

September 9, 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 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.

This letter solely addresses our comments concerning dementia care and chemical restraints. We are submitting comments on other aspects of the proposed regulations by separate letter.

The rewrite of the Requirements of Participation presents a once-in-a-generation opportunity to finally stop the pervasive chemical restraint of nursing home residents who suffer from dementia and to establish a humane standard of care that will achieve the goals of the Nursing Home Reform Law of 1987. CMS must seize this opportunity to comprehensively address this enduring public health crisis or it will doom another generation of dementia victims to the horrific abuses they face in nursing homes today.

Ending this abuse is the defining issue of our time in nursing homes. Nearly 30 years after the Reform Law required nursing homes to offer compassionate care in a homelike setting, far too many facilities routinely drug residents with dementia into submission. Consequently, public fear of nursing homes has never been greater.

For most persons with dementia, nursing homes are nothing like the image cultivated by the nursing home industry of places where elders go to get skilled therapy and treatment that enable them to return home and lead improved lives. Nursing home care of residents who have dementia is often characterized by profound ignorance, chemical restraint, erosion of their dignity and neglect. Entering a nursing home is typically a death sentence for someone with dementia.

As CMS acknowledges in the preamble, two-thirds of those dying with dementia die in nursing homes. In our experience, their deaths are often preceded by terrible suffering from falls, infections, bedsores, dehydration, malnutrition and other life-threatening conditions that are

caused by antipsychotic drugs and other types of chemical restraints. It would be a tragic mistake to reform the Requirements of Participation without taking the strongest possible steps to address this human rights crisis.

The severe harm antipsychotic drugs cause to people with dementia cannot be overstated. Mountains of studies and FDA warnings document the dangers of death and dangerous side effects.¹ Antipsychotic drugs cause mental anguish and devastating cognitive loss that dull the spirits, sap the personalities and crush the spirits of their victims. Placing the mind of someone who is already struggling to think into a chemical straight jacket is an act of extreme cruelty.

There are epidemic levels of chemical restraint in nursing homes today. Nursing homes report they are currently giving antipsychotic drugs to over 281,000 residents.² Even without taking into account the likely underreporting, this is a staggeringly high number of people being drugged. Nearly all of them have dementia – 88 percent according to Inspector General Daniel Levinson – a population the FDA has warned faces a significantly increased risk of death from these drugs and should not be taking them.³

In a January 2015 report, the GAO revealed that about one-third of older adults with dementia who spent more than 100 days in a nursing home in 2012 were prescribed an antipsychotic.⁴

The difference between the reality of pervasive use of chemical restraints and the Reform Law's requirement that residents be free from chemical restraints could not be starker. Despite the law, nursing homes are extraordinarily dangerous places for people with dementia to live.

We are deeply troubled by CMS's failure to adequately address these issues in the proposed regulations. The proposed rules are virtually silent on dementia care, give very little attention to chemical restraints and informed consent, and would reduce focus on antipsychotic drugs.

The proposed regulations are dangerously out of touch with reality when discussing the magnitude of antipsychotic abuse in American nursing homes. For example, without citing any data, they claim that "there has been a reduction in the number of antipsychotics prescribed to residents" since the LTC requirements became effective in 1992 and make the suggestion that we now need to be more concerned with the use of other psychoactive medications.

Whether today's drugging rate is slightly higher or slightly lower than the number of residents drugged in 1992 does not change the fact that hundreds of thousands of nursing home residents are today being subjected to antipsychotic drugs that are far more likely to harm or kill them than to help in any way. The misuse of these drugs is elder abuse on a massive scale. How much longer must we wait before CMS takes action that matches the severity of this crisis?

The recommendations presented below are common sense solutions that are long overdue. They include a standard for dementia care that is based on CMS's guidance on this subject. We recommend a new section on chemical restraints and unnecessary use of psychotropic drugs that is based on regulations HHS proposed in 1992. These are practical solutions that can make an enormous difference in the quality of care and quality of life of nursing home residents who have dementia.

A. Dementia Care

1. Establish a Standard of Care for Residents Who Have Dementia

It is critical that the Requirements of Participation establish a standard of care for persons with dementia. However, the proposed regulations are entirely silent on this subject.

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

The quality of care in most of our nation's nursing homes is shockingly low for persons who have dementia. Each day, over a quarter million nursing home residents who have dementia are chemically restrained by nursing staff and physicians who have little understanding of their needs. The current "standard of care" for many of these residents is to be drugged, abused and treated as if they are subhuman. Any attempt to modernize the Requirements of Participation should address this problem head on.

There is a huge disconnect between the promotion of the proposed regulations, the commentary in the preamble to the regulations and the actual content of the proposed regulations. The proposed regulations were announced with great fanfare at the July 13, 2015 White House Conference on Aging with promises that they would align the regulations with current professional standards and help improve care for persons who have dementia. The Conference on Aging also featured announcements about HHS plans to build a health care workforce with the skills to provide high quality dementia care and about a private initiative to establish "dementia friendly communities" throughout the nation.⁵

Nursing homes should be dementia friendly communities, but most are not. One of the saddest facts about U.S. nursing homes is how little most of them know about how to care for the core population of residents with dementia.

How can it be that the CMS found it necessary to establish its National Partnership to Improve Dementia Care in nursing homes in 2012, yet the proposed regulations treat "dementia" as a dirty word? The word "dementia" appears only once in the proposed regulations, at the very end, and in a very limited manner concerning in-service training of nurse aides. The lessons that CMS and nursing homes have learned about good dementia care through this campaign should be in these regulations, but they are not. The proposed regulations are silent on dementia care.

In its April 1, 2014 Report on the CMS National Partnership to Improve Dementia Care in Nursing Homes, CMS acknowledged that nursing home residents with dementia are in harm's way.⁶ The report makes the following points:

- As many as one in four nursing home residents receive at least one antipsychotic medication, many of whom have dementia and are at grave risk of harm from these drugs;

- Dementia care specialists and practitioners advocate for a person-centered supportive community with the knowledge, skills and expertise to meet the needs of persons with dementia as envisioned by the Nursing Home Reform Law.
- Non-drug approaches to optimize care for people with dementia living in nursing homes have not been widely implemented to date.

In other words, most nursing home residents who have dementia are being drugged instead of receiving the individualized, quality care that the Nursing Home Reform Law has required for nearly 30 years. With few exceptions, nursing homes are not staffed by persons who have the knowledge, skills and expertise to help residents with dementia attain or maintain their highest practicable level of physical, mental and psychosocial well-being. A major course correction is needed.

We recognize and appreciate that CMS aims to improve the care of all residents through its proposed requirements on person-centered care planning. Individualized care is one of the cornerstones of good dementia care and the Nursing Home Reform Act of 1987. However, requiring care to be person-centered is not a substitute for establishing dementia care standards within the regulations.

Nor is the proposed §483.40 on “Behavioral health services” a substitute for dementia care standards. It is not at all clear if this section is intended to target persons with dementia or, if so, what type of services would be required. The proposed section does not use the term “dementia,” does not define “behavioral health services” and does not identify who would provide these services. However, the following statement in the preamble to the proposed regulations suggests that this section is aimed at persons with dementia:

The potential overuse of antipsychotic agents is a symptom of a much larger problem—namely, that many nursing facilities may not have a systematic plan to provide comprehensive behavioral health care to residents with diagnoses such as dementia and BPSD.

Directing nursing homes to provide undefined “behavioral health services” to residents who have dementia is likely to be as confusing and ineffective as the current requirement at 483.25(l) to use “behavioral interventions” when attempting to discontinue use of antipsychotic drugs. Both terms are dated, restrictive and misleading in the dementia context because they give the mistaken impression that it is the behavior of residents who have dementia that needs to be fixed. It is well recognized that the “behavior” of persons with dementia is a form of communication, not an illness that requires an intervention or behavioral health service.

In most cases, a resident’s distress may be caused by the nursing home environment or the inadequacy of staff to meet her needs. In these cases, it is the nursing home that needs an intervention, not the resident.

The so-called “behaviors” of residents with dementia are often expressions of distress about illness, pain, overmedication, loneliness, hunger and other causes. A resident’s communication of needs does not require comprehensive behavioral planning but rather good care. Helping

residents who are agitated due to untreated pain or infection or upset about sitting in a soiled brief for hours isn't a behavioral health problem, it's neglect.

Characterizing needs or distress expressed by persons with dementia as “behavior problems” or “behavioral and psychological symptoms of dementia” has long contributed to a harmful medicalization of these communications that has been used to justify the use of dangerous and ineffective psychoactive drugs. Instead of reinforcing these misunderstandings by prescribing “behavioral health services” for residents with dementia, HHS should be setting strong, clear standards of care for dementia care in nursing homes.

Although they are nowhere to be found in the proposed regulations, CMS has established core standards on dementia care in nursing homes. They were published on May 24, 2013 in Survey & Certification Memorandum 13-35-NH on Dementia Care in Nursing Homes. The following core standards within this guidance should be codified in the regulations so they will be known and enforceable.

CANHR recommends the establishment of dementia care standards within the quality of care requirements at 42 CFR §483.25 or, alternatively, as a stand-alone section that establish the following requirements;

Care of residents who have dementia.

The facility shall:

- (1) Provide a supportive and safe physical and psychosocial environment for residents with dementia that promotes comfort and enables them to achieve their highest practicable physical, mental and psychosocial wellbeing;*
- (2) Individualize care for each resident with dementia by tailoring it to all relevant considerations for that individual, including physical, functional, and psychosocial aspects;*
- (3) Engage residents and their representatives in all aspects of decision-making about their care.*
- (4) Arrange staffing to optimize familiarity with the resident (e.g., consistent caregiver assignment).*
- (5) Treat behavioral expressions of distress as a form of communication and identify, to the extent possible, factors that may underlie a resident's distress, as well as applying knowledge of lifelong patterns, preferences, and interests for daily activities to enhance quality of life and individualize routine care.*
- (6) Evaluate residents who have new or worsening expressions of distress through its interdisciplinary team, including the physician, in order to identify and address treatable medical, physical, emotional, psychiatric, psychological, functional, social, environmental and other factors that may be causing the distress.*
- (7) Monitor any interventions to determine efficacy, risks, benefits and harm.*
- (8) Ensure that residents with dementia are free from unnecessary use of psychoactive drugs and chemical and physical restraints.*
- (9) Train all staff on dementia care and the facility's policies and procedures for meeting these requirements;*
- (10) Ensure that residents with dementia who cannot verbalize their wishes are not denied*

their right to be visited by family members and others with immediate access.

Establishing these requirements should not cost any money or create any new burdens for providers because they are existing requirements of the Nursing Home Reform Act expressed in a dementia care context. Nursing homes have had nearly 30 years to implement the Reform Law, so they should have taken these steps long ago. Operators who lack the expertise to provide good care to persons with dementia should not be in the nursing home business and certainly should not be allowed to participate in the Medicare and Medicaid programs.

2. Require All Nursing Home Employees to Receive Training on Care of Residents who have Dementia

As noted above, the word “dementia” appears only once in the proposed regulations, in §483.95(g)(2) on “Training requirements.” In accordance with the Affordable Care Act, this section calls for in-service “dementia management training” for nurse aides. Although we understand that the proposed regulations use the wording from the law, it is a poor choice of words. Nurse aides should not be taught to “manage” dementia but rather to become experts in dementia care. We recommend using “dementia care training” instead and to require all staff members to receive it, not just nurse aides.

We do not share CMS’s confidence, expressed at page 42240, that nursing homes will take advantage of high quality training programs, such as the Hand-in-Hand training materials that CMS produced and distributed to all nursing homes. It is our understanding that very few nursing homes are using these training materials and that many of them did not even open the free training guides CMS mailed to them. CMS should clarify in regulations that training in dementia care is subject to the same competency evaluation as other nurse aide training requirements. Unless CMS sets and enforces meaningful standards of care, it is unreasonable to expect that vague, limited training requirements will significantly improve the abysmal care so many nursing home residents with dementia are experiencing.

The regulations should require everyone who works in a nursing home, not just nurse aides, to be trained on dementia care. Training is especially important for the licensed nurses who often know very little about caring for someone with dementia and are not qualified to supervise the nurse aides who provide most of the direct care. Nurses who lack expertise in dementia care are not likely to stop handing out dangerous pills to residents with dementia or to know how to identify and respond to their needs.

B. Chemical Restraints

The proposed requirements on chemical restraints and antipsychotic drugs are very weak and will do little to stop the rampant abuse that has continued for decades. Stronger standards are needed that will give real meaning to each resident’s right to be free from chemical restraints.

The most serious flaw with the proposed requirements is that they are virtually silent on chemical restraints. The proposed requirements include the statutory language on chemical restraints without definition or any standards to provide meaning to this right.

The proposed rules governing use of antipsychotic drugs would make the following changes to current requirements on antipsychotic use.

- Move the “unnecessary drug” requirements at 483.25(1) to the re-designated §483.45 on “Pharmacy services.”
- Revise current requirements at 483.25(1)(2) on antipsychotic drugs to apply to all psychotropic drugs, including antipsychotics.
- Limit PRN (as needed) orders for psychotropic drugs to 48 hours, with exceptions.
- Define psychotropic drugs as any drug that affects brain activities associated with mental processes and behaviors.
- Require consultant pharmacists during drug regimen reviews to review the resident’s medical chart when psychotropic drugs are being used and require a resident’s attending physician to document in the resident’s medical record that he or she has reviewed any irregularities identified by the consulting pharmacist and explain what actions were taken, if any, and provide a rationale if no change is made.

Although we support some of the proposed changes, they are an extremely insufficient response to the abusive use of antipsychotic and other psychoactive drugs in nursing homes.

We strongly oppose the proposed move of the “unnecessary drug” requirements to the re-designated §483.45 on “Pharmacy services.” Moving these requirements in this manner creates the impression that misuse of antipsychotic drugs is primarily a “pharmacy” problem to be solved by pharmacists rather than the fundamental human rights and quality of care problem that it is. The unnecessary drug requirements must be elevated, not buried in “Pharmacy services” where they are highly unlikely to be enforced.

There is a disconcerting lack of attention on misuse of antipsychotic drugs. The preamble states that reducing misuse of antipsychotic drugs is a priority, however, the proposed regulations make only a single mention of antipsychotics as part of the definition of psychotropic drugs. Reducing the focus on antipsychotic drugs would be a big step backward.

The proposed improvements on drug regimen reviews are greatly compromised by CMS’s failure to address the widespread conflicts of interests involving consultant pharmacists. In many nursing homes, consultant pharmacists employed by national long-term care pharmacies promote selected antipsychotic drugs and other types of psychotropic drugs on behalf of their employers. Unless their lack of independence is addressed, consultant pharmacists are not suited to this watchdog role.

The proposed regulations give little sign that CMS is aware that there is rampant misuse of antipsychotics in nursing homes today or any indication that it is outraged by this crisis and determined to stop it. Rather, the proposed regulations appear to be a continuation of CMS’s slow-motion National Partnership to Improve Dementia Care, which relies on voluntary goals to reduce nursing home antipsychotic use by just 5 percent per year. In so doing, the campaign is tolerating an intolerable level of chemical restraint in our nation’s nursing homes that subjects huge numbers of residents to misery and abuse.

The education-oriented focus of the National Partnership leaves it to the discretion of nursing home operators whether to follow the law. While education is valuable to well-motivated providers, the history of the Reform Law shows that no amount of education will end the chemical restraint crisis. Both before and after the Reform Law was passed in 1987, there were many educational efforts on the dangers of antipsychotic use in nursing homes and non-drug care approaches for residents who have dementia.

For example, on July 22, 1991, national experts gathered in Washington, DC, for a major forum held by the Senate Special Committee on Aging called “Reducing the Use of Chemical Restraints in Nursing Homes.”⁷ It featured messages nearly identical to those of the National Partnership today. Leaders of the day attacked the inhumanity of drugging residents who have dementia, discussed studies showing that antipsychotic drugs are extremely dangerous and do not work for this population, explained that it is harder (not easier) to take care of drugged-up residents, identified successful non-drug approaches to care for residents with dementia, pointed out that it is the culture of the nursing home rather than residents’ needs that determines antipsychotic use, called for nursing homes and physicians to recognize that behavior is communication (not an illness), taught that nursing home caregivers need to change their own behaviors rather than the behavior of residents with dementia, criticized nursing homes for using chemical restraints as a substitute for staffing, bemoaned the hidden costs of treating illnesses and injuries caused by these drugs, expressed fear that a crackdown on antipsychotics in nursing homes would trigger a shift to other types of psychotropic drugs, and falsely promised strict enforcement of the Reform Law’s prohibition on chemical restraint.

David Sherman, a highly respected California pharmacist and national leader on stopping chemical restraints in nursing homes, moderated the forum and gave the opening presentation. He started with the following observation:

It was not too long ago that we routinely warehoused mentally ill people in facilities that came to be known as snake pits. In these places, meals were shoved under the doors, and electroshock was administered as punishment for lack of cooperation with institutional rules. Today, we look back at those times with disdain and even disbelief that we could have treated our fellow human beings in this way.

I think that at some time in the not too distant future we will similarly look back at this time, the routine drugging of our elders, as an equally barbaric form of treatment.

Mr. Sherman’s words were partially prophetic in that we do increasingly consider the routine drugging of our elders as barbaric. Astonishingly, this knowledge has not transformed chemical restraint practices in many nursing homes, where the barbaric treatment is as common now as it was in 1991. Presenters at the 1991 forum reported that 30 to 40 percent of nursing home residents who had dementia were given antipsychotic drugs, about the same level the GAO reported in its 2015 study on antipsychotic use.⁸

In California today, where the nursing home industry is boasting about the level of antipsychotic reduction, there are nearly 20,000 nursing home residents being given antipsychotic drugs.

California currently has 160 nursing homes that are giving antipsychotic drugs to over 30 percent of their residents, 74 facilities that are giving antipsychotics to more than 50 percent of residents and, incredibly, 26 nursing homes that are drugging more than 90 percent of their residents.⁹ Three federally certified nursing homes in California are giving antipsychotics to 100 percent of their residents.

As in 1991, the missing ingredients today are enforceable requirements and actual enforcement. Nursing home operators face no consequences for barbaric treatment of their residents.

Under the Reform Law, “each resident” is entitled to care and services that allow him or her to attain or maintain the highest practicable physical, mental and psychosocial well-being, including every one of the 281,000 nursing home residents throughout the nation who are being given antipsychotic drugs. The final regulations must ensure that “each resident’s” right to be free from chemical restraints and misuse of antipsychotic drugs really does matter and enable CMS and state survey agencies to vigorously protect their rights.

We make the following recommendations on chemical restraints.

1. Establish a New Section on “Freedom from Chemical Restraints and Unnecessary Psychotropic Drugs”

We recommend a new section be created named “Freedom from chemical restraints and unnecessary psychotropic drugs” for the same reasons CMS gives for establishing a new section on care planning.

To emphasize the level of importance for care planning and to increase the visibility of the requirements, we propose to remove the requirements for care plans from current § 483.20(k) and discharge planning in current § 483.20(l) (collectively referred to here as care planning) and relocate them to a new proposed § 483.21, entitled “Comprehensive Person-Centered Care Planning.” This new section would contain all of the existing requirements for care planning. We believe that relocating the requirements to a new section dedicated solely to care planning would emphasize the importance of care planning as well as provide clarity to the regulations.

As in care planning, a new section is needed on chemical restraints and unnecessary use of psychotropic drugs to emphasize their importance and to increase the visibility of these requirements. Although the rights to be free from chemical restraint and inappropriate use of psychotropic drugs are central tenets of the Nursing Home Reform Act of 1987, they are routinely ignored as demonstrated by the horrific antipsychotic drugging levels discussed earlier. To signify its critical importance, CMS should amend the definition of “substandard quality of care” at §488.301 to include this new section.

Our recommendations for this new section build upon the proposed regulations HHS published on February 2, 1992 to address chemical and physical restraints.¹⁰ Those regulations, which were originally intended to establish enforceable regulatory requirements for the Nursing Home

Reform Act of 1987's provisions on chemical restraints and psychoactive drugs, are far superior to the proposed regulations on these rights.

The preamble to the 1992 proposed regulations gives an important history lesson on why Congress enacted the chemical restraint protections:

We believe the proposed regulations on psychopharmacologic drugs and chemical restraints are necessary to cope with a significant public health problem in many, but not all of this nation's long-term care facilities. For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with this subject have appeared in a number of medical journals. These papers generally question the extent of the use of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.

Congress took action on this issue by enacting the chemical restraint provisions of OBRA '87. In enacting these provisions, Congress has determined that the facility, and not only the prescribing physician, can be held responsible for the inappropriate use of chemical restraints. They did this by giving the resident the right to be free of chemical restraints except under certain circumstances and held the skilled nursing facility or the nursing facility responsible for "protecting and promoting" this right for each resident (see sections 1819(c)(1)(A) and 1919(c)(1)(A)).

It is appalling that chemical restraint of nursing home residents can be traced back to 1975 and earlier while so little has been done to prevent it. To this day, HHS has not acknowledged why it abandoned the rules it proposed in 1992, which helped set the stage for the ongoing crisis that exists today.

CANHR recommends that a new section be added to the Requirements of Participation on the "Right to be free from chemical restraints and unnecessary psychotropic drugs." Elements of this section are discussed immediately below, followed by proposed language for this entire section beginning on page 22.

2. Restore the Right to Be Free from Chemical Restraints and Unnecessary Psychotropic Drugs

The purpose of this proposed section is to restore a resident's right under the Reform Law to be free from chemical restraints, which CMS and state survey agencies have almost universally ignored. The failure to treat unnecessary use of psychotropic drugs as a chemical restraint is a major barrier to enforcing the Reform Law and must be corrected.

Without objection from CMS, state survey agencies long ago abandoned enforcement of the right to be free from chemical restraint. Chemical restraint is one of the most common and most serious violations in nursing homes today, but it is almost never cited or enforced. A 2014 study

and report by the Long Term Care Community Coalition found that there were only 124 deficiencies issued to nursing homes in the entire U.S for violation of this right over a three year period, 2011-2013.¹¹ About half the states did not issue a single deficiency for violating a resident's right to be free from chemical restraints over this period.

In recent years, CMS has actively diminished the right to be free from chemical restraint. Its National Partnership to Improve Dementia Care in Nursing Homes has not focused any attention on this right and its 2013 revisions to its Surveyor Guidance concerning misuse of antipsychotics almost entirely ignored it. The 2014 CMS Interim Report on the National Partnership does not even discuss enforcement of the right to be free from chemical restraint even after giving lip service to it being a central tenet of the Reform Law.

The right to be free from chemical restraints is indeed a central tenant of the reform law and its importance must be recognized and restored in the final regulations. In calling inappropriate use of psychotropic drugs "chemical restraint," Congress signified that it was a violation of a fundamental liberty that had no place in nursing home care. Names and labels can have great power, especially the terms we use to describe crimes of abuse. If CMS and state survey agencies started treating unnecessary use of psychotropic drugs as "chemical restraint," and adopted the changes we propose below to give teeth to this right, it would profoundly improve conditions for the hundreds of thousands of nursing home residents who are daily subjected to chemical straight jackets.

The current CMS approach, which focuses mostly on whether antipsychotic drugs are necessary, almost invariably fails to consider the destructive impact they have on residents' lives. Rather than reforming this approach, the proposed regulations double-down on it.

CANHR recommends the following introductory language for this section. It ties "chemical restraint" and "unnecessary psychotropic drugs" together, consistent with the Reform Law's description of a "chemical restraint" as a drug "not required to treat the resident's medical symptoms."

(a) Each resident has the right to be free from chemical restraints and unnecessary psychotropic drugs.

3. Define "Chemical Restraint" as Unnecessary Use of a Psychotropic Drug

In the proposed 1992 regulations on chemical restraint, HHS defined "chemical restraint" in a manner that was brilliantly modeled on the "unnecessary drug" definition at §483.25(1). HHS proposed the following definition.

(7) In these regulations chemical restraint means a psychopharmacologic drug, as defined under paragraph (a)(2) of this section, that is used for the purpose of discipline or convenience and not required to treat the resident's medical symptoms, including when the drug is used in one or more of the following ways:

- (i) In excessive dose (including duplicate drug therapy);*
- (ii) For excessive duration;*

- (iii) Without adequate monitoring;*
- (iv) Without adequate indications for its use;*
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; and*
- (vi) In a manner that results in a decline in the resident's functional status.*

Linking “chemical restraint” to the “unnecessary drug” definition has important advantages. It precisely identifies when use of a psychotropic drug is a chemical restraint. This approach is fully consistent with the Reform Law’s prohibition on chemical restraints that “are not required to treat the resident’s medical symptoms.” Importantly for enforcement purposes, it removes the need to make the false choice between whether misuse of a psychotropic drug is an “unnecessary drug” or a “chemical restraint.”

Subject to the modifications discussed below, we strongly urge CMS to adopt the 1992 proposed definition in the final regulations.

In addition to the above-criteria, HHS should define “chemical restraint” to include situations where a nursing home is using antipsychotics and other types of psychotropic drugs without having carefully assessed the resident and tried appropriate non-drug approaches first.

Due to their dangers, antipsychotic drugs should only be used as a last resort even when they may be clinically appropriate. Although this point is not disputed, many nursing homes are using antipsychotics as a front-line treatment for dementia.

CMS acknowledged this concern in its May 24, 2013 Survey and Certification Memorandum (S&C: 13-35-NH) on unnecessary drugs and dementia care. The memo states:

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behaviors without first determining whether there is a medical, physical, functional, psychological, emotional, psychiatric, social or environmental cause of the behaviors.

During its campaign, CMS has strongly urged providers to use antipsychotics as a last resort and to master use of non- pharmacological options; yet the proposed unnecessary drug regulation is silent on the need to try non-pharmacological options first.

In its January 2015 report on antipsychotic drugs, the Government Accountability Office (GAO) made the following finding on this subject:

Clinical guidelines suggest the use of antipsychotic drugs for the treatment of behavioral symptoms of dementia only when other non-pharmacological attempts to ameliorate the behaviors have failed and the individuals pose a threat to themselves and others.¹²

This principle must be included in the regulations or nursing homes will continue to ignore it.

CANHR recommends the following definition of “chemical restraint.”

(b) Chemical Restraint –

- 1) Definition: Chemical restraint is the use of a psychotropic drug that is imposed for purposes of discipline or convenience and not required to treat the resident’s medical symptoms, including when the drug is used in one or more of the following ways:*
 - (i) In excessive dose (including duplicative drug therapy); or*
 - (ii) For excessive duration; or*
 - (iii) Without adequate monitoring; or*
 - (iv) Without adequate indications for use; or*
 - (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or*
 - (vi) In a manner that results in a decline in the resident’s functional status; or*
 - (vii) Before the facility carefully assessed medical, physical, functional, psychological, emotional, psychiatric, social and environmental factors that may have caused the symptoms or distress for which the drug was prescribed; or*
 - (viii) Before the facility planned, implemented, assessed and documented individualized, non-pharmacological approaches based on its assessment to alleviate the resident’s symptoms or distress; or*
 - (ix) Any combination of the above circumstances.*

4. Establish Presumption that Chemical Restraints Harm Residents

Chemical restraint is a horrific type of abuse that is inherently harmful to its victims. Chemical restraints cause mental anguish, degrade a person’s dignity, and pose life-threatening risks. As it has done for other types of abuse, HHS should establish a presumption within the regulations that chemical restraint harms residents.

The proposed definition of “abuse” at §483.5 contains the following statement:

“This presumes that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish.”

The proposed definition of abuse would codify the current definition of abuse at F223 of the CMS Guidance to Surveyors for Long Term Care Facilities in Appendix PP of the State Operations Manual.

We strongly support codifying this presumption because it sends a strong message that abuse is not tolerated in any situation, even if abuse victims are not able to express distress and clinicians are not able to measure harm.

It should be no different for chemical restraint, which is banned by the exact same sentence of the Reform Law. By its very nature, chemical restraint is an attack on a person’s dignity and mental wellbeing that is no less harmful because its damage cannot be precisely measured. Drugging nursing home residents who have dementia into submission is inherently harmful and a crime against humanity.

There are endless examples of the harm residents suffer when chemically restrained, but we will share one here. On August 16, 2015, Steve McCrea published a blog titled "[My Father-in-law on Risperdal – A Case Study Gets Personal](#)."¹³ Mr. McCrea eloquently describes his late father-in-law as a well-loved college professor with an unforgettable personality. In late life, years after he was diagnosed with Alzheimer's Disease, his father-in-law was admitted to a nursing home where he was put on the antipsychotic drug Risperdal without his knowledge or consent. His wife and daughter learned that he had been put on Risperdal after finding him in a near catatonic state, highly disoriented, unable to move or speak despite desperate efforts. His head and eyes were rolling from side to side, hands shaking and gripping the sides of his bed in obvious discomfort. Four days after they found out about the Risperdal and got it stopped, the misery disappeared and he was talking, singing and helping to meet some of his own needs. In closing, Mr. McCrea posed the following questions:

How many elderly dads and moms are out there, heads and eyes rolling from side to side, desperately trying to but unable to speak, who are not so fortunate? How many are forced to live in this state for months or years, while the staff and doctors turn a blind eye or attribute their difficulties to dementia, rather than considering the possibility that these powerful drugs are unnecessarily destroying the fragile quality of their remaining time on this earth?

The answer, sadly, is there are currently hundreds of thousands of moms and dads, brothers and sisters, husbands and wives, grandmothers and grandfathers throughout the nation who are being tortured in exactly this manner. Use of antipsychotic drugs in this way is chemical restraint and it is devastatingly harmful. Yet, in the eyes of CMS and state survey agencies, the immense suffering caused by these drugs is almost always treated as harmless.

Establishing a presumption that chemical restraint is harmful would reverse and correct the current approach.

A 2013 study by the Center for Medicare Advocacy and Dean Learner Consulting, conducted in cooperation with CMS, examined all antipsychotic drug deficiencies cited in seven states over a two-year period.¹⁴ The primary finding from the analysis of the F329 citations reflecting antipsychotic drugs is that 95% of the deficiencies are cited at a "no harm" level on the scope and severity grid, regardless of the poor outcomes for the residents, the total number or proportion of residents affected by the deficient practice, and the number of federal requirements violated by the facility. Consequently, no enforcement actions are taken.

The April 11, 2014 Interim Report on the CMS National Partnership to Improve Dementia Care in Nursing Homes, which contains national data, had even more alarming findings. It reported that the percentage of all F329 citations on annual surveys that were treated as harmful (G level or above) declined from 1.91 percent in 2009 to 0.93 percent in 2013.

These findings mirror our experiences in California. Despite having over 1,200 federally certified nursing homes, including some that drug all or nearly all of their residents with antipsychotics, we have not been able to identify any federal enforcement actions that have been taken since 2012 that were triggered by findings of antipsychotic misuse or chemical restraint.

As a partner in the CMS National Partnership to Improve Dementia Care, CANHR has been in regular discussion with CMS Region IX enforcement officials since 2012 about the need to strengthen enforcement practices related to misuse of antipsychotics. During this three-year period, Region IX officials have not identified a single case where it imposed any type of enforcement sanction due to a nursing home's inappropriate use of antipsychotics.

These practices are making a mockery of the Reform Law. In thousands of nursing homes throughout the nation, anyone can walk in and observe large numbers of residents who are drugged into oblivion with antipsychotic drugs that the FDA has warned may kill them and are much more likely to induce illness, injury and misery. Yet CMS trained surveyors can spend an entire career in these nursing homes without ever once citing a facility for harming a single resident through misuse of antipsychotic drugs.

The folly of the current approach puts helpless people with dementia at the mercy of nursing home operators who have no reservation about subjecting them to chemical restraints because there are no consequences for doing so. The entire CMS regulatory process favors the perpetrators of chemical restraint, who do not have to worry that their victims will speak out about their abuse to surveyors.

CANHR recommends that CMS adopt the following language establishing a presumption that use of chemical restraints is harmful, modeled on its proposed definition of abuse:

Harm: Instances of chemical restraint and unnecessary use of psychotropic drugs are presumed to cause harm to residents by inflicting mental anguish, violating their dignity, eroding their independence or diminishing their physical, mental and psychosocial well-being.

5. Modify the Definition of Psychotropic Drugs

The proposed regulations would establish the following definition of a "psychotropic drug."

A psychotropic drug is any drug that affects brain activities associated with mental process and behavior. These drugs include, but are not limited to the following:

- i. Antipsychotic;*
- ii. Antidepressant*
- iii. Antianxiety*
- iv. Hypnotic;*
- v. Opioid analgesic; and*
- vi. Any other drug that results in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section.*

We are concerned about how the proposed definition would be applied. Would a drug like Depakote, which does not fit into any of the listed drug types but is often used as a chemical restraint, always or never be considered a drug that affects brain activities associated with mental process and behavior?

In the absence of information on how appropriately the proposed definition would include drugs that are commonly used in nursing homes as chemical restraints, but are outside of the listed categories, we recommend that CMS expand the definition to include drugs that are prescribed with the intent of controlling mood, mental status or behavior, as HHS proposed in its 1992 proposed rule on chemical restraints.

CANHR recommends that CMS adopt the following definition of a “psychotropic drug.”

Definition: A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior or a drug that is prescribed with the intent of controlling mood, mental status or behavior. These drugs include, but are not limited to, drugs in the following categories:

- i. Antipsychotic;*
- ii. Antidepressant;*
- iii. Antianxiety;*
- iv. Hypnotic;*
- v. Opioid analgesic; and*
- vi. Any other drug that results in effects similar to the drugs listed in paragraphs (d)(1)(i) through (v) of this section.*

6. Strengthen Focus on Antipsychotic Drugs While Addressing Misuse of Other Types of Psychotropic Drugs

CMS is proposing to revise current requirements at 483.25(1)(2) on antipsychotic drugs to apply to all psychotropic drugs. The proposed regulations would accomplish this by identifying antipsychotic drugs as a type of psychotropic drug and would otherwise strip the regulations of any mention of antipsychotic drugs.

We strongly oppose the diminished attention to antipsychotic drugs within the regulation. At a time when nursing home misuse of antipsychotic drugs remains at crisis levels, this change would signal to nursing home operators, state survey agencies and the public that CMS is changing its focus away from abusive use of these drugs. The regulations should intensify the focus on preventing inappropriate use of antipsychotic drugs.

There is a better way to extend gradual dose requirements and other protections to other psychotropic medications while giving antipsychotics the attention they deserve within the regulations. **CANHR recommends this be accomplished by directing each of the requirements toward “antipsychotic drugs or other types of psychotropic drugs,” which is the approach we have taken in the following recommendations related to this section.**

7. Require physicians to examine nursing home residents before antipsychotic drugs or other types of psychotropic drugs are prescribed or administered, and require them to clinically justify their use.

Although it is highly inappropriate and dangerous, many physicians prescribe antipsychotic drugs and other types of psychotropic drugs to nursing home residents without seeing and examining them to assess their medical needs. By definition, this practice constitutes chemical

restraint because the nursing home would not be able to establish that the drug was required to treat a resident's symptoms.

Residents with dementia may be unable to describe pain or other discomfort caused by common medical problems, such as urinary tract infections, dehydration, malnutrition, diabetes, pressure sores, dental disease, and broken bones. Confusion, anxiety, aggression, and other symptoms resulting from undiagnosed or untreated medical conditions are often mischaracterized as behavioral symptoms of dementia and lead to prescribing antipsychotic drugs. When antipsychotic drugs are administered that suppress residents' ability to communicate, serious medical problems and even abuse often remain untreated; and residents are at risk of developing new and potentially fatal medical conditions caused by the drugs themselves.

CANHR recommends that CMS adopt the following language to require doctors to examine residents for underlying medical causes of their symptoms before prescribing antipsychotic drugs or other types of psychotropic drugs, to weigh any anticipated beneficial effect of the drug against its potential harmful effects, and to closely monitor side effects.

Based on a comprehensive assessment of a resident, the facility must ensure that residents are not given antipsychotic drugs or other types of psychotropic drugs unless:

- i. The medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;*
- ii. The prescribing physician has personally examined the resident immediately prior to prescribing it and clinically justified the need for the drug;*
- iii. The prescribing physician has reviewed the risks and benefits of the particular medication with the resident and, if applicable, the resident's representative and obtained informed consent in accordance with paragraph (d) of this section; and*
- iv. The prescribing physician and facility monitor side effects of the drugs, notify residents and their representatives promptly when side effects occur and respond appropriately to reports or observations that residents are experiencing adverse reactions.*

8. Establish standards governing use of antipsychotics and psychoactive drugs

The 1992 HHS proposed regulation on chemical restraints included specific safeguards to protect against inappropriate use of antipsychotic drugs and other types of psychotropic drugs that CMS should adopt in its final regulations.

For example, the earlier rule would have required nursing homes to justify that the beneficial effects of the drug clearly outweigh its potential harmful effects. This requirement is of particular importance for antipsychotics drugs prescribed for residents with dementia because the drugs would rarely pass this test. We strongly support the following preamble statement on this point from the proposed 1992 regulations and urge CMS to include this message in its final rule.

We propose that such drugs must not be used until the facility can justify that the beneficial effects of the drug clearly outweigh its potential harmful effects. We are proposing this requirement because we believe that it is necessary to the health and safety of residents that

there be a thoughtful analysis of the relative benefits versus the potential harm of drug use in each case. Drugs that are used to alter behavior, mood or mental status may have long-lasting or permanent adverse effects on the functional level of residents and should be prescribed only where the potential adverse effects are outweighed by the benefits of drug use.

The PRN use of antipsychotic drugs is another area of concern. We strongly urge CMS to completely ban PRN orders for antipsychotic drugs and other types of psychotropic drugs rather than restricting their use to 48 hours, with the possibility of extensions, as the proposed rules would permit.

Physicians should not be allowed to delegate responsibility to nursing staff to determine when and for how long antipsychotics and other psychoactive drugs are used. The use of standing orders for antipsychotic drugs is a recipe for abuse. This practice, almost by definition, negates fundamental residents' rights under the Reform Law. Not only is nursing home staff unqualified to make case-by-case determinations about antipsychotic use; but there is no medical justification for treating these drugs as if they were the equivalent of a mild pain reliever or other over-the-counter medication.

CANHR recommends that CMS adopt the following safeguards to protect against inappropriate use of psychotropic drugs, which are modeled on HHS's 1992 proposed rule on chemical restraints.

Any antipsychotic drug or other type of psychotropic drug administered to a resident must –

- i. Be ordered by a physician who specifies the dose, duration and reason for the use of the drug;*
- ii. Be used only as an integral part of the resident's comprehensive care plan that is directed specifically towards the elimination or modification of the symptoms for which the drugs are prescribed;*
- iii. Not be used unless it is justified in the clinical record that the potential beneficial effects of the drug clearly outweigh its potential harmful effects;*
- iv. Not be ordered or used on a standing, blanket, PRN or "as needed" basis;*
- v. Be monitored closely, in conjunction with the drug regimen review requirements at §483.60(c) for desired responses and adverse consequences by facility staff;*
- vi. Be used only when a record is maintained of the administration of the drug, the dose, the route of administration, side effect monitoring, a description of the behavior, mood or mental status which the drug is intended to alter, the effect of the drug on the behavior, mood and mental status of the resident, and any other change in behavior, mood, mental status or adverse drug reaction which occurs with the administration of the drug.*
- vii. Be reviewed at least annually by a physician who has training or experience in geriatrics and psychopharmacology and who must not serve a facility with which he or she has had a contractual, financial, employment or familial relationship with the facility, its owner, its attending physicians, medical director or administrator within any of the 36 consecutive months prior to the date of the review. The written report from the review shall be sent to the attending physician, the resident, the resident's*

representative and become a permanent part of the resident's clinical record. The review shall determine whether –

- A. The drug has an appropriate indication for use;*
- B. The dose is appropriate;*
- C. The duration of therapy is appropriate;*
- D. The benefits of using the drug outweigh the risks to the resident;*
- E. Non-drug therapy approaches have failed.*

9. Strengthen Gradual Dose Reduction Requirements

Medical literature does not support long-term administration of antipsychotic drugs. In fact, the opposite is true.

CMS addressed this point in its April 11, 2014 Interim Report on the CMS National Partnership to Improve Dementia Care in Nursing Homes. It states:

One question was, “Why are so many residents continued on these medications for long periods of time?” despite studies showing that behavioral and psychological symptoms of dementia do not worsen when many patients are tapered off antipsychotics. Even with this evidence and the risk of serious side effects, patients with dementia often remain on antipsychotic medications for extended periods of time and at higher than recommended dosages. Physicians with more knowledge of non-pharmacologic interventions may be more likely to consider those therapies; however, some studies suggest that providers may not choose a non-pharmacologic approach because of nursing staff requests for drug therapy.

The practices described in this excerpt are a form of chemical restraint. CMS should revise the Requirements of Participation to prevent residents from being left on dangerous drugs that serve no beneficial purpose.

As noted previously, the current requirement at 483.25(1)(2)(ii) that residents on antipsychotic drugs receive “behavioral interventions” is dated and misleading. Instead, nursing homes should be required to use individualized care, services, attention and environmental modifications that are directed specifically towards the elimination or modification of the symptoms or distress for which the drugs are prescribed.

CANHR recommends the following requirements on efforts to discontinue antipsychotic drugs or other types of psychotropic drugs for each resident who receives them.

- 4) In an effort to discontinue these drugs, each resident who uses antipsychotic drugs or other types of psychotropic drugs shall receive;*
 - (i) Gradual dose reductions, unless clinically contraindicated;*
 - (ii) Individualized care, services, attention and environmental modifications that are directed specifically towards the elimination or modification of the symptoms or distress for which the drugs are prescribed;*
- 5) The facility shall ensure that the prescribing physician reexamines a resident who has a diagnosis of dementia or a related disease within two weeks of ordering an antipsychotic*

drug and at least every 30 days thereafter to determine whether the drug can be discontinued. The facility shall ensure that the examinations are documented and made part of the resident's permanent clinical record.

10. Require written informed consent before use of psychotropic drugs.

Establishing strong, enforceable informed consent requirements on the use of psychotropic drugs is the single most important action CMS can take to help end the chemical restraint crisis in our nation's nursing homes.

The widespread use of chemical restraints is made possible because residents and their representatives are routinely kept in the dark about medication decisions and the dangers associated with their use. Very few residents on antipsychotics are told that the FDA has warned against their use as a treatment for dementia, are given information on black box warnings, or are advised that these drugs are being used for off-label purposes. Most residents on antipsychotics are told nothing at all before the drugs are prescribed.

The practice of giving residents life-threatening drugs without any information about the known dangers and without their consent violates the most central requirements of the Reform Law to be fully informed in advance about care and treatment and to make choices about care and treatment options. The need for strong regulatory action to protect these rights is desperately needed, especially given all that is known today about FDA warnings, the lack of efficacy of antipsychotic drugs, their many dangers, less dangerous care approaches for persons with dementia, and the impact of illegal marketing schemes by antipsychotic drug manufacturers.

Informed consent must be in writing to ensure that the purposes, risks and warnings about these drugs are accurately conveyed and to give residents and their representatives information to review and consider before making decisions. Nursing home physicians and staff are notoriously misinformed about antipsychotic drugs due to two decades of relentless, illegal promotion by drug companies that these drugs are effective treatments for dementia. The staggering impact of this unlawful marketing is powerfully documented in the Huffington Post's 15-part, September 2015 series, *America's Most Admired Lawbreaker*, which examines how drug giant Johnson & Johnson (J&J) made billions of dollars by illegally promoting its antipsychotic drug, Risperdal, as a treatment for dementia to nursing homes and physicians who treated the elderly.¹⁵

Although the Department of Justice has prosecuted nearly every major antipsychotic manufacturer for this crime, including J&J, and collected billions of dollars in civil and criminal settlements, these prosecutions have not undone the harm of their misinformation campaigns. Residents need trustworthy written information to consider, not just the often-misinformed opinions of the nurses and physicians who are pushing use of antipsychotic drugs.

A July 2012 report by the HHS Office of Inspector General on nursing home care planning for residents receiving antipsychotic drugs illustrates how little effort nursing homes make to involve residents and their representatives in decisions about using these drugs.¹⁶ The report reveals that "91 percent of records did not contain evidence that the resident, the resident's family, or the resident's legal representative participated in the care plan process." When

residents on antipsychotics do participate in care planning, their doctors are nowhere to be found. The OIG report states that only two out of 371 care plans in its study involved a psychiatrist, geriatrician or psychologist.

We are appalled that the proposed regulations are entirely silent on informed consent regarding use of psychoactive drugs. In the 1992 proposed rule on chemical restraint, HHS sought written informed consent and acknowledged then it was a necessary protection against chemical restraint. The need for written informed consent is far clearer and greater today.

The currently proposed regulations do, however, establish a right to informed consent concerning the use of bed side-rails, confirming that CMS has the full authority to require and regulate informed consent under the Reform Law.

The proposed new provisions on person-centered planning do not address our concerns. In our view, person-centered care is little more than a slogan without informed consent. The use of mind-altering drugs without consent violates perhaps our most precious and fundamental human right: the right to control what goes into our bodies and the freedom to make our own decisions. Informed consent lies at the heart of residents' ability to ultimately direct the course of their health care treatment.

CANHR recommends that the regulations provide the right to written informed consent prior to use of a psychotropic drug, with the following requirements:

- (d) Informed Consent: Before an antipsychotic drug or other type of psychotropic drug is used, the facility, in coordination with the prescribing physician, must –*
- (1) Explain the proposed use of the drug to the resident, and, if applicable, to the resident's representative, and provide the following information:*
 - (i) The specific medical reason the drug is being prescribed and reasonable alternatives;*
 - (ii) Non-pharmacologic approaches that could address the resident's needs;*
 - (iii) The nature, degree, duration and probability of side effects and significant risks associated with the proposed drug, including any FDA black box warnings;*
 - (iv) Whether the drug is being prescribed for off-label purposes;*
 - (v) Medication guides designed to inform patients about side effects of the drug;*
 - (vi) The proposed duration, dose and frequency of administration, and information on how the prescriber has taken the resident's age and health status into account for this purpose;*
 - (vii) Possible interactions with other medications the resident is receiving;*
 - (viii) How the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects.*
- (2) Explain the resident's right to refuse the drug;*
- (3) Obtain the written consent of the resident or, if applicable, the resident's representative and make this document a permanent part of the resident's clinical record;*
- (4) Explain the resident's right to withdraw consent at any time;*
- (5) Provide copies to residents and their representatives of any consent forms they sign.*

The complete language for the recommended new section on “Freedom from Chemical Restraints and Unnecessary Psychotropic Drugs” is presented below.

Freedom from chemical restraints and unnecessary psychotropic drugs

(a) Each resident has the right to be free from chemical restraints and unnecessary psychotropic drugs.

(b) Chemical Restraint –

(1) Definition: Chemical restraint is the use of a psychotropic drug that is imposed for purposes of discipline or convenience and not required to treat the resident’s medical symptoms, including when the drug is used in one or more of the following ways:

- (i) In excessive dose (including duplicative drug therapy); or
- (ii) For excessive duration; or
- (iii) Without adequate monitoring; or
- (iv) Without adequate indications for use; or
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (vi) In a manner that results in a decline in the resident’s functional status; or
- (vii) Before the facility carefully assessed medical, physical, functional, psychological, emotional, psychiatric, social and environmental factors that may have caused the symptoms or distress for which the drug was prescribed; or
- (viii) Before the facility planned, implemented, assessed and documented individualized, non-pharmacological approaches based on its assessment to alleviate the resident’s symptoms or distress; or
- (ix) Any combination of the above circumstances.

(2) Harm: Instances of chemical restraint are presumed to cause harm to residents by inflicting mental anguish, violating their dignity, eroding their independence or diminishing their physical, mental and psychosocial well-being.

(c) Antipsychotic and Psychotropic Drugs –

(1) Definition: A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior or a drug that is prescribed with the intent of controlling mood, mental status or behavior. These drugs include, but are not limited to, drugs in the following categories:

- (i) Antipsychotic;
- (ii) Antidepressant
- (iii) Antianxiety
- (iv) Hypnotic;
- (v) Opioid analgesic; and
- (vi) Any other drug that results in effects similar to the drugs listed in paragraphs (d)(1)(i) through (v) of this section.

(2) Based on a comprehensive assessment of a resident, the facility must ensure that residents are not given antipsychotic drugs or other types of psychotropic drugs unless:

- (i) The medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

- (ii) The prescribing physician has personally examined the resident immediately prior to prescribing it and clinically justified the need for the drug;
 - (iii) The prescribing physician has reviewed the risks and benefits of the particular medication with the resident and, if applicable, the resident's representative and obtained informed consent in accordance with paragraph (d) of this section; and
 - (iv) The prescribing physician and facility monitor side effects of the drugs, notify residents and their representatives promptly when side effects occur and respond appropriately to reports or observations that residents are experiencing adverse reactions.
- (3) Any antipsychotic drug or other type of psychotropic drug administered to a resident must –
- (i) Be ordered by a physician who specifies the dose, duration and reason for the use of the drug;
 - (ii) Be used only as an integral part of the resident's comprehensive care plan that is directed specifically towards the elimination or modification of the symptoms for which the drugs are prescribed;
 - (iii) Not be used unless it is justified in the clinical record that the potential beneficial effects of the drug clearly outweigh its potential harmful effects;
 - (iv) Not be ordered or used on a standing, blanket, PRN or "as needed" basis;
 - (v) Be monitored closely, in conjunction with the drug regimen review requirements at §483.60(c) for desired responses and adverse consequences by facility staff;
 - (vi) Be used only when a record is maintained of the administration of the drug, the dose, the route of administration, side effect monitoring, a description of the behavior, mood or mental status which the drug is intended to alter, the effect of the drug on the behavior, mood and mental status of the resident, and any other change in behavior, mood, mental status or adverse drug reaction which occurs with the administration of the drug; and
 - (vii) Be reviewed at least annually by a physician who has training or experience in geriatrics and psychopharmacology and who must not serve a facility with which he or she has had a contractual, financial, employment or familial relationship with the facility, its owner, its attending physicians, medical director or administrator within any of the 36 consecutive months prior to the date of the review. The written report from the review shall be sent to the attending physician, the resident, the resident's representative and become a permanent part of the resident's clinical record. The review shall determine whether –
 - (A) The drug has an appropriate indication for use;
 - (B) The dose is appropriate;
 - (C) The duration of therapy is appropriate;
 - (D) The benefits of using the drug outweigh the risks to the resident;
 - (E) Non-drug therapy approaches have failed.
- (4) In an effort to discontinue these drugs, each resident who uses antipsychotic drugs or other types of psychotropic drugs shall receive;
- i. Gradual dose reductions, unless clinically contraindicated;
 - ii. Individualized care, services, attention and environmental modifications that are directed specifically towards the elimination or modification of the symptoms or distress for which the drugs are prescribed;

- (5) The facility shall ensure that the prescribing physician reexamines a resident who has a diagnosis of dementia or a related disease within two weeks of ordering an antipsychotic drug and at least every 30 days thereafter to determine whether the drug can be discontinued. The facility shall ensure that the examinations are documented and made part of the resident's permanent clinical record.
- (d) Informed Consent: Before an antipsychotic drug or other type of psychotropic drug is used, the facility, in coordination with the prescribing physician, must –
 - (1) Explain the proposed use of the drug to the resident, and, if applicable, to the resident's representative, and provide the following information:
 - (i) The specific medical reason the drug is being prescribed and reasonable alternatives;
 - (ii) Non-pharmacologic approaches that could address the resident's needs;
 - (iii) The nature, degree, duration and probability of side effects and significant risks associated with the proposed drug, including any FDA black box warnings;
 - (iv) Whether the drug is being prescribed for off-label purposes;
 - (v) Medication guides designed to inform patients about side effects of the drug;
 - (vi) The proposed duration, dose and frequency of administration, and information on how the prescriber has taken the resident's age and health status into account for this purpose;
 - (vii) Possible interactions with other medications the resident is receiving;
 - (viii) How the facility and prescriber will monitor and respond to any adverse side effects and inform the resident of side effects.
 - (2) Explain the resident's right to refuse the drug;
 - (3) Obtain the written consent of the resident or, if applicable, the resident's representative and make this document a permanent part of the resident's clinical record;
 - (4) Explain the resident's right to withdraw consent at any time;
 - (5) Provide copies to residents and their representatives of any consent forms they sign.

C. Drug Regimen Reviews

As noted earlier, the proposed changes to strengthen the drug regimen reviews are compromised by the widespread conflicts of interests influencing consultant pharmacists. CMS must deal with these conflicts directly and ensure that residents are notified of irregularities identified during drug regimen reviews.

1. Mandate the Independence of Consultant Pharmacists

The consultant pharmacists who are supposed to monitor and detect problems with residents' drug regimens often serve as an extension of the sales workforce of long term care pharmacies. Under their watch, nursing home use of antipsychotics to sedate and subdue residents who have dementia surged over many years. They are the proverbial fox guarding the hen house.

As we write these comments, Omnicare – the nation's largest long term care pharmacy – is in the news once again for taking kickbacks for promoting use of chemical restraints in nursing homes. On July 8, 2015, McKnight's Long Term Care News reported that Omnicare announced it is settling two False Claims Act lawsuits with the Department of Justice over allegations it took millions of dollars of bribes for promoting the use of Depakote in nursing homes.¹⁷ Depakote is

an anti-seizure drug that is commonly used to chemically restrain nursing home residents. The kickbacks allegedly led to a spike in Depakote claims to Medicare and Medicaid, from less than \$3 million in 1998 to \$92 million in 2008.

CMS is well aware that consultant pharmacists are often severely compromised. When CMS proposed regulations in October 2011 to require nursing homes to employ consultant pharmacists who were independent of drug providers, many pharmacists submitted public comments describing practices that strongly influenced the overutilization of drugs and the prescribing of inappropriate types of drugs. CMS said the comments had convinced it that conflicts of interest existed and that concerns about the impact on quality of care were well founded. Despite this determination, CMS decided not to act, claiming a broader approach to this problem is needed.

The time for broader action is now. As part of the comprehensive reform of the Requirements of Participation, CMS should require the independence of consultant pharmacists.

CANHR recommends that proposed section 483.45 be revised as follows:

§ 483.45 Pharmacy services.

(b) Service consultation. *The facility must employ or obtain the services of an independent licensed pharmacist who—*

(1) *Provides independent consultation on all aspects of the provision of pharmacy services in the facility;*

(2) *Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and*

(3) *Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.*

(c) Drug regimen review.

(1) *The drug regimen of each resident must be reviewed at least once a month by an independent licensed pharmacist.*

(2) *This review must include a review of the resident's medical chart at least every 6 months and:*

(d) *To be considered "independent," a licensed pharmacist must not have any individual incentive, financial or otherwise, to overprescribe or to prescribe inappropriately.*

Accordingly, an independent licensed pharmacist must not be employed, under contract, or otherwise affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate, subsidiary, or parent of such entities.

2. Notify Residents of Irregularities Identified in Drug Regimen Reviews

Residents should not be kept in the dark when consultant pharmacists identify drug irregularities, which in some cases are life threatening. Transparency on this process will help ensure that nursing homes comply with their legal duty to keep residents fully informed about their health status and treatments. The notification to residents and their representatives should include a copy of the consultant pharmacist's recommendations and the physician's written response.

CANHR recommends that proposed section 483.45 be revised as follows:

~~(4)~~ (3) The **independent licensed** pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph ~~(d)~~ (l) of ~~this~~ section 483.25 for an unnecessary drug **or paragraph (b) of section** (insert number of new section on Freedom from chemical restraints and unnecessary psychotropic drugs) **for a chemical restraint**.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. **The report shall become a permanent part of the resident's clinical record.**

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(4) The facility shall promptly provide copies of the independent licensed pharmacist's written report on irregularities and the attending physician's written response to the affected resident and, if applicable, the resident's representative.

D. Adequate Staffing

We are submitting comments on other aspects of the proposed rule, including staffing requirements, by separate letter; however, we would be remiss not to summarize our concerns here about the strong connection between understaffing and chemical restraint.

We have long observed a direct connection between understaffing and chemical restraints. Invariably, nursing homes with high use of chemical restraints have dangerously low staffing levels. CANHR has received thousands of complaints about chemical restraints over many years and they almost always include complaints about insufficient staffing. It is apparent that nursing homes have a greater incentive to chemically restrain residents when they do not have enough staff to meet their needs.

This point is undisputed. The GAO succinctly summarized it in its January 2015 report on antipsychotic drug use.

In addition, experts and research have reported that nursing home staff levels, particularly low staff levels, lead to higher antipsychotic drug use.

Studies confirm our experience that nursing home use of chemical restraints often has little to do with the needs of residents. Instead, it is the prescribing culture of the facility that determines if you will be drugged.¹⁸ Nursing homes that rely heavily on chemical restraints are generally led by poorly trained nurses and are severely understaffed.

Chemical restraints are not the only nursing home problem associated with understaffing. Almost every aspect of poor care in nursing homes can be traced to insufficient and poorly trained staff. No matter how the Requirements of Participation are changed, nursing homes that are poorly staffed will remain very dangerous places for residents to live.

We oppose the “competency-based approach” proposed by CMS because 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.

We strongly urge CMS to set minimum nurse staffing levels for nursing homes and require 24-hour RN care in all U.S. nursing homes.

CANHR 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.

In summary, the Nursing Home Reform Law of 1987 was intended to transform nursing homes into places where residents were treated with dignity and were free from abuses such as chemical restraint. It speaks very poorly of nursing homes and efforts to regulate them that these indignities remain so very common today. The systematic violation of this law for so many years is a tremendous injustice that has claimed and ruined many lives.

This is a once-in-a-generation opportunity to fix the Requirements of Participation. The decisions CMS makes now will affect current nursing home residents and many millions more in the years to come. They deserve to be protected from the insidious impact of chemical restraints.

Education is no substitute for enforceable requirements and actual enforcement. It is wrong to allow nursing home operators to chemically restrain residents with impunity.

Over a quarter century of experience tells us that regulating around the edges of this crisis won't work. CMS must not abdicate its responsibility to address this crisis in the name of provider flexibility or burden reduction. Instead, it should pick up where its predecessors left off in 1992 and establish strong, comprehensive requirements on chemical restraints, informed consent and dementia care.

Good dementia care is not rocket science. Almost all of the lessons being rediscovered today about meeting the needs of persons with dementia were known 25 years ago. To ensure that they will not be ignored or forgotten again, CMS should translate these lessons into a standard of care within the Requirements of Participation.

The recommended changes will not cost CMS anything and will save money. Medicare and Medicaid will save hundreds of millions of dollars each year in unnecessary psychotropic drug costs and much more money by reducing hospitalizations for injuries and illnesses caused by chemical restraints. Nursing homes that are heeding the law and not using chemical restraints will not have to make changes. Facilities that are endangering residents through a culture of chemical restraint and understaffing will have to stop putting profit before care if they want to continue receiving federal funds.

Please seize this opportunity to humanize care of residents who have dementia for decades to come.

Sincerely,



Michael Connors
Advocate



Anthony Chicotel
Staff Attorney



Patricia L. McGinnis
Executive Director

¹ An extensive list of key studies on antipsychotic drugs is available on CANHR's stop drugging website: <http://www.canhr.org/stop-drugging/news-and-resources>

² MDS 3.0 Frequency Report, Second Quarter 2015, N0410A: Medications – Medications Received – Antipsychotic, Accessed August 26, 2015, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report.html>

³ OIG, Medicare Atypical antipsychotic Drug Claims for Elderly Nursing Home Residents, OEI-07-08-00150 (May 2011).

⁴ GAO, Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings, GAO 15-211, January 2015. Available at: <http://www.gao.gov/assets/670/668221.pdf>

⁵ White House Conference on Aging, July 13, 2015. Available at: <http://www.whitehouseconferenceonaging.gov>

⁶ Interim Report on the CMS National Partnership to Improve Dementia Care in Nursing Homes, CMS, S&C Letter 14-19-NH, April 11, 2014.

⁷ Senate Special Committee on Aging, Reducing the Use of Chemical Restraints in Nursing Homes, July 22, 1991. Available at <http://www.aging.senate.gov/imo/media/doc/publications/7221991.pdf>

⁸ GAO, Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings, GAO 15-211, January 2015. Available at: <http://www.gao.gov/assets/670/668221.pdf>

⁹ The antipsychotic drugging rates are from MDS data, 1st quarter 2015, supplied by CMS.

¹⁰ 57 FR 4516, February 2, 1992.

¹¹ Molloy, Richard J., Antipsychotic Drug Use in NY State Nursing Homes: An Assessment of New York's Progress in the National Campaign to Reduce Drugs and Improve Dementia Care, March 2014. Available at

http://www.ltccc.org/publications/documents/LTCCCReportAntipsychoticDrugsnh2014_000.pdf

¹² GAO, Antipsychotic Drug Use: HHS Has Initiatives to Reduce Use among Older Adults in Nursing Homes, but Should Expand Efforts to Other Settings, GAO 15-211, January 2015. Available at: <http://www.gao.gov/assets/670/668221.pdf>

¹³ McCrea, Steve, "My Father-in-law on Risperdal — A Case Study Gets Personal," August 16, 2015. Available at <http://www.madinamerica.com/2015/08/my-father-in-law-on-risperdal-a-case-study-gets-personal/>

¹⁴ Edelman, Toby and Lerner, Dean, "Examining Inappropriate Use of Antipsychotic Drugs in Nursing Facilities" (December 12, 2013). Available at <http://www.medicareadvocacy.org/examining-inappropriate-use-of-antipsychotic-drugs-part-one-how-seven-states-cite-antipsychotic-drug-deficiencies/>

¹⁵ Brill, Steven, *America's Most Admired Lawbreaker*, Huffington Post, September 15-30, 2015.

Available at: <http://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/>

¹⁶ OIG, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs, OEI-07-08-00151, July 2012. Available at <http://oig.hhs.gov/oei/reports/oei-07-08-00151.pdf>

¹⁷ Emily Mongan, "Omnicare will settle with DOJ in Depakote kickback cases," McKnight's Long Term Care News, July 8, 2015. Available at <http://www.mcknights.com/news/omnicare-will-settle-with-doj-in-depakote-kickback-cases/article/425386/>

¹⁸ Chen, Y, et al, Unexplained Variation Across US Nursing Homes in Antipsychotic Prescribing Rates, *Arch. Intern. Med.*, Vol. 170, January 11, 2010.