated that this made her feel scolded like a child, adding that she is completely dependent and helpless. The resident stated it was a terrible feeling to be at the mercy of a system that does not provide enough staffing to meet resident needs. The resident stated it was humiliating, undignified and not respectful. The resident went on to explain that the other day while eating a meal in her room, she was choking. She put her call light on and no one came. The resident didn't remember how long it took for staff to come, she thought it was about a half hour, but when they did come, she no longer needed help. The resident stated this was a very scary experience. The resident went on to explain that she did not get out of bed today because her CNA had too many showers to give and did not have time to get her up.*[4]

Indeed, it is a terrible feeling to be at the mercy of a system that does not provide enough staff to meet your needs. This resident, like hundreds of thousands of others who live in understaffed nursing homes, is a victim of a system that sets no minimum (let alone optimal) requirements for staffing, even to protect residents against imminent danger. The idea that CMS would now see fit to expand this bottomless system is beyond comprehension.

The excuse that "we do not believe that we have sufficient information at this time to require a specific number of staff or hours of nursing care per resident" is endangering residents. Residents in understaffed nursing homes routinely die and suffer serious harm due to neglect, while more than 100 studies show the connection between staffing and quality, and CMS's own research found *conservatively* that 4.1 hours per resident day of combined RN, LPN and CNA care were necessary – not to provide high quality care, but to *avoid harm* to residents. If now is not the time to act, when would it ever be?

The apparent CMS view that no information is ever enough to justify mandatory staffing levels has trickled down to surveyors and their supervisors, who are equally unwilling to make judgments on the adequacy of staffing. A March 7, 2014 report by the Center for Medicare

Advocacy, *Staffing Deficiencies in Nursing Facilities: Rarely Cited, Seldom Sanctioned*, reveals that very few nursing homes (.022 percent in 2013) are cited for staffing deficiencies.[5] Moreover, almost 94 percent of staffing deficiencies that were cited from 2010 through 2013 were classified as causing "no harm." In the whole country in 2013, only three nursing homes were cited for placing residents in jeopardy because of insufficient staff.

The preamble solicits comments on whether the proposed "competency based approach" can reasonably be expected to enable facilities to determine and provide adequate levels of staffing to meet the needs of each resident.

The answer is no. It does not get to the root cause of this problem.

The Reform Law has always required nursing homes to use "qualified persons" to provide services to residents. Changing the term "qualified" to "competent" will not have any impact on how nursing homes are operated.

Nor will the proposed annual facility resource assessment help improve staffing. If nursing homes are already doing these assessments, as CMS believes, how will the proposed assessments produce different results? Nursing homes will be free to produce assessments stating they need exactly the type and numbers of staff they already have and state survey agencies and CMS will not be in a position to tell them otherwise.

Unless CMS sets strong staffing requirements, proposed reforms on person-centered care planning, infection control, and discharge planning will be implemented poorly, if at all. More staff will be needed to carry out these duties. For example, involving nursing assistants in care planning meetings is a great idea if it does not come at the expense of having enough staff on a unit at all times to meet other residents' needs.

The preamble reports that states have found that requirements for increased staffing levels improved resident care outcomes and asks whether CMS should adopt such an approach.

The answer is yes. The Nursing Home Reform Act of 1987 is a national law and Medicare and Medicaid are national programs. Every federally certified nursing home in the nation must have enough staff to meet residents' needs. It is not justifiable to continue to leave sufficient staffing levels to the states when a third of Medicare beneficiaries admitted to a skilled nursing facility for recuperation or therapy are harmed as a result of their SNF stay.

CANHR strongly recommends that CMS mandate 24-hour RN care in all U.S. nursing homes and require a minimum of 4.1 total nursing care hours per resident day (hprd) with at least 0.75 RN hprd, 0.55 LVN/LPN hrpd, and 2.8 to 3.0 nursing assistant hprd. In addition, nursing homes should be required to increase the staffing levels for higher resident acuity taking into account CMS's calculations of "expected nursing hours" for the Medicare Nursing Compare website.

Diminishment of Quality of Life, Residents' Rights and Quality of Care Requirements

The structure of the proposed regulations greatly diminishes the quality of life, residents' rights and quality of care requirements.

Quality of Life: We strongly oppose combining the Quality of Care and Quality of Life sections.

One of the groundbreaking and revolutionary aspects of the Reform Law 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. 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 throughout 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.

Residents' Rights: The proposed regulations would move many rights, or elements of rights, from the current Requirement of Participation on Resident Rights, §483.10, to the proposed new section on Facility Responsibilities, §483.11. This structure would make it more difficult for residents and their families to know their rights, is unduly complicated and confusing, and will undermine the rights.

Residents and their representatives who are trying to identify their rights are unlikely to understand why they are labeled " Facility Responsibilities." Residents who get information about their rights through facility postings of their "rights" and admission agreement descriptions of their "rights" may never be informed of key protections afforded to them by the law that have been relabeled as "Facility Responsibilities." Residents' rights should be designated as rights in the Requirements of Participation to avoid diluting the rights or depriving residents of information about their entitlement to them.

The proposed regulation inappropriately splits apart key rights between these two sections. For example, the rights of residents and family members to participate in resident and family councils would be divided between proposed §§483.10(e) and 483.11(d)(3). Someone reading proposed §483.10 would not know that resident and family councils have the right to private space for their meetings, that staff or visitors can attend only at their invitation, that the facility must provide a designated staff person to the councils and that the facility must consider their views and act upon their grievances and recommendations. Separating residents' rights into components in different sections of the regulations is unwise and unnecessary.

California has established laws that extend the rights in §483.10 to all skilled nursing facilities, regardless of federal certification,[6] and provide a private right of action to residents and former residents to enforce their rights.[7] The structure of the proposed regulations could undermine these laws without providing any benefits to residents.

The proposed regulations are trying to fix something that is not broken. **CANHR recommends that the existing rights be fully retained in §483.10.**

Quality of Care: The proposed rules dilute the strength and power of the current quality of care regulations. For most of the specific care categories identified under quality of care, the current regulations at §483.25 use a similar approach. They provide that if a resident is admitted to a facility without the problem, the resident should not develop the problem unless it was medically unavoidable for that individual. The facility must then take steps both to correct the problem and to prevent its recurrence, if possible. For example, if a resident did not have pressure sores at admission, the resident should "not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable."[8] The current regulations then provide that if a resident has pressure sores, the resident must receive "necessary treatment and services to promote healing, prevent infection and prevent new sores from developing."[9] This regulatory language brilliantly implements two key provisions of the 1987 Nursing Home Reform Law: the focus on *each resident* and the recognition that the law creates each resident's entitlement to care and services "to attain or maintain the highest practicable physical, mental, and psychosocial well-being."[10]

That initial point in many of the current quality of care standards is missing in the revision – notably in pressure ulcers.

The current quality of care regulation gives full and enforceable meaning to these key statutory directives. **We recommend that the language and approach of the current quality of care requirements be retained in the revised rule on quality of care.**

Binding Arbitration Agreements, Section 483.70(n)

The Nursing Home Reform Law and its implementing regulations were meant to transform how nursing home care is delivered. The original rules were unique because public health issues had traditionally been left to the states; whereas in the Reform Law and subsequent regulations, the federal government used its considerable influence in health care and nursing home spending, through the Medicare and Medicaid programs, to assure good quality care for all nursing home

residents. Federal nursing home standards are not only traditional health standards to protect citizens: they are the contractual terms of a special federal government / nursing home compact, to ensure accountability for the services that the taxpayers are funding.

Pre-dispute binding arbitration agreements exist solely to evade the accountability that the Reform Law and the regulations impose. The purpose of arbitration agreements is to limit the dispute resolution options of frail, infirm nursing home residents who suffer harm as a result of care that deviates from the standards specified in the federal requirements. Civil lawsuits have long protected the health and safety of nursing home residents and ensured better quality of care for all, and in that regard, we enthusiastically endorse the September 10, 2015 letter from the Center for Justice & Democracy to CMS.

In the proposed regulations, CMS is attempting to ensure that binding arbitration agreements are knowing, intelligent, and voluntary waivers of a resident's dispute resolution rights. California state law already imposes rules nearly identical to those proposed by CMS but they have proven to be ineffective. Our Health and Safety Code Section 1599.81 and 22 Cal. Code Regs. Section 72516(d) require binding arbitration agreements be presented on separate documents from admission agreements and include bold-faced warnings that signing arbitration agreements cannot be a condition of admission to a facility. These rules have not made pre-dispute arbitration agreements any more "voluntary." In California, as elsewhere in the country, arbitration agreements continue to be buried in stacks of admission papers, signed by overwhelmed residents or their family members in the midst of a health care crisis or imminent hospital discharge. Regardless of what the agreement says or how it is represented, the process is wholly one-sided, where the desperation of residents and their families yields them uniformly bad deals.

The proposed regulations would *reduce* the quality of care in nursing homes by tacitly endorsing arbitration agreements' use and by giving judges and courts a credible list of criteria for declaring an agreement conscionable – whether or not, in fact, it was conscionable under common understandings of the word. Currently, nursing home residents are able to argue that pre-dispute arbitration agreements are unenforceable due to contract law claims that they are unconscionable, meaning they are so grossly unfair that enforcing them would create profound injustice. By setting minimum criteria in an effort to improve the understanding of what residents are getting themselves into, the proposed rules will give nursing homes the chance to argue that satisfaction of those criteria means the federal government believes the subsequent agreements are fair. **For this reason, we ask that the proposed arbitration "limitations" be excised from the proposed regulations unless a much-needed comprehensive ban of pre-dispute arbitration agreements is imposed.**

Virtually all nursing home arbitration agreements are completed under unconscionable conditions. The resident is almost certainly suffering from an acute care condition that has led to or exacerbated profound mental or physical incapacity or both. Most residents are sent from a hospital which itself is under financial pressure to transfer patients who have not fully recovered from their injuries. Thus, residents are transferred to nursing homes with very little, if any, advance notice or the ability to meaningfully assess their options. Invariably, pre-dispute arbitration agreements are presented to the resident during this very difficult time as one small

part of a much more complex admission agreement process where residents are given dozens of pages to initial and sign with absolutely no real opportunity to negotiate terms or raise objections. In this context, residents or their representatives have no idea what they are doing when they sign a pre-dispute arbitration agreement and, even if they do, are in no position to assert themselves and risk their placement or their care or risk the retaliation of the facility staff. The process capitalizes on obtaining waivers of residents' dispute resolution rights at a time when they are most vulnerable to making decisions that are contrary to their interests and moreover, probably have no concept that a "dispute" that arises may be related to serious, avoidable injuries and their premature death.

Another unique aspect of nursing home care that renders pre-dispute arbitration agreements so unconscionable is the totality with which they influence the resident's life. Nursing homes are institutions, where the resident lives, eats, sleeps, receives health, nursing, and social services, participates in activities, and engages with friends and family. By signing a pre-dispute arbitration agreement, nursing home residents lose the ability to seek justice for virtually anything that could go wrong in their world. The agreements they (or more likely, their family or other representatives) sign deprive them of much more than their right to challenge minor billing errors or service failures: it denies them their most important dispute resolution forum to address critical problems affecting every part of their lives. Because residents rely on their facilities for virtually all activities of daily living and their safety and health, the breadth of sacrifice they make when signing pre-dispute arbitration agreements is singularly vast.

To support their business practice to push residents into binding pre-dispute arbitration agreements, nursing homes have long-argued that arbitration offers advantages to residents; for example, that arbitration is fast and inexpensive. If that was truly the case, then there is absolutely no reason why facilities should not be able to convince residents to forego their right to sue after a dispute has arisen.

Pro-industry commentary – such as the Arbitration Agreements in Long-Term Care report available from Omnisure (http://www.omnisure.com/specialties/senior-living/) or a recent editorial from McKnight's Long-Term Care News (http://www.mcknights.com/daily-editors-notes/the-lawsuits-are-coming-the-lawsuits-are-coming/article/428240/) – demonstrates that pre-dispute arbitration agreements are offered by nursing homes solely to avoid the accountability that comes from civil lawsuits filed by victims of serious neglect and abuse. The notion that residents who bind themselves to arbitration in advance of any dispute are gaining a benefit is a fraud. Pre-dispute arbitration agreements are imposed by facilities because they benefit facilities, solely at the expense of residents.

Every argument in support of arbitration disintegrates when subjected to even the mildest bit of scrutiny:

- Pre-dispute arbitration is not voluntary. During the admission process, the arbitration agreement is included among dozens of other pages, often marked with "sign here" post-it notes. The terms are dictated entirely by the nursing home, using pre-written forms that are not subject to any negotiation, and the power among the parties is completely balanced in favor of the nursing home.

- Arbitration is not neutral. In an arbitration proceeding between a nursing home and an aggrieved resident, the nursing home probably has the advantage of having been to multiple arbitration hearings. But, more important, nursing homes represent a likely repeat customer to arbitrators, whose job depends on being selected for future arbitration cases. Myriad studies show that consumers do much more poorly in arbitration than they do in court and a significant factor is the financial incentives of arbitrators to side with businesses.

- Arbitration is not faster. In state courts, nursing home residents who are elderly or have disabilities can petition for expedited hearings, giving them a reasonably fast and efficient forum for dispute resolution. This is especially important when the resident is seeking equitable or injunctive relief to end an illegal and harmful nursing home practice. In arbitration, there are no provisions for expedited hearings and the proceedings are often time-consuming and slow.

- Arbitration is not cheap. While residents who file lawsuits often pay little to no money for their cases due to fee waivers and contingency fee agreements, they may have to pay half of the costs of arbitration. So for most residents, binding pre-dispute arbitration is often far costlier than traditional dispute resolution. The only savings realized in arbitration belongs to nursing homes, who are not only able to have residents foot half of the bill, but also face significantly smaller judgments from arbitrators who are financially motivated to side with them.

- There is no equitable relief. Arbitrators lack any equitable jurisdiction, which means they can only consider monetary issues and cannot issue orders, such as injunctions, prohibiting bad facilities from engaging in illegal practices. Equitable relief has been an increasingly effective tool in forcing California facilities to ensure residents see their physicians, receive adequate care planning, are free from inappropriate antipsychotic drugs, and have enough staff to meet their needs. Forcing residents into dispute resolution forums that do not offer equitable relief deals a crippling blow to all resident care and nursing home accountability.

Federal law, and particularly the Federal Arbitration Act (FAA), do not preclude CMS from banning pre-dispute arbitration agreements. Several executive agencies, such as the Commodity Futures Trading Commission and the Bureau of Consumer Financial Protection, have adopted regulations to prohibit pre-dispute arbitration agreements in certain contracts and the White House has banned pre-dispute arbitration agreements in employer-employee contracts involving certain federal contractors. A ban on pre-dispute arbitration agreements based on their universal unconscionability in nursing homes would be consistent with the FAA and its recent interpretation in the federal courts, which have always held that unconscionable arbitration agreements are not subject to FAA protection.

In conclusion, pre-dispute arbitration agreements exist solely to escape the accountability for quality care that the federal rules are supposed to impose.[11] They take advantage of vulnerable nursing home residents, whom the Reform Law and regulations are supposed to protect. They are designed to keep nursing homes out of court and to keep them from answering for the harm, loss, and death they sometimes cause. They are anti-choice, anti-justice, and ultimately anti-

accountability. Our federal system of regulatory standards was established to ensure nursing homes are accountable for the billions of taxpayer dollars they receive. Binding pre-dispute arbitration agreements are antithetical to this system. Nothing short of a comprehensive ban on these "agreements" will sufficiently protect residents and protect the integrity of our system.

CMS has taken a zero-tolerance position on pre-dispute liability waivers for property loss that should be applied as well to cases involving physical harm, loss of liberty, and death. Proposed section 483.15(a)(2)(iii) of the new regulations bans residents from waiving a facility's liability for losses of personal property while section 483.70(n) would allow them to waive a fundamental right to seek court redress when a facility causes an injury or commits abuse or neglect. CMS should not treat the protection of personal property as more important than a resident's health and right to be free from abuse.

We recommend that proposed Section 483.70(n) be amended as follows:

483.70(n) Binding arbitration agreements. A facility may not enter into a pre-dispute agreement for binding arbitration with its residents.

Definition of "Transfer and discharge," Section 483.5

The draft regulations would move the existing definition of "transfer and discharge" from current §483.12(a)(1) to draft §483.5(p) (Definitions).

Although CMS interpretive guidance on the definition of "transfer and discharge" at F177 states that transfer and discharge protections apply to transfers or discharges that are initiated by the facility, not by the resident, nursing homes routinely ignore all transfer and discharge due process protections for residents unless residents or their relatives actively oppose the transfer or discharge. In most cases when nursing homes initiate the transfer or discharge, residents do not even receive notice of their transfer and discharge rights.

For example, Vintage Faire Nursing & Rehab, a skilled nursing facility in Modesto, California, summarily evicted seven residents in March 2015 to *"get rid of long term care residents,"* and to *"free up more space for . . . residents from the acute care setting who needed short term rehabilitation."*[12] The seven residents were treated like animals. They were moved with no notice, no orientation, no preparation and no consideration of the trauma they were subjected to. One of the residents had lived at Vintage Faire for 11 years, another for 8 years. They were moved to facilities at least 35 miles away where they have been isolated from their family and friends. Many of their friends and family members, including legal representatives, were not told of the move until they came to the facility to visit and discovered that they were gone. As a result of the transfers, the residents are sad, depressed, and confused.

According to the June 22, 2015 Statement of Deficiency issued to Vintage Faire by the California Department of Public Health, the Social Service Aide (SSA) who handled the transfers did not communicate any information to the residents or their representatives about their rights. It states: *"SSA 3 stated she had not been instructed to provide orientation or to*

complete care plans. SSA 3 stated, If they (the Residents) said they were ok with the transfer, I would process the paperwork."

The CMS guidance states that *"transfer and discharge provisions significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility."* The truth, however, is that, many nursing homes believe that it is perfectly acceptable to evict residents without any notice by simply telling them they must go and claiming they have secured an "ok" from them. This practice is resident abuse.

We strongly recommend that CMS codify the following paragraph from the interpretive guidance at F177 and include it as part of the "transfer and discharge" definition in order to help stop the trampling of residents' transfer and discharge rights.

> *This requirement applies to transfers or discharges that are initiated by the facility, not by the resident. Whether or not a resident agrees to the facility's decision, these requirements apply whenever a facility initiates the transfer or discharge. "Transfer" is moving the resident from the facility to another legally responsible institutional setting, while "discharge is moving the resident to a non-institutional setting when the releasing facility ceases to be responsible for the resident's care.*

Additionally, if this definition is moved from the section on transfer and discharge rights to the section on definitions, as proposed, the definition should be referenced at the beginning of the transfer and discharge rights section so that persons reading the regulation will be aware of it.

Exercise of Rights, Section 483.10(a)

The new rules regarding the exercise of a resident's rights when the resident has questionable mental capacity are a welcome improvement over the current rules. The new rules recognize that residents that have not been adjudicated incompetent by a court under state laws retain complete control over the exercise of their rights and may overrule decisions made by their representatives. In addition, the new rules clarify that even residents who have been adjudicated incompetent have a right to participate in their care planning and to have their preferences considered by their representative. This is a very important concept to recognize in the regulations because legally incompetent residents often retain their right to refuse unwanted treatment but have no way to make an informed refusal unless they continue to be included in the normal process for making care decisions.

Planning and Implementing Care, Section 483.10(b)

Under the right to be fully informed in advance of care or treatment, the new regulations describe the right to be informed of treatment risks, benefits, and alternatives and the right to choose or decline the treatment options available. A more succinct definition of informed consent could hardly be found so why not use the term "informed consent"? Informed consent is a concept with a rich legal history and using the term would anchor this specific resident right in a well-developed context. In fact, the term is used in proposed new section 483.25(d)(2)(iii) regarding

the use of bed rails. If "informed consent" can be used in the context of individual care decisions, it ought to be used when discussing important care decisions generally.

We recommend revising subsection (b) as follows:

(b) Planning and implementing care. The resident has the right to ~~be informed of,~~ give or withhold informed consent and participate in, his or her treatment, including:

Physician Choice, Section 483.10(c)

The new rules curtail residents' right to receive care from a physician of their choosing. The current regulation simply states residents have the right "to choose a personal attending physician." Adding requirements that the physician must be licensed to practice and "meet the professional credentialing requirements of the facility" unnecessarily limit that right and in the case of a credentialing requirement dictated by the facility, gives a great deal of discretion to facilities to reject a resident's choice of physician. The proposed new limits on a resident's right to choose a physician clash with and are therefore preempted by 42 USC Section 1395i-3(c)(1)(A)(i), which gives residents an unfettered right to choose their physician.

We recommend deleting proposed sections 483.10(c)(1) – 483.10(c)(3).

Visitation, Sections 483.10(e)(3) and 483.11(d)(iii)

The current regulations provide nursing home residents with an unequivocal right to virtually unfettered visitation from their family members and friends. These regulations reflect the statutory mandate of 42 USC Sections 1395i-3(c)(3)(B) and 1396r(c)(3)(B). The proposed regulations impose new restrictions on the ability of residents to see visitors because of unneeded alterations to the language, in contravention of the federal law.

The proposed regulations predicate the receipt of visitors on the residents' "choosing" and on avoiding imposition "on the rights of another resident." For a significant percentage of nursing home residents with cognitive disabilities such as dementia, it may be impossible to express a clear "choice" regarding proposed visitation; therefore, the nursing homes in which they live will have the discretion to determine whether a visitor may visit. In this context, the lack of an affirmative "choice" may be construed as the resident's rejection of a visitor, turning the resident's right to visitation on its head. Limiting visits "in a manner that does not impose on the rights of another resident" also invites nursing homes to prohibit visitors who strongly advocate for improved care or treatment of their family member or friend. Restricting visitation to intimidate or retaliate against family members and other resident representatives who complain about poor care was addressed by Congress in the Affordable Care Act with the addition of subsection (f) in Sec. 1128I, 42 U.S.C. 1320a-7j, requiring states to develop procedures *"to ensure that the legal representative of a resident of a facility or other responsible party is not denied access to such resident or otherwise retaliated against if they have complained about the quality of care provided by the facility or other issues relating to the facility."* Facilities that sincerely believe that a visitor is imposing on the rights of other residents have state law remedies, such as the police or protective orders, to limit visitation.

The proposed rules also erode resident visitation rights in section 483.11(d)(iii) by subjecting non-family visitors to ambiguous "reasonable clinical and safety restrictions." There is no statutory authority for adding the term "clinical and safety." Federal law subjects non-family visitors only to reasonable restrictions, such as visitation hours. Citing to clinical or safety restrictions seems to give facilities a "best interests" veto over residents' right to visitation. Thus, when a facility determines that a visit is not in the "best interests" of a resident, they are free to apply a "clinical" prohibition. A "clinical" reason for restricting a visit could serve as a recommendation to a resident regarding visitation but like any other "clinical" issue, the resident is free to reject that recommendation.

The proposed regulations therefore take resident rights backward and contrary to CMS's stance in favor of strong "open" visitation rights enunciated in the preamble at 42185 and in 56 Fed. Reg. 48837 (1991). When discussing residents' right to visitation in the 1991 Federal Register, CMS specifically cited the desire of facilities to limit visitation to "reasonable" times. CMS rejected that proposal, citing OBRA 87, which gives residents the right to immediate access from family, other relatives, and friends with no qualifiers. Congress was clear in establishing broad resident rights to visitation, recognizing the critical importance of visits to the health and well-being of residents.

We recommend returning Sections 483.10(e)(3) and 483.11(d)(iii) to the language used in the current regulations and required under federal law:

(1) The resident has the right and the facility must provide immediate access to any resident by the following:
(i) Any representative of the Secretary;
(ii) Any representative of the State:
(iii) The resident's individual physician;
(iv) The State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965);
(v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);
(vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);
(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives and representatives of the resident; and
(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.
(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.
(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.

Additionally, we recommend adding the following language to this section to implement the requirement in subsection (f) of Sec. 1128I, 42 U.S.C. 1320a-7j with respect to denying access to resident representatives who have complained about quality of care or other issues in the facility:

(4) A facility shall ensure that a resident's representative (including an immediate family member, other relatives, and other representatives) shall not be denied access to a resident as retaliation if they have complained about the quality of care or other issues relating to the facility).
(5) In the case of a resident who, because of dementia, illness, or physical condition, cannot give consent to an immediate family member or other relative or representative's access, there shall be a presumption that the resident has exercised his or her right to give immediate access to that individual.

Electronic Communications, Sections 483.10(g)&(h) and 483.11(e)(13)

We strongly support the updating of residents' privacy and communication rights to include electronic communications. However, we have recommendations to clarify and improve these rights.

There are potential conflicts between the proposed language in subdivision (g) on "Privacy and confidentiality" and subdivision (h) of §483.10 on "Communication" related to electronic communications. Subdivision (g)(1) gives a resident the right to privacy in "electronic communications" while subdivision (h)(2) limits residents' right to privacy "in their use of electronic communications such as email and video communications and for internet research" to when "access is available to the facility." The language should be clarified so that it is clear that residents have a right to privacy in email and video communications and use of the internet that is not contingent on availability through the facility.

The final rule should also clarify that the facility has a duty, not an option, to provide internet access to residents via Wi-Fi or other connection for residents who have personal computers or other devices and through other means for those who do not have their own devices. It is not at all clear what "if access is available to the facility" means at a time when there is near universal internet access in this nation. In today's world, the opportunity to communicate electronically is every bit as important as access to a telephone was 25 years ago when these requirements originally took effect. Medicare and Medicaid funded nursing homes should be expected to find a way to provide access for residents rather than be allowed to use "lack of availability" as an excuse to isolate residents from the modern world.

The related provisions at 483.11(e)(13) should also be clarified in this respect.

We also question the appropriateness of allowing facilities to pass on costs to residents for mere "access" to electronic communications and the internet. Why is this access treated differently than access to a telephone, where the regulations do not permit such charges? Are internet access costs not built into Medicare and Medicaid payments nursing facilities receive? The regulations should not allow nursing homes to bill residents for costs that are reflected in Medicare and

Medicaid payments. In California, residents on Medicaid (Medi-Cal) are allowed to keep only $35 of their income per month as their personal needs allowance, so every penny matters to them. The regulations should require nursing homes to provide basic internet access to residents without additional cost to them. Otherwise, most residents will not be able to afford access and, for communication purposes, they will be left in the last century.

A final recommendation on this issue is to change the term "internet research" to "use of the internet." As CMS expressed in the preamble, "research" is just one of many purposes for using the internet. Residents should not have to identify educational purposes to justify access to the internet.

We recommend the following amendments to sections 483.10(g)&(h) and 483.11(e)(13):

Section 483.10(g)&(h)
(g) Privacy and confidentiality. The resident has a right to personal privacy and confidentiality of his or her personal and medical records.
(1) This includes the right to privacy in his or her verbal (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service. Electronic communications include e-mail, text messaging, video communications and other forms of electronic communication and social media.
…
(h) Communication. (1) The resident has the right to have reasonable access to the use of a telephone, including TTY and TDD services, and a place in the facility where calls can be made without being overheard. This includes the right to retain and use a cellular phone at the resident's own expense.
(2) The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for use of the internet ~~research~~. This includes the right to retain and use electronic devices that the resident provides at his or her own expense.
(i) ~~If the access is available to the facility.~~ The facility shall provide internet access to residents and, for residents who have personal computers or other electronic devices, shall provide Wi-Fi or comparable connection to enable their access to the internet.
(ii) ~~At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.~~

Section 483.11(e)(13)
(13) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, consistent with § 483.10(h), including reasonable access to:
(i) A telephone, including TTY and TDD services;
(ii) The internet, ~~to the extent available to the facility,~~ including Wi-Fi or comparable internet connection for residents who have personal computers or other electronic devices; and
(iii) Stationery, postage, writing implements and the ability to send mail.

Equal Access to Quality Care, Section 483.11(a)(2)

We support this statutorily mandated requirement that is intended to prevent discrimination against applicants and residents based on their care needs or payment source.

There are two significant omissions from the regulation. First, it should explicitly prohibit discrimination in admission. The regulation's mandate to provide "equal access to quality care" necessarily includes an obligation not to discriminate in admissions, and that should be made explicit by inclusion of the word "admission" in the next sentence.

The purpose of the Medicaid Act and the Reform Law in this respect is to ensure that Medicaid beneficiaries are treated as first class citizens when they seek admission to or reside in Medicaid certified nursing facilities. Yet, the reality is that many Medicaid certified nursing homes treat Medicaid eligible persons seeking admission as third class citizens.

This illegal practice has a disparate impact on low-income minority populations, who are disproportionately dependent on Medicaid for their coverage. There is considerable research showing that minority elders on Medicaid are subjected to poor care in nursing homes due to lack of access to higher quality facilities.

A 2014 national study by the Center for Public Integrity found that nursing homes serving minorities offered substantially less care than those housing whites.[13] Its report included these findings:

- Majority-white nursing homes had average registered nurse care levels 60 percent higher than Latino-majority homes and 34 percent higher than predominantly black facilities;
- Majority-black nursing homes averaged about 20 minutes of registered nurse care per resident day;

These disturbing disparities exist because Medicaid certified nursing homes are denying equal access to care to Medicaid eligible applicants, in direct defiance of the Reform Law, the Civil Rights Act of 1964 and other civil rights laws and regulations.

The second omission is that the prohibition against discrimination should extend to services provided under the terms of a waiver, as well as under a State plan.

CANHR recommends that §483.11(a)(2) be amended as follows:

(a) Exercise of rights. (1) ….
(2) The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding admission, transfer, discharge, and the provision of services under the State plan or waiver for all applicants and residents regardless of payment source.

Admissions Policy, Section 483.15(a)

We recommend deletion of proposed new paragraph (a)(6), which would direct a nursing facility to give notice, at or before admission, of special characteristics or service limitations of the facility. This proposal would be an open invitation to facilities to discriminate against residents based on their care needs and other factors.

Nursing homes would use this provision to justify discrimination against residents and potential residents based on their disability, religion, age, sexual orientation, source of payment and other factors that are prohibited by federal and state civil rights laws, and the Reform Law.[14]

The preamble invites this discrimination, stating CMS believes this kind of notice "is current standard business practice" and giving the example of "residents requiring psychiatric care" as persons a nursing home could force out if it could not meet their needs. This type of discrimination is not permitted by the Reform Law, which specifically requires nursing facilities to provide "treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State."[15] It is illegal to transfer or discharge a resident on the basis that the resident needs a service that the Reform Law requires the facility to provide.

The preamble also states that religious affiliation could result in "special characteristics, requirements, or limitations" that would have to be communicated to potential residents at admission. It is not hard to imagine how religiously affiliated facilities could use this open-ended provision to justify discrimination against same sex couples, for example, claiming faith based exemptions from laws, requirements and rulings against this type of discrimination.

The provision should be deleted because it is fundamentally at odds with overarching laws against discrimination, residents' transfer and discharge rights and required services. Nursing homes that cannot or do not want to provide federally mandated services to residents or that do not wish to comply with federal civil rights laws are not eligible to participate in the Medicare and Medicaid programs.

Transfer / Discharge Rights, Section 483.15(b)

Removing resident protections from unsafe and poorly planned evictions and resident bed hold rights from a section labeled "rights" (Section 483.12) and placing them into "transitions of care" mutes the critical nature of these rights, which residents rely on in nursing homes every single day in this country. Federal law has always rightfully treated nursing facilities foremost as homes for the residents, not "transition" points. **We strongly recommend placing these very important rights in a section labeled "resident rights."**

CMS has added language "due to the clinical or behavioral status of the resident" for the transfer or discharge of a resident when the safety of individuals in the facility is endangered. While the additional language may seem like limiting language – meaning that discharges for danger not caused by the clinical or behavioral status of a resident will no longer justify a proposed discharge – it is impossible to think of a situation in which anything other than clinical or

behavioral status would cause the danger justifying the proposed discharge. Instead, the additional language will increase the number of discharges by lending further justification for finding a resident is a danger to other individuals. In other words, the additional language shifts the focus from residents' "dangerousness" to their clinical or behavioral "status." Status could be interpreted as a mere diagnosis or perhaps a diagnosis coupled with a current clinical impression. The new language will give cover to facilities to discharge residents based on their "status" as opposed to their actual dangerousness.

We recommend returning Section 483.15(b)(1)(ii)(C) back to a section labeled "transfer and discharge rights" and restoring the original language used in the federal law at 42 USC 1395i-3(c)(2)(A)(iii) and 42 USC 1396r(c)(2)(A)(iii):

(C) The safety of individuals in the facility is endangered ~~due to the clinical or behavioral status of the resident.~~

Ombudsman Notification: The section on notice before transfer (Section 483.15(b)(3)(i)) adds a requirement for the facility to send a copy of a transfer or discharge notice to the long-term care Ombudsman office. This is a welcome addition but we are puzzled why CMS would condition this requirement on the "resident's agreement." If it is important that the Ombudsman office is alerted when transfers and discharges are occurring at facilities, then making it subject to the resident's agreement makes no sense. Facilities would have little reason to do anything other than insert a clause in their admission agreements that restrict sharing of transfer or discharge notices with Ombudsmen. In addition, subjecting sharing of the notice to resident agreement would mean the Ombudsman would receive no notice in cases where the resident was incapable of providing affirmative consent – just the kind of case where the involvement of an Ombudsman is perhaps most critical.

If the goal is to protect residents' confidentiality when sharing transfer or discharge notices with Ombudsman programs, a better option would be to require copies be shared subject to a resident's right to restrict; thus, requiring an active objection from the resident. This method would set up an opt-out system wherein notices would presumably be sent to the Ombudsman unless the resident or their representative objects after being told of their right to object.

We recommend the following change to Section 483.15(b)(3)(i):

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. ~~Subject to the resident's agreement~~, The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman unless the resident or the resident's representative(s) objects.

Changes to the Notice: Proposed new paragraph (b)(6) requires facilities to update the recipients of the notice as soon as practicable once the updated information becomes available. We strongly oppose this requirement unless it is modified to require the nursing home to issue a new notice that meets all of the requirements of current §483.12(a)(6) and restarts the 30-day timeframe provided in current §483.12(a)(5).

Unless these changes are made, residents will be deprived of their due process rights. For example, last month CANHR represented a resident who was being illegally evicted by a nursing home that claimed she did not need nursing home care. On the 29th day after the notice was issued, as the resident was waiting for a state hearing to be held, the facility notified her that it was now planning to discharge her to a skilled nursing facility far from her home the very next day, rather than to an assisted living facility as per the facility's original notice. Had we not intervened, the resident would have been transferred to a nursing home she had never seen or considered, on one day's notice, and without any opportunity to challenge this overnight change in plans before she was moved. Moreover, the nursing home's last minute decision to move her to another nursing home certified identically to itself demonstrated that the resident did need continuing nursing home care and that the facility did not have a legal basis to transfer her in the first place.

It would be fundamentally unfair to residents if the regulations allowed nursing homes to change transfer and discharge notices in this manner.

If a facility finds it necessary to revise its notice, it should issue a new notice that fully complies with all notice requirements and the notice clock should be reset so that residents are not deprived of their due process rights.

We recommend paragraph (b)(6) be revised as follows:

Changes to the notice. If the information in the notice changes prior to effecting the transfer or discharge, the facility must ~~update the recipients of the notice as soon as practicable once the updated information becomes available~~ issue a new notice that meets all of the content requirements specified in paragraph (a)(6) and the timing requirements of paragraph (a)(5). The facility shall provide the new notice to all of the recipients of the original notice.

Bed-holds, Section 483.15

Residents' right to have their beds held open and subsequently returned to them following temporary hospitalizations is one of the most abused resident protection in nursing homes today. Our office is confronted with dozens of cases each year in which a nursing home has refused to honor a resident's bed-hold during a hospitalization or a resident's right to return to the first available bed when their hospitalization exceeds the bed-hold period. The regulations regarding bed-hold have proven vitally important to preventing unplanned, unsafe "discharges" where a hospitalization becomes a pre-text for avoiding all of the notice, preparation, and orientation requirements of a safe, orderly discharge. Advocates know this common practice as the "hospital dump."

While the regulations regarding bed-holds have always been critical to nursing home residents, particularly those receiving Medicaid benefits, one oddity in current regulations that has been exploited by facilities is that the bed-hold rules are contained in a facility requirement for a "written policy." So rather than a plain requirement that facilities hold beds and readmit

hospitalized residents, they are required to have "written policies" that allow residents to "be permitted to be readmitted."

In 2013, we represented a nursing home resident in a court trial against a nursing home that had refused to readmit her after a short hospital stay. The judge found the facility had not violated any applicable federal rule because the regulations only require a written policy and the policy could include criteria that ultimately give facilities complete discretion over whether they readmit residents following hospitalizations that exceed the bed-hold period. See pages 10-11 of the attached Exhibit A to this letter, particularly lines 18-21 of page 11.

While we believe the judge made an erroneous interpretation, the fact is the current regulatory language is unnecessarily indirect and needs clarification that makes the bed hold rules airtight for protecting residents from irresponsible discharges.

In order to prevent facilities from using hospitalizations to avoid compliance with any of the transfer and discharge requirements, we strongly suggest the above-referenced ambiguities be removed through the following amendment:

(3) Permitting resident to return to facility. A nursing facility must ~~establish~~ ~~and follow a written policy on~~ ~~permitting~~ readmit residents ~~to return~~ to the facility after they are hospitalized or placed on therapeutic leave. ~~The policy~~ ~~must provide for the following.~~ ~~(i)~~ A resident, whose hospitalization or therapeutic leave exceeds the bedhold period under the State plan~~, is~~ must be readmitted to the facility to their previous room if available or immediately upon the first availability of a bed ~~in a semi-private room~~ if the resident—

Right to Readmission: The most ill-advised of the proposed changes to the transfer and discharge requirements occurs in proposed section 483.15(c)(3)(ii), which we recommend be entirely deleted. The section attempts to impose a notice requirement on facilities that decide a hospitalized "resident cannot be readmitted to the facility." The reference to facilities' determinations of when residents cannot be readmitted implies that facilities have such discretion. Under federal law, (1396r(c)(2)(D)(iii)), they clearly do not.

If facilities are given the ability to determine for themselves which residents can be readmitted and which ones cannot, then the bed-hold and the right to be readmitted after a hospitalization will be eviscerated. We strongly oppose such a dramatic, dangerous, and illegal weakening of resident's bed-hold and readmission rights. The results would be horrendous for residents: when faced with a possible hospitalization, residents would be confronted with the impossible choice of receiving needed acute care or risking the loss of their placement in the facility. Such erosion to resident protections would open Medicaid recipients to naked discrimination by nursing homes based on their payment status.

Attached as Exhibit B to this letter, is Page 48841 of the Sept. 26, 1991 Federal Register in which CMS highlighted a comment to the proposed nursing home regulations that requiring readmission of a hospitalized resident should "be contingent upon the facility's continued ability to provide appropriate care." CMS's response was unequivocal: hospitalized residents who

continue to need nursing home services must be readmitted. The proposed regulation would completely undermine CMS's prior position, as well as federal law.

Additionally, proposed subsection (3)(ii) refers to information specified in paragraphs (b)(5)(iv) through (vi) of the section. Those paragraphs don't exist in the proposed regulations.

We strongly recommend that Section 483.15(c)(3)(ii) be deleted in its entirety.

~~*(ii) A resident who is hospitalized or placed on therapeutic leave with an expectation of returning to the facility must be notified in writing by the facility when the facility determines that the resident cannot be readmitted to the facility, the reason the resident cannot be readmitted to the facility, and the information specified in paragraphs (b)(5)(iv) through (vi) of this section.*~~

Bed Rails: §483.10(d) Residents' Rights; §483.25(d)(2) and §483.90(c)(3) — To Require Nursing Homes to Assess Safety and Environmental Risks Associated with the Use of Bed Rails

We support CMS's intent to revise the Requirements of Participation to require nursing homes to assess residents' risk of serious injury and death from bed rails and to conduct regular inspections and maintenance of bed rails, bed frames and mattresses ("bed systems") to improve safety. Thirty years of documented deaths of elderly adults from entrapment, entanglement, and asphyxiation on bed rails without effective government regulation is unconscionable – especially since they are often used in the name of protecting the frail elderly with dementia who are overwhelmingly the victims. The actual numbers of injuries and deaths are unknown since the FDA relies on voluntary incident reporting for products it regulates, but hospital data showing almost 37,000 emergency room admissions for portable bed rail injuries between 2003 and 2012 suggest that the scope of the problem is considerably greater than the hundreds of injuries and deaths that have been voluntarily reported to the FDA and Consumer Product Safety Commission.

There is little evidence that bed rails have the benefits many caregivers perceive and want for their loved ones, or that minimal benefits outweigh the risk of serious harm or death. According to the FDA,

> *Even when portable bed rails and hospital bed rails are properly designed to reduce the risk of entrapment or falls, are compatible with the bed and mattress, and are used appropriately, they can present a hazard to certain individuals, particularly to people with physical limitations or altered mental status, such as dementia or delirium.*[16]

It is noteworthy that the FDA has found that bed rails can be hazardous even when properly designed, assembled, and "used appropriately." Since most nursing home residents have "physical limitations or altered mental status," this warning provides a framework for strengthening CMS's proposed regulations to protect residents from bed rail endangerment, either when used as a physical restraint, as addressed in current guidelines, or as a therapeutic device a resident requests to assist with mobility and rising from bed.

Alternatives—such as reducing bed height and cushioning floors—successfully reduce the risk of injury for residents for whom rolling out of bed or falling are often cited as reasons for applying bed rails.

CMS must ensure that facilities do not use bed rails with any resident unless they have followed safety protocols based on meaningful individual assessments of residents and bed systems that are conducted by professionals who are trained specifically in such assessments, and who have the proper tools to make the necessary measurements. William A. Hyman, a leading expert on bed rail safety, noted in a 2008 article in *McKnight's* that analyzing bed rails to determine whether they pose entrapment hazards and assessing patients to determine whether they are safe candidates for beds with rails, are challenges that require "ongoing vigilance by trained and knowledgeable people" who can make "informed judgments about the suitability of a bed system for a particular patient or type of patient:"

> *Such training must include specific and measurable criteria. For example, an instruction to "make sure the gap is not too big" is basically meaningless since it does not adequately address whether the gap in question is viewed from the side or above or at an angle, whether it is actually measured or just eyeballed, and what in fact makes a gap "too big."*
>
> *. . . it may be the case that the hazard is "obvious" to a knowledgeable observer, and can be readily demonstrated. . . However, in the absence of specific training about the hazard and its meaningful assessment, such obviousness will likely not actually be within the working knowledge of the caregivers.*[17]

While we support CMS's plan to impose stronger safeguards for bed rails, whether or not they are intended as physical restraints, our comments do not imply that the imposition of the criteria we recommend would always make bed rails safe. In fact, we do not see any way in which they would be safely used as a physical restraint because—even if every entrapment zone were eliminated—many residents would attempt to defeat the restraint by climbing over it. Moreover, the substitution of other types of bed rails for side rails does not obviate the need to adhere to the guidelines for side rails. Products sold under names such as bed handles, bed canes or halo rings, for example, pose an equal or sometimes greater entrapment and entanglement risk; and portable bed rails usually marketed for use at home should never be permitted in a long term care facility because of their greater risk of failure once installed.

Our comments do not address psychosocial effects of being confined for hours a day or for weeks, months or years in a hospital-like environment, but the right to a quality of life and a homelike environment should be considered.

The proposed rules leave to chance whether providers will have adequate processes to ensure that staff who have appropriate knowledge and equipment evaluate the complex factors associated with entrapment and other risks in bed systems with rails. Perfunctory observations will not achieve the reduction in risk that is necessary.

Recommendations on Bed Rails

Add under § 483.10(d) – Right to be free from bed rails used as a physical restraint or without the consent of the resident to treat a medical symptom

CANHR recommends the creation in § 483.10(d) of a standalone resident right to be free from bed rails used as physical restraints or for any reason for which the resident himself or herself has not requested them to treat a medical symptom, such as assistance to facilitate mobility and independence; for which safety assessments proposed in the sections designated as § 483.25(2) and § 483.90(c)(3) have not been met; for which alternatives have not been attempted; and for which informed consent has not been given by the resident. Inability to give informed consent should be considered as a risk factor for endangerment.

Even if a resident is fully informed about bed rail hazards, decides that there are benefits that outweigh any risks, and requests a bed rail, informed consent does not obviate the responsibility of the facility to comply with the requirements in this regulation. Eliminating dementia and other factors that affect cognition reduces but may not eliminate risk, especially if the resident's medical condition or mental status changes unexpectedly or even temporarily. A resident who ordinarily realizes that trying to climb over a bed rail would be foolish may forget if a new drug or a urinary tract infection makes her confused. The movement of a mattress away from a bed rail, the addition of a mattress overlay, or the loosening or breaking of a bed rail's attachment to the bed frame could create a hazard. Periodically scheduled assessments of facilities' bed systems must be conducted, as well as prompt reassessments when there are even temporary changes in the resident's health, physical condition, or mental status, or when there is any change in the bed or bed rail. Alternative devices marketed as mobility assists (such as bed handles, bed canes, and halo rings) should be subject to the same concern and scrutiny as side rails because they carry the same entrapment hazards; and portable bed rails should be prohibited for use with any resident.

CANHR recommends that the following right be added under proposed §483.10(d).

> ***Right to be free from bed rails used as a physical restraint or without the consent of the resident to treat a medical symptom.*** *The resident has the right to be free from bed rails used as a physical restraint, for purposes of discipline or staff convenience, or for any purpose for which the resident himself or herself has not requested them to treat a medical symptom, such as the need to improve mobility and increase independence; for which all safety protocols in § 483.25(2) and § 483.90(c)(3) have not been complied with; for which alternative methods have not been attempted; and for which written informed consent has not been given by the resident. For a resident who gives informed consent, the facility must document that he or she has received information about the risks of entrapment and falls prior to installation of bed rails. Such consent shall not obviate the need for proper initial and ongoing assessment of patients and equipment.*

Requirements When a Facility Uses Bed Rails, Section 483.25(d)(2)

When other criteria for using a bed rail for a resident have been met (§ 483.10(d) and §483.90(c)(3)), a protocol should be in place for a risk assessment to be conducted by a qualified interdisciplinary team. Determining a resident's risk for bed rail injury and the safety of bed rails and bed components should not be left to a perfunctory review by staff who do not have the knowledge to conduct such assessments.

CANHR recommends removing this provision from section (d), Special care issues, but keeping it in § 483.25, Quality of care and quality of life, and strengthening the requirements proposed in this section as follows:

When the requirements in § 483.10(d) – The right to be free from bed rails used as a physical restraint or without the consent of the resident – are met, the facility shall have an interdisciplinary team of licensed staff, including at least a registered nurse, physician, and licensed physical and/or occupational therapist with knowledge of how to conduct risk assessments of residents and bed components. Risk assessments shall follow a protocol that includes:

(1) Documentation of alternatives the facility attempted with the resident prior to installing a bed rail.

(2) An interdisciplinary individualized risk assessment of a resident prior to installing bed rails and a reassessment each time there is a change in the resident's medical, physical or mental condition, including medications that may cause confusion or impaired cognition and reduced mobility. Risks include but are not limited to: small body dimensions, dementia, confusion, agitation, reduced mental capacity, and limited mobility.

(3) A safety assessment of each bed that is used with a resident, including the position of the bed rail(s) and mattress; the security of the attachment of the bed rail to the bed frame; the type of mattress used (including air mattresses, mattress overlays, air fluidized beds, and flotation therapy beds, which pose greater entrapment risk); and gaps within rails and between rails and the mattress, the headboard, and the footboard, regardless of whether the bed rail used is a side rail or other rail-type device, such as a bed handle, bed cane, or halo ring.

(4) An assessment of the bed for potential movement of the rail or mattress and for spaces between the parts of the rail large enough to trap a resident's head or chest; and a regular process for repeating this assessment when any components of the bed system are changed, or bed systems are obtained from rental agencies.

(5) Prohibition of portable bed rails because variables that increase risks to residents—such as mattress type and width, rail position, and secure installation – cannot be adequately controlled.

(6) Documentation of the results of the assessment.

(7) A provision to ensure that all staff have basic knowledge about bed rail risks and facility protocols and observe and immediately report any condition or incident involving a resident and a bed rail that has the potential for injury or death.

(8) Requirements for all personnel who provide care or services to residents in the facility (such as a hospice) to comply with the facility's bed rail protocols.

Inspections and Maintenance of Bed Frames, Mattresses and Bed Rails, Section 483.90(c)(3)

CANHR recommends strengthening proposed § 483.90(c)(3) related to inspection and maintenance of bed frames, mattresses, and bed rails as follows:

The facility must:

1) Conduct regular inspections of all bed frames, mattresses, and bed rails, as part of a regular maintenance program and compliance with protocols specified in § 483.25(d)(2),

including the use of an interdisciplinary team of licensed staff with knowledge of bed rail safety assessment.
2) Ensure that all components are compatible when bed rails and/or mattresses are used or obtained separately from a bed frame for which they were designed to be used.
3) Ensure that when bed rails or bed systems with bed rails are purchased or rented already assembled or configured by a supplier, the facility should follow its own protocol to assess the bed's components to ensure that there is no risk of entrapment.
4) Ensure that the bed and bed rail are assembled according to the manufacturer's specifications and do not have gaps within or between components that could cause entrapment.
5) Repeat inspections whenever any component of the bed system is replaced since even "look-alike" parts can have differences that affect safety.
6) Replace bed systems for which compatible components are no longer available; and discard bed rails that do not have a manufacturer's label because they cannot be identified in case of a recall or properly reported in the case of an incident.

Discharge Planning, Section 483.21(c))

We strongly support the proposed discharge planning requirements, subject to the modifications recommended below. The proposed requirements are far superior to the current requirements and will help protect residents from the dangerous consequences of unplanned discharges. In our experience, many nursing home residents are discharged with little to no planning and without consideration of their needs and preferences. Other residents who would like to return to the community are unable to due to lack of meaningful discharge planning. The weak current requirements on discharge planning are contributing to this problem.

We are concerned, however, that the proposed requirements do not address or reference residents' transfer and discharge rights. It is critical that they do so because many nursing home operators may otherwise read these requirements to authorize them to discharge residents who still need nursing home care after their Medicare coverage ends, in the name of "transitioning" residents from SNF to post-SNF care, per the proposed requirements.

"Discharge" for many residents is a form of eviction. In California and elsewhere, countless nursing homes have adopted a business model focused on attracting lucrative short-term residents paying through Medicare and then throwing them out once their Medicare coverage ends. This crisis was the subject of an April 14, 2015 cover story in the New York Times, *In Race for Medicare Dollars, Nursing Home Care May Lag.*"[18]

As CMS knows, the race for Medicare dollars is fueled by sky-high profit margins for Medicare funded nursing home care, which the Office of Inspector General reported this month to be nearly 30 percent for therapy services alone.[19] Given that windfall profits from Medicare overpayments are providing a great financial incentive to nursing home operators to transfer or evict residents who need long term care, the Requirements of Participation should strongly guard against this practice.

Many residents need continuing nursing home care when their Medicare coverage ends and are not ready for discharge. Rather than needing to "transition" to another setting, they need long term care in the nursing "home" where they reside. Residents in this situation are routinely told by nursing homes that Medicare is discharging them, with the idea that residents and their representatives will go along with what is presented as a government determination that they must leave the facility. For residents still needing nursing home care, what is described as a "discharge" is actually a form of involuntary transfer, or eviction. District offices of the California Department of Public Health have described this type of illegal eviction as an "epidemic."

Another concern is that the proposed regulation refers to effective transition of the resident from "SNF to post-SNF care." Perhaps unintentionally, this language gives the impression that the requirements apply only to Medicare certified SNFs and not to Medicaid certified NFs. The final regulation should be modified so that the requirements clearly apply to both SNFs and NFs.

Finally, we are concerned that the provision at subdivision (c)(v) to involve the resident in the development of the discharge plan and then "inform" the resident of the final plan is not in keeping with the spirit of these requirements. Nursing homes are likely to construe this language to allow them final say in the plan even in situations where residents oppose the plan. We recommend clarifying this provision to prevent this interpretation.

We recommend amending subdivision (c) as follows:

(c) Discharge planning—(1) Discharge planning process. The facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals and preparing residents to be active partners in post-discharge care, effective transition of the resident from SNF to post-SNF care <u>or from NF to post-NF care</u>, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must—
(i) Ensure that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident.
(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.
(iii) Involve the interdisciplinary team, as defined by § 483.20(b)(2)(ii), in the ongoing process of developing the discharge plan.
(iv) Consider <u>and assess</u> caregiver/support person availability and the resident's or caregiver's/support person(s) <u>willingness,</u> capacity and capability to perform required care, as part of the identification of discharge needs.
(v) Involve the resident and resident representative ~~in~~ <u>throughout</u> the development of the discharge plan and ~~inform~~ <u>provide</u> the resident and resident representative <u>a copy</u> of the ~~final~~ plan.
(vi) Address the resident's goals of care and treatment preferences.
(vii) <u>Fully comply with the residents' transfer and discharge rights established at sections 483.12 and 483.10(o) and ensure that residents are not subjected to inappropriate transfers or discharges.</u>
~~(vii)~~ (viii) Document that a resident has been asked about their interest in receiving information regarding returning to the community.

Physician Services, Section 483.30

Proposed §483.30(e) would require a physician, a physician assistant, nurse practitioner, or clinical nurse specialist to conduct an in-person evaluation before a resident is transferred to a hospital, except in an emergency. We strongly urge you to delete this change because it will do far more harm than good.

One of the most common complaints we receive about nursing homes is that residents do not receive timely medical attention or hospitalization when they become seriously ill due to neglect. Residents and their families often report that they had to arrange hospitalization themselves during a life-threatening emergency because the nursing staff at the facility did not recognize the emergency or administrative staff advised against hospitalization.

It would be particularly cruel and ill-advised to prevent residents whose lives are endangered by nursing home neglect from getting transferred to the hospital without first being examined by physicians who may also have been neglecting them.

The preamble states that the proposed requirement is needed to help avoid unnecessary hospitalizations, while saying nothing about the failure to arrange timely hospitalization when residents suffer an acute illness or experience life-threatening medical problems. Both problems are caused by the lack of qualified nursing staff, especially RNs, in nursing homes, and by the very limited presence of physicians, physician assistants, nurse practitioners and clinical nurse specialists in nursing homes. In failing to address the broader problem, CMS would be putting many residents' lives in danger by making it harder for them to get hospitalized when they need it.

Residents routinely die when substandard nursing homes fail to arrange timely hospitalization during medical crises.

To cite one example, California Attorney General Kamala Harris issued a press release on August 28, 2015 announcing involuntary manslaughter charges against Verdugo Valley Skilled Nursing & Wellness Centre involving the "senseless, tragic and unnecessary death" of a resident who received "grossly negligent" care.[20] The resident, James Populus, suffered severe weight loss, sepsis and pneumonia that led to his death on August 30, 2014. The facility's director of nursing and supervising nurse were charged with dependent adult abuse causing death, in part because the facility failed to send Mr. Populus to the hospital immediately when he experienced a changed level of consciousness and needed to be hospitalized. The Declaration in Support of Arrest Warrant alleges that staff delayed calling 911 and failed to document critical changes in their patient's condition, in addition to making false entries in medical records.

The proposed emergency exception does not diminish our concerns because nursing home staff members are too often unable to recognize emergencies and are frequently unprepared to respond to them. The following examples are California nursing homes that were cited for not recognizing or responding appropriately to serious changes of conditions for residents who died.

Windsor Redding Care Center – Delayed Assessment and Treatment After Resident Fractured Femur in Avoidable Fall – February 27, 2014 Complaint Investigation Survey**:** The victim was subjected to repeated avoidable injuries due to neglect. The deficiency states: "These failures resulted in repeated avoidable bruises and skin tear injuries, two avoidable falls, one with multiple injuries, two emergency hospital transfers, and a broken leg." The broken leg led to her death when the facility failed to promptly notify her physician and seek treatment. At least three staff nurses failed to report the injury and seek treatment in a timely manner. When the resident was eventually hospitalized, the ER physician described it as a "severe injury" and noted that an APS complaint was made because of discrepancies between the claimed time of injury versus the appearance of the bruises. Surgery was ruled out, the resident was put on hospice, returned to the facility and died.[21]

Yuba Skilled Nursing Center – Delayed Assessment and Treatment After Fall and Hip Fracture – February 20, 2014 Complaint Investigation Survey: A resident unnecessarily suffered pain for 12 hours after he fell out of bed and broke his hip. Except for a Tylenol, he got no pain medication during this period. The assigned CNA told the investigator the nurses ignored the resident even after she told them he was in intense pain. She reported that *"RN A never touched him and did not do any assessment… CNA G said she approached RN A three times to tell her Resident 1 was hurt and needed to go to the hospital, but RNA seemed irritated and walked away. CNA G said she then went to LVN B to tell her that Resident 1 was hurt and needed to go to the hospital, but LVN B said that Resident 1 was not her resident and she could not interfere."* Eventually the resident was taken to the hospital, where it was determined that fractures could not be repaired. He was put on comfort measures and died.[22]

Valley West Care Center – Delayed Assessment and Treatment after Fall and Head Injury – January 9, 2014 Standard Survey: The facility did not assess the resident after he was found kneeling on the floor of his room on 12/15/13 with abrasions on both knees. The facility failed to conduct a neurological assessment. Over the next two days, he had three headaches, two episodes of vomiting and fever, and by the second morning after his fall he was unresponsive. The facility did not contact his physician for more than 12 hours after observing a change in his condition. Upon hospitalization, it was determined that he had suffered a large subdural hematoma. The resident died in the hospital on 12/20/13.[23]

Windsor Chico Creek Care and Rehab Center – Nurses Ignore Dying Resident – November 1, 2013 Complaint Investigation Survey: The victim was admitted for short-term therapy with a plan to return home. He had a POLST calling for full resuscitation/CPR. On the day of his death, 10/4/13, the resident was in distress and a CNA reported to his nurse, a LVN, that his oxygen levels were dangerously low. The LVN did not notify his physician or the RN for further assessment as required, telling the investigator her skills were better than the RN's. Instead of getting emergency care for the resident, she told him (the resident) that he wasn't responding well. The LVN reported knowing the resident was a full code but ignored that too, stating that she thought it unusual for someone with cancer to have this status. According to the LVN, it was a sign that "you are not realizing your status." Making matters worse, another LVN entered the resident's room and found him looking lifeless. Instead of calling an alarm, the LVN reported that he "left the room and went to check on other residents." Eventually EMS was summoned and pronounced the resident dead.[24]

The Pavilion at Sunny Hills (formerly Fullerton Healthcare & Wellness) – Too Busy to Aid Dying Resident – October 23, 2013 Standard and Complaint Investigation Surveys: This facility was cited for the neglect of several residents, one of whom died. On the morning of the victim's death, a CNA reported at 8 am that the resident was having difficulty breathing, was making a loud gurgling sound and needed to be suctioned. The CNA informed a nurse about the resident's distress but the nurse continued passing medications and did not go to the resident. According to the CNA, the ADON and another nurse came to the resident's room at 10 am but neither nurse suctioned the resident. At noon, the CNA stated she returned to the resident's room and he had expired. Another nurse claimed to have suctioned the resident at 10 am but says she did not notify his physician because his condition had not changed. A family member who lived nearby and was his representative reported she was not alerted to his change of condition and would have gone to be with him if she had known he was dying. The facility did not call her until 1:15 pm, long after he died.[25]

Sea Cliff Healthcare Center – No Monitoring or Emergency Care for Dying Resident – October 4, 2013 Complaint Investigation Survey: This deficiency identifies three residents who were neglected, including one who died. The resident had a serious change of condition around 11 pm. He vomited, had an elevated heart level and dangerously low oxygen saturation level. The resident's family was not informed and the resident was not sent to the hospital. A nurse working the next shift reported she did not closely monitor his situation because she was not informed of the change of his condition. At 10:54 the next morning, a CNA found the resident unresponsive with no heart rate and brown vomit. A nurse called his doctor but did not reach him. 911was not contacted. The nurse stated that the physician was upset with the facility for not contacting 911.[26]

Lassen Nursing & Rehabilitation (previously Country Villa Riverview Rehabilitation) – Resident Dies Because Incompetent Nurses Unable to Process Basic Lab Tests – September 5, 2013 Complaint Investigation Survey: A resident died from septic shock due to an extreme urinary tract infection that worsened and went without any treatment for over two months due to the nursing staff's repeated failures to process or follow-up on physician ordered urine specimens. Several weeks went by while the facility sent three urine specimens that were rejected by the lab due to contamination or other errors. As the resident's condition declined and the infection became life threatening, the nursing staff failed to submit an acceptable urine specimen during a two-month period. The lab did alert the facility that the resident had a UTI but this information was not shared with the resident's doctor. The doctor and the facility's registered dietitian also requested blood and stool tests during this period, but the nursing staff neglected to act on these and the tests were never completed. The resident's physician expressed no awareness that the tests he ordered were never completed or reported back to him. After the resident went into septic shock, she was hospitalized (only upon request of her child) and then transferred to a major medical center due to her dire condition. She died three days later.[27]

Glenwood Gardens Skilled Nursing Facility – Death Due to Failure to Provide Critical Lab Results to Physician – May 29, 2013 Complaint Investigation Survey: On 4/19/13, a 75-year old resident died after the facility failed to report critical laboratory results to his physician.

The physician ordered the tests on 4/17/13 and directed the facility to notify him of the results as soon as they arrived. The facility received the results the next day, which showed critical problems requiring immediate attention, but did not review them or notify the physician. On 4/19/13, the resident was found unresponsive and was transferred to the hospital where he was diagnosed with septic shock, renal insufficiency and anemia. He died within a few hours. After he died, his physician went to the facility and found the critical laboratory results that had not been relayed to him. During the investigation, the resident's physician reported he had a meeting with the DON and other nurses at the facility on 4/18/13, before the resident's critical laboratory results were received, to advise them to call him for all laboratory results because he had been having problems getting notified. The physician stated, "I told them you guys are going to kill somebody."[28]

Mission View Health Center – Death Due to Multiple Nursing Failures – February 19, 2013 Complaint Investigation Survey: The victim was admitted for therapy after knee replacement surgery and was expected to return home to his wife, a retired nurse, in 2-4 weeks. Soon after he was admitted, his appetite began to decline and he started experiencing nausea and diarrhea. On 10/25/12, his physician told him he had an infection, possibly C-diff. In the words of the resident's roommate, for "two and one half days, he couldn't eat because he was nauseated. I heard him vomiting a lot. In the night, he had diarrhea all over the place." Despite these life-threatening changes, the facility did not reassess his condition. His wife reported he "suffered with horrible abdominal pain" on 10/28/12 but no pain medication was given. The facility did not report the abdominal pain to his physician for hours after it was observed. After notification, the physician went to the facility and sent him to the hospital immediately where he died. The death certificate stated the cause of death was C.diff and septic shock.[29]

Healdsburg District Hospital – Death After Nurse Reinserts Feeding Tubing Outside of Resident's Stomach – January 29, 2013 Complaint Investigation Survey: A resident who was fed by a gastric tube died after a nurse reinserted the tube outside of the stomach on 6/5/12, which led to sepsis, kidney failure and death. A nurse found the feeding tube lying on the resident's stomach when she went into his room to turn the feeding tube on. She inserted a new tube with some difficulty but did not detect that the tube was misplaced. The resident turned gray within 2 hours and worsened through the evening as tube feedings were continued through the misplaced tube. He displayed signs of septic shock throughout the night but the nurses did not conduct an assessment and did not notify his physician. The nurses did not know the signs and symptoms of sepsis. The nurses also failed to seek an X-ray to check the placement of the tube. At 8 am the following morning, the hospital Rapid Response Team was called because the resident was in full-blown septic shock. The hospital intensive care nurse who responded said the team should have been called much earlier. The resident was transferred to the hospital ICU, then to another hospital ICU and died on 6/17/12.[30]

We provided several examples to illustrate how common it is for nursing home residents to die in these circumstances, however, the case examples are the tip of the iceberg. There are hundreds of similar cases documented in statements of deficiencies issued to nursing homes throughout the nation. Moreover, the deaths identified and cited by the survey process are a tiny fraction of the nursing home residents who are harmed by barriers to timely hospitalization when their lives are endangered by medical crises.

The proposed regulation would make matters far worse for many residents. Nursing homes will have new incentives to delay contacting residents' physicians who are not immediately available to carry out an in-person evaluation.

A better way to accomplish the goal of reducing avoidable hospitalizations would be to mandate 24-hour RN care in all nursing homes and require facilities to provide a minimum of 0.75 hours of RN care per resident per day, and more as may be required by resident needs. Improving the quality of nursing assessment will improve resident care, help prevent residents from being unnecessarily hospitalized and help identify when hospitalization is needed in a timely manner.

CANHR recommends that proposed section 483.30(e) be deleted.

Administration, Section 483.70

The proposed regulations move former Section 483.75(i), regarding facility medical directors, to Section 483.70(h) with no changes in the language. We recommend that CMS use this opportunity to address a role that medical directors are often asked to serve and rightfully should serve: to provide physician services to residents who do not have an attending physician. We have observed several cases where a resident's physician is no longer able to serve as an attending physician and the facility responds by evicting the resident. Medical directors seem perfectly suited to provide physician services in the interim until a permanent attending physician can be found.

We recommend that Section 483.70(h) be amended to add

(3) The medical director shall provide physician services to residents who do not have an attending physician.

Competency of Contract Staff, Section 483.35

We are aware and appalled that the American Health Care Association (AHCA) is urging nursing homes nationwide to fight the proposed requirement that all nursing staff members have the appropriate competencies and skill sets to meet resident needs. According to AHCA's website instructions to its members on this issue, *"requiring the center to be responsible for the competency of contract staff is unreasonable and should be the responsibility of the contractor."*

We strongly disagree with the AHCA position and support the requirement that a nursing home is responsible for the competency of all of its staff members, including contract staff. The use of incompetent contract nurses and nurse aides is a common source of abuse and neglect in nursing homes. The presence of incompetent contract staff in nursing homes seriously diminishes residents' ability to attain or maintain the highest practicable physical, mental, and psychosocial well-being.

If a nursing home cannot ensure the competency of contract staff, it should not use them. Nursing homes that choose to use incompetent contract staff must be held accountable when this choice affects residents' care or quality of life.

Medical Records, Section 483.70(i)

The proposed regulations do not address the pervasive falsification of records in nursing homes and fail to establish any requirements on the integrity of electronic health records.

Intentional falsification of records is a common occurrence in nursing homes, some of which are known to hold "charting parties" before surveys to create the appearance that residents received care and services that were never delivered, or to otherwise cover-up neglect. It is part of the culture in many nursing homes to chart medications, therapy, baths, treatments and other types of care that were never given and to fabricate information on how much residents eat and drink.

The deliberate falsification of nursing home records was the subject of an extensive investigation by the Sacramento Bee and a two-part series, *Falsified patient records are the untold story of California nursing home care*.[31] The series reported that nursing homes have been caught altering entries and outright lying on residents' medical charts with disastrous human consequences. Here are some of the examples the Sacramento Bee cited.

- A supervising nurse admitted under oath that she was ordered to alter the medical records of a 92-year-old resident, who died after developing massive, rotting bedsores at the facility.
- On at least 28 occasions, a nursing home charted that therapy was provided to a resident by an aide who was not at work on those days;
- Lawyers for a woman severely re-injured at a nursing home discovered a string of false entries – several written by nonexistent nurses.

Mark Zahner, former chief of prosecutions for the California Attorney General's Bureau of Medi-Cal Fraud and Elder Abuse is quoted in the articles:

"The idea that they chart things before they happen or make things up way after the fact if something hits the fan – those are things that we're familiar with. And we see (this) with regularity."

Nursing home survey reports are filled with evidence of falsified records, with very few consequences for the perpetrators.

For example, Windsor Elmhaven Care Center, a skilled nursing facility in Stockton, California received two "D" level deficiencies during a complaint investigation survey involving a resident's death that was completed on July 30, 2013.[32] During a 5-week stay at the facility, the resident who was the subject of the complaint gained 73 pounds due to severe fluid retention. According to the survey report, he gained almost 30 pounds during the first week of his stay, while the facility had not acted on the hospital's recommendation for an oral diuretic. His family member reported she was very worried about the resident's swelling and fluid retention and

talked to the staff about putting him on medications he used at home to reduce the swelling. There were delays in contacting his doctor and implementing orders for medication. After becoming unresponsive, the resident was hospitalized and died the next day. The facility recorded on the MDS that the resident gained only 5 pounds during his stay, rather than the 73 pounds he actually gained. The MDS nurse stated that her signature only indicated that the MDS document was complete, not accurate.

As is often the case, the California Department of Public Health treated both the resident's death and the falsification of records as minor violations.

The current requirements on clinical records at §483.75(l) requires that they be "accurately documented" but is silent on falsification and facilities' obligation to prevent alteration of the records. **We recommend that CMS strengthen the clinical record requirements to address this issue by adding the following language to proposed §483.70(i).**

(5) The facility shall ensure that all clinical records, including electronic health records, are free from material falsifications or omissions.
(i) Material falsification means any entry in a resident's clinical record that falsely reflects:
(A) The condition of the resident;
(B) The care, treatment, medications or services provided to the resident;
(C) Assessments, lab results, tests and vital signs involving the resident;
(D) Effects of any medication, treatment or other care provided to the resident;
(E) Communications concerning the resident; or
(F) Any adverse event involving the resident.
(ii) Material omission means the failure to record any untoward event or change of condition that has affected the health, safety, security, or dignity of a resident.

Additional protections are needed for electronic health records. Given CMS's stated goal of modernizing the Requirements of Participation, we are surprised that the draft rules do not include any requirements on the integrity of electronic health records. The preamble describes CMS's intent to "recognize the advent of electronic health information technology," but the proposed rules do not provide any standards for their use. Standards are needed to prevent the type of fraud described above.

We are not experts on the security of electronic health records but we strongly urge CMS to apply its expertise in this area and at a very minimum to codify the security requirements for electronic health records that are established at F514 of Appendix PP of the State Operations Manual. These provisions call for built-in safeguards to prevent fraud; that each staff responsible for an attestation has an individual identifier; that the date and time is recorded from the computer's internal clock at the time of entry; that an entry is not to be changed after it has been recorded; and that the computer program controls what sections any individual can access and enter data based on the individual's personal identifier.

Additionally, we recommend that:

- **The regulations use the current term, "clinical records," rather than the narrower term, "medical records," that is used in the draft regulations.**
- **CMS codify the definition/description of a "complete clinical record" established at F515 of Appendix PP of the State Operations Manual.**
- **The regulations be amended to require facilities to report instances or allegations of material falsification or material omission to the State Survey Agency and to applicable State licensing boards governing administrators, physicians, nurses, therapists, certified nursing assistants, social workers and other licensed personnel when these health professionals falsify records.**
- **CMS establish separate regulatory authority to impose automatic, strong civil monetary penalties and other sanctions against facilities whose records have been compromised by material falsification or omission.**
- **The draft Compliance and Ethics program requirements at proposed §483.85 be amended to address the facility's obligation to maintain the integrity of all its records, including clinical records, and to prevent falsification and alteration of any records.**

Disclosure of Quality Assurance and Performance Improvement (QAPI) Information, Section 483.75(h)

Subdivision (h) gives state and federal surveyors access to QAPI reports, data, analysis of adverse events and other documentation considered necessary to determine compliance with QAPI requirements.

We are aware that national and state industry trade associations are objecting to these provisions, claiming that surveyors should not have access to the content of QAPI data.

We strongly disagree. If nursing homes are able to cloak information on adverse events from surveyors or others by labeling them as QAPI documents, it will turn the law on its head. The purpose of the quality assurance provisions is to ensure that nursing homes identify and act on information about neglect, abuse and other adverse events, not that they be able to hide this information by making it part of a QAPI record. Federally funded nursing homes must not be allowed to use the QAPI process to shield information that surveyors, law enforcement and other authorities need to assess or sanction poor care or abuse.

Surveyors should have access to all QAPI records and be fully authorized to assess compliance with QAPI requirements.

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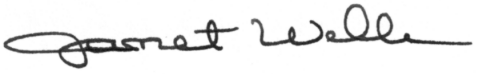
Thank you for considering our comments.

Sincerely,

Michael Connors
Advocate

Anthony Chicotel
Staff Attorney

Patricia L. McGinnis
Executive Director



Janet Wells
Consultant

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[7] California Health and Safety Code Section 1430(b).
[8] Current 42 C.F.R. §483.25(c)(1).
[9] Current 42 C.F.R. §483.25(c)(2).
[10] 42 U.S.C. §§1395i-3(b)(2), 1396r(b)(2), Medicare and Medicaid, respectively.
[11] Just last week, the Consumer Financial Protection Bureau stated "arbitration clauses enable companies to avoid being held accountable for their conduct." Consumer Financial Protection Bureau, "*CFPB Considers Proposal to Ban Arbitration Clauses that Allow Companies to Avoid Accountability to Their Customers,*" October 7, 2015 Press Release, p. 2. Available at: http://www.consumerfinance.gov/newsroom/cfpb-considers-proposal-to-ban-arbitration-clauses-that-allow-companies-to-avoid-accountability-to-their-customers/
[12] June 22, 2015 Statement of Deficiency issued to Vintage Faire Nursing & Rehab, 3620 B Dale Rd., Modesto, CA. The complaint investigation survey report is available on Nursing Home Compare at:

https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555355&SURVEYDATE=06/22/2015&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&loc=MODESTO,CA&lat=37.6390972&lng=-120.9968782&name=VINTAGE FAIRE NURSING %26 REHAB&Distn=5.8

[13] Center for Public Integrity, *Nursing homes serving minorities offering less care than those housing whites*, November 17, 2014. Available at: http://www.publicintegrity.org/2014/11/17/16275/nursing-homes-serving-minorities-offering-less-care-those-housing-whites

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[21] February 27, 2014 statement of deficiency issued to Windsor Redding Care Center, 2490 Court Street, Redding, CA 96001. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=056258&SURVEYDATE=02/27/2014&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=WINDSOR REDDING CARE CENTER&Distn=0.0

[22] July 20, 2014 statement of deficiency issued to Yuba Skilled Nursing Center, 521 Lorel Way, Yuba City, CA 95991. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=056346&SURVEYDATE=02/20/2014&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=YUBA SKILLED NURSING CENTER&Distn=0.0

[23] January 9, 2014 statement of deficiency issued to Valley West Care Center, 1224 E Street, Williams, CA 95987. The standard survey inspection report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555200&INSPTYPE=STD&SURVEYDATE=01/09/2014

[24] November 1, 2013 statement of deficiency issued to Windsor Chico Creek Care and Rehab Center, 587 Rio Lindo Avenue, Chico, CA 95926. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=056074&SURVEYDATE=11/01/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=WINDSOR CHICO CREEK CARE AND REHAB CENTER&Distn=0.0

[25] October 23, 2013 statement of deficiency issued to The Pavilion at Sunny Hills, formerly Fullerton Healthcare and Wellness Centre, 2222 N. Harbor Blvd. Fullerton, CA 92835. The survey report is posted on Nursing Home Compare at:

https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555733&SURVEYDATE=10/23/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&Distn=2.3&loc=FULLERTON,CA&lat=33.8702923&lng=-117.925338

[26] October 4, 2013 statement of deficiency issued to Sea Cliff Healthcare Center, 18811 Florida Street, Huntington Beach, CA 92684. The survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555249&SURVEYDATE=10/04/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=SEA CLIFF HEALTHCARE CENTER&Distn=0.0

[27] September 5, 2013 statement of deficiency issued to Lassen Nursing & Rehabilitation, formerly Country Villa Riverview Rehabilitation and Healthcare Center, 2005 River Street, Susanville, CA 96130. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=056231&SURVEYDATE=09/05/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=LASSEN NURSING %26 REHABILITATION CENTER&Distn=0.0

[28] May 29, 2013 statement of deficiency issued to Glenwood Gardens SNF, 350 Calloway Drive, Building C, Bakersfield, CA 93312. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555771&SURVEYDATE=05/29/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=GLENWOOD GARDENS SNF&Distn=0.0

[29] February 19, 2013 statement of deficiency issued to Mission View Health Center, 1425 Woodside Drive, San Luis Obispo, CA 93401. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=055079&SURVEYDATE=02/19/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=Mission View&Distn=0.0

[30] January 29, 2013 statement of deficiency issued to Healdsburg District Hospital DP/SNF, 1375 University Avenue, Healdsburg, CA 95448. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=555590&SURVEYDATE=01/29/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&state=CA&lat=0&lng=0&name=HEALDSBURG DISTRICT HOSPITAL DP%2FSNF&Distn=0.0

[31] Sacramento Bee, Falsified patient records are untold story of California nursing home care, September 18-19, 2011. Available at: http://www.sacbee.com/news/investigations/article2573412.html

[32] July 30, 2013 statement of deficiency issued to Windsor Elmhaven Care Center, 6940 Pacific Avenue, Stockton, CA 95207. The complaint investigation survey report is posted on Nursing Home Compare at: https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=055735&SURVEYDATE=07/30/2013&INSPTYPE=CMPL&Inspn=HEALTH&profTab=1&Distn=5.2&loc=STOCKTON,CA&lat=37.9577016&lng=-121.2907796