

September 16, 2019

Administrator Seema Verma  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3347-P  
P.O. Box 8010  
Baltimore, MD 21244-1850

**Re: CMS-3374-P; Federal Register, Vol. 84, No. 138 (July 18, 2019)**

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

Dear Administrator Verma:

The Center for Medicare Advocacy and the Long Term Care Community Coalition respectfully submit the following comments on behalf of our and the below named organizations.

The Center for Medicare Advocacy (Center) is a national, private, non-profit law organization, founded in 1986, that provides education, analysis, advocacy, and legal assistance to people nationwide, primarily the elderly and people with disabilities, to obtain necessary health care, therapy, and Medicare. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care and provides training regarding Medicare and health care rights throughout the country. It advocates on behalf of beneficiaries in administrative and legislative forums, and serves as legal counsel in litigation of importance to Medicare beneficiaries and others seeking health coverage.

The Long Term Care Community Coalition (LTCCC) is a non-profit organization dedicated to improving care, quality of life, and dignity for residents in nursing homes and other long-term residential care settings. For over 25 years, LTCCC has conducted policy studies and analyses of nursing home laws, standards and their implementation. In addition to its work on systemic nursing home issues, LTCCC works closely with residents, families, and their advocates to improve care.

### **Basis of Comments**

Nursing home residents are among the most vulnerable members of our society. With half of all seniors needing nursing home care at some point, the safety and dignity of residents is of concern to every family in the United States. Nevertheless, widespread and serious problems persist in nursing homes across the country. Though the federal Nursing Home Reform Law requires that every nursing home resident be provided with the services needed to attain and maintain his or her “highest practicable physical, mental, and psychosocial well-being,” inadequate enforcement of these requirements has resulted in the abuse and neglect of many vulnerable residents year after year. Decades of research, federal audits, and reports have indicated that stronger quality assurance and oversight are needed to both protect residents and ensure the fundamental integrity of the public programs that pay for most nursing home care in our country.

Thus, our organizations have been increasingly troubled by the Centers for Medicare & Medicaid Services' (CMS) ongoing efforts to ease provider "burden" by rolling back the rights and protections of nursing home residents. Since 2017, CMS has taken actions to deregulate the nursing home industry, which increase the risk of resident harm. For instance, CMS placed an 18-month moratorium on the full enforcement of several standards of care,<sup>1</sup> proposed to rollback emergency preparedness requirements,<sup>2</sup> and reversed the ban on pre-dispute arbitration agreements.<sup>3</sup> We believe that the proposed rule<sup>4</sup> continues the dangerous trend of putting the financial priorities of the nursing home industry before the health and safety of nursing home residents.

Following are our general and specific comments on provisions of the proposed rule that will affect both safety and dignity for residents, as well as the integrity of the Medicare and Medicaid programs.

## **Background**

On October 4, 2016, CMS published a final rule revising the standards of care that nursing homes must adhere to as a requirement for participating in the Medicare and Medicaid programs.<sup>5</sup> CMS explained that the nursing home Requirements of Participation (RoPs) had not been comprehensively reviewed and updated since 1991, "despite substantial changes in service delivery in this setting."<sup>6</sup> Thus, CMS revised the RoPs "in an effort to improve the quality of life, care, and services in LTC facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations."<sup>7</sup>

On December 16, 2016, the leading nursing home industry trade association sent a letter to then President-Elect Donald Trump asking for relief from so-called regulatory burdens (referring to the minimum standards of care that facilities agree to meet – or exceed – in order to participate in the Medicaid or Medicare programs).<sup>8</sup> In the fall of 2017, before the 2016 final rule had been fully implemented, CMS announced, in the Unified Agenda of Regulatory and Deregulatory

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<sup>1</sup> *Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare Background*, Survey and Certification Group, CMS (Nov. 24, 2017), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf> (noting that it applies to critical standards of care, including antipsychotic drugs and baseline care plans).

<sup>2</sup> Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction, 83 Fed. Reg. 47,686, 47,725-47,727 (Sept. 20, 2018), <https://www.gpo.gov/fdsys/pkg/FR-201809-20/pdf/2018-19599.pdf>.

<sup>3</sup> Medicare and Medicaid Programs; Revision of Requirements for Long- Term Care Facilities: Arbitration Agreements, 84 Fed. Reg. 34,718 (July 18, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-07-18/pdf/2019-14945.pdf>.

<sup>4</sup> Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions To Promote Efficiency, and Transparency, 84 Fed. Reg. 34,737, 34740 (July 18, 2019) (to be codified at 42 C.F.R. pts. 410, 482, 483, 485, and 488), <https://www.govinfo.gov/content/pkg/FR-2019-07-18/pdf/2019-14946.pdf>.

<sup>5</sup> Medicare and Medicaid Programs; Reform of Requirements for Long- Term Care Facilities, 81 Fed. Reg. 68688 (Oct. 4, 2016), <https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23503.pdf>.

<sup>6</sup> *Id.* at 68,688.

<sup>7</sup> *Id.*

<sup>8</sup> Letter from Mark Parkinson, President and CEO, AHCA, to Donald Trump, President-Elect (Dec. 15, 2016), <https://theconsumervoice.org/uploads/files/issues/AHCANCAL-Letter-TrumpAdmin-Attachments.pdf>

Actions, that it would initiate rulemaking to once again revise the RoPs, “seek[ing] to reduce burdens for long-term care facilities . . . .”<sup>9</sup> CMS published the proposed rule on July 18, 2019.<sup>10</sup> The 32-page proposed rule would partially or completely roll back numerous critical standards of care that were promulgated, with considerable industry and other stakeholder input, to address widespread and often serious deficiencies.

## General Comments

Under the federal Nursing Home Reform Law, the Secretary’s duty is to ensure that the RoPs and their enforcement are “adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.”<sup>11</sup> Nevertheless, CMS offers no meaningful explanation for how rolling back the RoPs would further these goals by resulting in improvements to resident care or the more appropriate spending of public funds. Rather, the proposed rule too often advances the hollow claim that reducing provider “burdens” would free up staff time to result, somehow, in better resident care. In fact, CMS uses the term “burden” or “burdensome” a striking 102 times in the proposed rule, while never mentioning that nursing homes have a primary responsibility, when they voluntarily participate in Medicare and/or Medicaid, to provide the staffing and services sufficient to meet the needs and goals of each of their residents. The proposed rule appears to be predicated on the incorrect assumption that nursing homes can first fulfill their profit-making goals and then dedicate whatever is left over to hiring staff and other expenses related to resident care. Thus, as detailed below, our organizations believe that the specific changes made by the proposed rule disregard the Secretary’s mandate to protect resident health and safety in favor of the longstanding desires of the nursing home industry to reduce accountability for substandard care, resident abuse, and neglect.

## Choice of Attending Physician

**The requirement that facilities keep residents informed of their health care professionals should be maintained, given the significant control that facilities have over their residents’ care, life, and communications, as well as the particular vulnerability of most residents.**

Current regulations require facilities to ensure that residents remain informed of the name, specialty, and contact information of the physician and primary care professionals responsible for their care.<sup>12</sup> The reason for this requirement is that, too often, a lack of coordination of resident care and access to appropriate professional services have resulted in significant harm to residents and costly hospitalizations. CMS is now proposing to revise the regulations to specify that residents should be informed of only their primary care physician’s information at admission, when there is any change, and upon request. Facilities would have no obligation to inform residents, at any time, of the other “primary care professionals” who are responsible for

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<sup>9</sup> Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P), Office of Information And Regulatory Affairs, OMB, <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0938-AT36> (last visited Aug. 6, 2019).

<sup>10</sup> Regulatory Provisions To Promote Efficiency, and Transparency.

<sup>11</sup> 42 U.S.C § 1395i-3(f), 1396r(f), Medicare and Medicaid, respectively.

<sup>12</sup> 42 C.F.R. § 483.10(d)(3).

their care. CMS notes that the current regulations “could have the potential to substantially burden facilities with maintaining an exhaustive list of professionals for each resident.”<sup>13</sup> Viewing this reason as insubstantial and not informed by any evidence identified by CMS, we support retaining the current rule’s requirement that facilities ensure that residents “remain informed” of all of the primary health care professionals responsible for their care.

By voluntarily participating in the Medicaid and Medicare programs, facilities agree (and are paid) to take virtually total responsibility for the care of their residents. The Reform Law, Requirements, and Interpretive Guidance all make clear that residents are to be treated as individuals with the right (to the extent possible for each) to participate in their care. Being provided with knowledge about one’s professional caregivers is an important component of a resident’s humanity and essential to the ability to effectively participate in care planning and implementation.

Facilities also need to maintain a complete and accurate list of a residents’ health care professionals in order to know whom to contact in the event of a resident’s health emergency and to assist the resident in making appointments to see the health care professional, as necessary and appropriate. It is unreasonable to expect residents, who typically have multiple physical and mental impairments, to be able to maintain these lists on their own.

Furthermore, CMS provides no evidence to suggest that residents normally have an extensive roster of professional caregivers outside of the facility. In fact, the inability to exercise a resident’s right to choose a doctor (other than the one the facility provides) is a frequent complaint of residents and their families.

## **Grievances**

**The requirement that facilities have a designated grievance officer to whom residents can file a grievance is essential to addressing longstanding (and universally acknowledged) care problems and should be maintained.**

The existence of persistent and pervasive quality of care, quality of life, and dignity violations has been recognized by all stakeholders. Furthermore, the failure to address substandard care and other violations of residents’ rights in a timely and effective manner has been well-documented over the decades by both government entities (such as the GAO and OIG), academic researchers, news reports, and thousands of CMS’s own Statements of Deficiencies (SoDs).

Sadly, these problems are, too often, exacerbated because facilities fail to respond to resident and family complaints in a timely, respectful, and meaningful manner. In addition to resulting in resident harm (when a problem is not addressed in a timely manner), facilities ignoring residents’ complaints has fostered a culture in which the vast majority of residents and families we have encountered over the years feel that their concerns do not matter to either the nursing home industry or the government agencies responsible for ensuring resident safety.

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<sup>13</sup> *Id.*

In response to the persistent failure of many nursing homes to address quality and dignity concerns raised by residents and families, the 2016 final rule requires facilities to address their grievances in a meaningful way. Nursing homes are not required to do what the resident or family member asks but, for the first time, the federal standards make clear that when a resident or family member raises a concern, he or she will be treated with the respect that any customer in any other situation would expect to receive. In our view, this requirement is among the most significant improvements made by the 2016 revised regulations.

The 2016 regulatory provision requires each facility to establish a grievance policy to receive and promptly resolve grievances.<sup>14</sup> It requires facilities' grievance policies to inform residents of the process;<sup>15</sup> to identify a grievance official to oversee the grievance process;<sup>16</sup> to take "immediate action" to prevent further violations while a grievance is investigated,<sup>17</sup> as already required by §483.12(c)(1); to immediately report all alleged violations of neglect, abuse, and/or misappropriation of resident property to the administrator, and as required by state law;<sup>18</sup> to prepare written grievance decisions, with specified information;<sup>19</sup> to take appropriate corrective action;<sup>20</sup> and to maintain evidence of the results of the grievance process for 3 years.<sup>21</sup> The regulatory provision does not require prescriptive timeframes and does not require facilities to hire a new individual, giving considerable flexibility to facilities to implement their grievance process.<sup>22</sup>

CMS now proposes four changes that would essentially gut the grievance process. First, CMS proposes "to remove the specific duties required of the grievance official who is responsible for overseeing the grievance process."<sup>23</sup> The removal of all duties eliminates any substantive or enforceable standard and makes the requirement for a grievance official a hollow and meaningless requirement. In addition, the removal of the duties leaves facilities with complete discretion to decide what their grievance officials do and how they do it.

Second, CMS's preamble contains an exhaustive discussion of a distinction between "grievances" and "general feedback or complaints."<sup>24</sup> The sole purpose of this new distinction is reducing the number of "grievances" that are subject to the new regulatory requirement. CMS claims that general feedback or complaints "stem from general issues that can typically be resolved by staff present at the time a voice is concerned, while grievances are more serious and generally require investigation into allegations regarding the quality of care."<sup>25</sup> This distinction is nonsensical. CMS further suggests that only if a facility has failed to respond to a resident's

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<sup>14</sup> *Id.* at § 483.10(j)(4).

<sup>15</sup> *Id.* at § 483.10(j)(4)(i).

<sup>16</sup> *Id.* at § 483.10(j)(4)(ii).

<sup>17</sup> *Id.* at § 483.10(j)(4)(iii).

<sup>18</sup> *Id.* at § 483.10(j)(4)(iv).

<sup>19</sup> *Id.* at §483.10(j)(4)(v).

<sup>20</sup> *Id.* at § 483.10(j)(4)(vi).

<sup>21</sup> *Id.* at § 483.10(j)(4)(vi).

<sup>22</sup> 81 Fed. Reg. at 68,724.

<sup>23</sup> *Id.* at 34,741.

<sup>24</sup> *Id.*

<sup>25</sup> 84 Fed. Reg. at 34,741.

repeated complaints or multiple residents' similar complaints would the issue rise to the level of a grievance.

Third, CMS proposes to eliminate the specific requirements for grievance decisions,<sup>26</sup> under the pretense that, somehow, limiting the grievance decision enables facilities “to focus on the true intent of the requirement, which is to clearly inform residents of grievance decisions and any corrective actions.”<sup>27</sup> Without specific standards for what a grievance decision should contain, the requirement for grievance decisions becomes a meaningless, hollow mandate, rather than an enforceable standard.

Fourth, CMS proposes to reduce the amount of time, from three years to 18 months, that a facility must maintain evidence of compliance with the grievance requirement. Maintaining records pertaining to residents' concerns is not burdensome.

CMS offers no explanation or any reasons to support the proposed changes, other than provider complaints of burden and cost.<sup>28</sup> By diluting the requirement that facilities receive and respond appropriately to residents' concerns, the proposed changes would only serve to quiet the voices of residents and their representatives. It would signal a profound step backwards in the agency's – and our nation's – growing recognition of the rights and humanity of the elderly and disabled people who live in nursing homes.

### **Admission, Transfer, and Discharge Rights**

#### **CMS must require a copy of all transfer or discharge notices to be sent to a representative of the Office of the State Long-Term Care Ombudsman.**

Inappropriate and illegal transfers and discharges are a growing national problem. They are the most frequent complaint received by the LTC Ombudsman Programs (LTCOPs). CMS has recognized the seriousness of transfer/discharge problems and directed Regional Offices to hear complaints.<sup>29</sup>

The 2016 final rule requires facilities to send a copy of transfer or discharges notices to a representative of the Office of the State Long-Term Care Ombudsman.<sup>30</sup> The final rule states “that sending these notices to the State Long-Term Care Ombudsman will provide added protection to the resident and assist the State Long-Term Care Ombudsman to keep informed of facility activities.”<sup>31</sup> Rather than promulgating meaningful Guidance to implement the rule, in 2017, CMS rolled back the requirement by stating that it only applied to “facility-initiated transfers and discharges.”<sup>32</sup> CMS also noted that facilities still had to send notices in cases of

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<sup>26</sup> 42 C.F.R. § 483.10(j)(4)(v).

<sup>27</sup> 84 Fed. Reg. at 34,741.

<sup>28</sup> 84 Fed. Reg. at 34,740.

<sup>29</sup> *An Initiative to Address Facility Initiated Discharges that Violate Federal Regulations*, CMS (Dec. 22), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-08.pdf>.

<sup>30</sup> 81 Fed. Reg. at 68,733-4

<sup>31</sup> *Id.* at 68,734

<sup>32</sup> *Implementation Issues, Long-Term Care Regulatory Changes: Substandard Quality of Care (SQC) and Clarification of Notice before Transfer or Discharge Requirements*, CMS (May, 12, 2017),

emergency transfers but that such notices “may be sent when practicable, such as in a list of residents on a monthly basis.”<sup>33</sup>

CMS is now proposing to revise the regulations to formally incorporate these rollbacks, requiring facilities to send transfer and discharge notices to the Office of the State Long-Term Care Ombudsmen “only in the event of facility-initiated involuntary transfers or discharges.” CMS defines involuntary transfer or discharge as one that “the resident objects to, did not originate through a resident’s verbal or written request, and/or is not in alignment with the resident’s stated goals for care and preferences.” While notice should not apply when a resident informs a facility that he or she will be moving out of the facility, CMS proposes to define involuntary transfer/discharge in two ways that are likely to eviscerate this much needed safeguard of residents’ rights.

First, CMS suggests that a transfer/discharge is voluntary if the resident does not “object.” Such a loophole would effectively gut the resident protection. What does “object” mean? Would a resident be expected to write a formal objection? Would silence be considered assent? How would CMS and state survey agencies monitor facilities’ unilateral determination that a resident did not object?

Second, CMS defines a voluntary transfer as one that aligns with a resident’s stated goals. This exception, too, could swallow the protection. A resident might be planning to return home after the completion of therapy, but may not believe that he or she has achieved therapy goals. The fact that the resident would like to leave and return home when therapy is completed does not mean the resident automatically agrees to move when the *facility* decides therapy is completed. In such an instance, the facility would be initiating the transfer and should be required to provide a copy of the discharge notice to the ombudsman.

Providing the ombudsman with a copy of the transfer/discharge notice serves two critically important purposes. It enables the ombudsman program to both offer assistance to individual residents who might want to contest their proposed transfer/discharge and identify systemic issues that are affecting residents in a community or state. For example, over the course of 17 months, one Maryland nursing home operator issued over a thousand notices to residents, more than all other Maryland facilities combined.<sup>34</sup> Documenting the corporation’s violation of federal law, ombudsmen in Maryland worked with the state’s Attorney General to take legal action against that operator, which was alleged to have “dumped numerous vulnerable residents in homeless shelters and predatory unlicensed assisted living facilities, where they faced financial exploitation and abuse.”<sup>35</sup>

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<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-27.pdf>

<sup>33</sup> *Id.*

<sup>34</sup> *Attorney General Frosh Announces Settlement with Neiswanger Management Services, LLC in Resident Dumping Case: Companies to Pay \$2.2 Million and to be Prohibited from Operating Nursing Homes in Maryland; State Alleged that NMS Engaged in Unlawful Resident Evictions*, MarylandAttorneyGeneral.Gov (Oct. 26, 2018), <http://www.marylandattorneygeneral.gov/Press/2018/102618.pdf>

<sup>35</sup> *Id.*

## Quality of Care

### **Current restrictions on the installation and use of bed rails should be maintained.**

For the vast majority of residents, including those at risk for wandering or falling, bed rails are a hazard that can result in pain, broken bones, and even death. Thus, current regulations require that facilities attempt to use appropriate alternatives prior to installing bed rails onto a resident's bed.<sup>36</sup> Facilities must also assess residents for risk of entrapment and obtain informed consent prior to installing bed rails.<sup>37</sup> CMS is now proposing "to remove references to the 'installation' of bed rails and replace them with 'use' of bed rails." CMS notes that "industry stakeholders" are concerned by "prior to installation" because beds may be purchased with bed rails already installed.

Requiring a facility to assess a resident for risk of entrapment "prior to installation" is not the same protection as requiring an assessment prior to "use." Having pre-installed bed rails will likely increase the chances of staff using them without a meaningful resident assessment or the resident's informed consent. For example, a 2017 Statement of Deficiencies described the circumstances under which a resident of a Massachusetts facility died of entrapment.<sup>38</sup> Staff recalled that the resident's head was twisted sideways and stuck between the bottom of the bed rail and the bedframe. One staffer noted that the resident was gray and blue with "saliva running out of his/her mouth onto the floor." The surveyor found that facility had no documentation of a resident assessment, noting generally that the "facility does not have records of any assessments, evaluation of risk versus benefits, and consents related to side rail use." The resident's death likely could have been prevented had the facility undertaken a resident assessment "prior to installation."

Facilities must not get a free pass on bed rails simply because they chose to buy beds with rails pre-installed. If facilities voluntarily decide to buy beds with pre-installed rails, then CMS should require them to remove those rails until there has been an assessment as to whether bed rails would place the resident at risk of entrapment and the resident has provided informed consent. CMS must not change critical safety standards solely for the convenience of the nursing home industry.

## Nursing Services

### **The current requirement that facilities maintain daily nurse staffing data for a minimum of 18 months should not be reduced to 15 months, as CMS proposes, to ensure that the records are available when a facility is surveyed.**

CMS is now proposing to require that facilities only maintain their daily nurse staffing data for 15 months. CMS has provided no justification for the proposed change other than stating that the

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<sup>36</sup> 42 C.F.R. § 483.25(n).

<sup>37</sup> *Id.*

<sup>38</sup> Statement of Deficiencies for Jewish Nursing Home of Western Mass, CMS, <https://www.medicare.gov/nursinghomecompare/inspectionreportdetail.aspx?ID=225040&SURVEYDATE=08/31/2017&INSPTYPE=CMPL>.



rollback would reduce the burden on providers and that “15 months of this facility-stored data would be sufficient to support any potential surveyor investigations.”<sup>39</sup> Unfortunately, despite requirements that states survey nursing homes within a 15 month window (and on average once a year), not all states fulfill this requirement on a regular basis. As a result, some facilities are not surveyed within 15 months. CMS’s decision to rollback this requirement is unnecessary and arbitrary and could interfere with the ability of surveyors to have access to these records. We support retention of the current standard.

## **Behavioral Health**

**We strongly support CMS’s proposal to retain standards regarding behavioral health and strongly urge CMS to retain language regarding staffing sufficiency and competency in this section.**

The 2016 final rule created a new section called behavioral health.<sup>40</sup> As CMS notes in the 2019 NPRM, “a focus on the care and treatment for residents with mental disorders or psychosocial adjustment difficulties is necessary.”<sup>41</sup> The behavioral health requirements are predicated on, and essential to, current understanding of the rights and needs of individuals who depend on long-term care services as well as current standards of practice for individuals with disabilities, the frail elderly, and people with dementia. They address longstanding concerns about the dehumanizing treatment of people with disabilities and the historical disregard of the needs and individuality of people with dementia.

For these reasons, we strongly urge CMS to retain the language related to staffing in this part. Staffing (in regard to both competency and sufficiency) is widely acknowledged to be the most important factor in respect to a facility’s quality and safety. Nevertheless, a significant majority of facilities lack adequate staffing. To help address the pervasive problem of insufficient staffing, CMS has included and referenced staffing considerations in numerous agency memoranda over the years and, in consultation with industry representatives, consumers, and other stakeholders, included these considerations throughout both the 2016 final rule and Interpretive Guidance. Particularly given the growing numbers of people living longer with disabilities and dementia, staffing considerations are critical to behavioral health and should be retained in this section.

In addition, facilities already have both the right and the responsibility to accept residents for whom they can provide appropriate care and services. This obviates the argument by “LTC stakeholders” that CMS refers to in the proposed rule, in which it expresses concern that the reference to staffing in the behavioral health rule risks both added burden and “turning LTC facilities into mental health institutions.” The expectation for sufficient staff with appropriate skills is not meaningless or redundant and should be retained.

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<sup>39</sup> 84 Fed. Reg. at 34,742.

<sup>40</sup> 42 C.F.R. § 483.40.

<sup>41</sup> 84 Fed. Reg. at 34,742.

## Pharmacy Services

**Administering antipsychotic drugs to residents with dementia is a violation of established clinical standards of care. Therefore, it is essential that the current, sensible limitations on PRN prescriptions for antipsychotic drugs are maintained to ensure both resident safety and the efficient use of public funds.**

Current regulations limit PRN (“as needed”) prescriptions for antipsychotic drugs to 14 days.<sup>42</sup> PRN orders for antipsychotic drugs can be extended beyond 14 days if “the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.”<sup>43</sup> According to CMS’s Interpretive Guidelines, evaluation “entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident’s current condition and progress to determine if the PRN antipsychotic medication is still needed.”<sup>44</sup>

CMS now proposes to revise the regulations so that the attending physician or prescribing practitioner can, without a direct examination and assessment of the resident, extend PRN orders beyond 14 days in “accordance with the facility’s policy if he or she documents his or her rationale in the resident’s medical record and indicates the duration for the PRN order.”<sup>45</sup> This proposal flies in the face of standards of professional practice and clinical care and will, if implemented, undoubtedly result in unnecessary harm to thousands of residents every year.

There is no medical indication for any antipsychotic to be given PRN and there is no basis for extending a time limit on something that is not the standard of care. Furthermore, the standard of care is for doctors to see a patient when prescribing a medication. No other insurance company would accept the argument that the doctor did not want to see a patient in person before prescribing a drug. Allowing nursing homes and residents’ doctors to circumvent this standard of care would not “only” harm residents, it would also likely cost American taxpayers billions of dollars for unnecessary medications and avoidable hospitalizations.

Antipsychotic drugs are only indicated to treat specific clinical conditions, such as schizophrenia. Less than two percent of the population has a diagnosis of a clinical condition that would warrant the use of these drugs, as identified by CMS when it risk-adjusts for potentially appropriate uses. However, nursing homes still continue to administer antipsychotic drugs to approximately 20 percent of residents nationwide.<sup>46</sup> Sadly, and too often, nursing homes use these drugs as a way of chemically restraining residents exhibiting the behavioral symptoms of dementia, despite the Food and Drug Administration’s (FDA) “black box” warning against using antipsychotic drugs

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<sup>42</sup> 42 CFR § 483.45(e)(4).

<sup>43</sup> *Id.* at § 483.45(e)(5).

<sup>44</sup> State Operations Manual – Appendix PP – Guidance to Surveyors for Long Term Care Facilities, CMS, Rev. 173, 11-22-17, [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf).

<sup>45</sup> 84 Fed. Reg. 34,743-44.

<sup>46</sup> Letter from Richard E. Neal, Chairman, U.S. House Committee on Ways and Means, to Bill Osborn, President, National Community Pharmacists Association (Aug. 28, 2019), [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF\\_Antipsychotics%20letter\\_LTC%20Pharmacists\\_Final\\_2.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF_Antipsychotics%20letter_LTC%20Pharmacists_Final_2.pdf).

on elderly patients with dementia.<sup>47</sup> The FDA warning provides that the use of these drugs on elderly patients is associated with a significantly increased risk of death.

The U.S. government has long acknowledged the seriousness of the crisis surrounding the inappropriate antipsychotic drugging of nursing home residents. The HHS Inspector General (IG) made the following statement in 2011:

Too many [nursing homes] fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use . . . [g]overnment, taxpayers, nursing home residents, as well as their families and caregivers should be outraged—and seek solutions.<sup>48</sup>

The IG's statement came in the wake of a report from his office which found that 83 percent of antipsychotic drug use in nursing homes was off-label and that 88 percent of antipsychotic drug use was associated with the condition specified in the FDA's "black box" warning.<sup>49</sup>

Importantly, for just the first six month period in 2007 reviewed, the OIG identified close to 580,000 inappropriate Medicare claims for atypical antipsychotic drugs. The net cost of these inappropriate claims, for the six-month period of 2007, was over \$63 million. CMS's proposal to relax PRN usage of these drugs would substantially increase waste of Medicare dollars.

In the aftermath of the IG's statement and the OIG report, CMS launched, in 2012, the National Partnership to Improve Dementia Care in Nursing Homes with the goal of reducing antipsychotic drug rates. In October 2017, CMS announced that it had reduced antipsychotic drug use by 30 percent over the years of its Partnership.<sup>50</sup> Nevertheless, reports indicate that CMS's 30 percent reduction may be exaggerated. For example, a 2017 study found that the reduction in antipsychotic drug use was correlated with an increase in the diagnoses of the three excluded conditions. The researchers noted that since the launch of the CMS Partnership, "nationally reported rates of these diagnoses increased by 12 percent in nursing homes . . . [and] as much as 20 percent of the reduction . . . could be explained by increased reporting of exclusionary diagnoses rather than a true reduction in medication use."<sup>51</sup> Similarly, a 2018 study found that the overall decline in the use of antipsychotic drugs among residents has been met by an increase

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<sup>47</sup> "They Want Docile": How Nursing Homes in the United States Overmedicate People with Dementia, Human Rights Watch (Feb. 5, 2018), <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia> ("The FDA has not approved antipsychotic drugs for treating symptoms of dementia.").

<sup>48</sup> Daniel R. Levinson, *Overmedication of Nursing Home Patients Troubling*, HHS OIG (May 2011), [https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson\\_051011.asp](https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp).

<sup>49</sup> Daniel R. Levinson, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, HHS OIG (May 2011), <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>.

<sup>50</sup> *Data show National Partnership to Improve Dementia Care achieves goals to reduce unnecessary antipsychotic medications in nursing homes*, CMS (Oct. 2, 2017), <https://www.cms.gov/newsroom/fact-sheets/data-show-national-partnership-improve-dementia-care-achieves-goals-reduce-unnecessary-antipsychotic>.

<sup>51</sup> Jonathan D. Winter et al., *Increased Reporting of Exclusionary Diagnoses Inflate Apparent Reduction in Long-Stay Antipsychotic Prescribing*, *Clinical Gerontologist* (Oct. 24, 2017), <http://www.tandfonline.com/doi/abs/10.1080/07317115.2017.1395378>.

in the use of mood stabilizers.<sup>52</sup> The study indicated that “[r]ather than increasing the use of non pharmacological treatments, prescribers may have shifted prescribing from antipsychotics to mood stabilizers even though mood stabilizers have less evidence of benefit for the behavioral and psychological symptoms of dementia.”<sup>53</sup>

As these reports indicate, inappropriate antipsychotic drug use continues to be a widespread and ongoing problem in nursing homes throughout the country. Even CMS’s overly optimistic claim of a reduction in antipsychotic drug use leaves more than 200,000 residents receiving these drugs. CMS must not change the requirements to make it easier for facilities to administer antipsychotic drugs. Rather, CMS should bolster efforts to stop inappropriate, harmful, and expensive antipsychotic drugging by strengthening enforcement of longstanding safeguards against the use of chemical restraints and implementing meaningful informed consent protections.

Given the ongoing and widespread misuse of antipsychotic drugs, CMS must not revise resident protections to make it easier for facilities to drug residents with these potentially fatal medications. Rather, in line with its mission, CMS should advance regulatory changes that strengthen resident protections around antipsychotic drugs, such as requiring facilities to obtain a resident’s written informed consent prior to administering these drugs.

### **Food and Nutrition Services**

**Poor management of food and nutrition services is dangerous, especially to an already vulnerable population. The credentialing requirements in the current standards should be maintained to safeguard both the health and quality of life of residents.**

The 2016 rule specifies that a director of food and nutrition services must have state or federally recognized professional credentials. It also gives directors of nutrition services five years to achieve the necessary credentials. In addition, the 2016 rule expands the authority of the food services director to prescribe a resident’s dietary needs, if delegated by the attending physician. CMS now proposes to remove the credentialing requirement and to allow an individual who has two or more years of experience or who has completed a minimum course of study in food safety to serve as the director of food and nutrition. This weakening of standards is especially troubling in light of the food service director’s expanded role of prescribing diets.

Poor management of food and nutrition services is dangerous, especially to an already vulnerable population. Far too many residents suffer from malnourishment, which is associated with depression, cognitive impairment, functional impairment, and increased mortality.<sup>54</sup> In addition,

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<sup>52</sup> Donovan T. Maust et al., *Association of the Centers for Medicare & Medicaid Services’ National Partnership to Improve Dementia Care With the Use of Antipsychotics and Other Psychotropics in Long-term Care in the United States From 2009 to 2014*, JAMA (May 2018), [https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2674245?utm\\_source=silverchair&utm\\_medium=email&utm\\_campaign=article\\_alert-jamainternalmedicine&utm\\_content=olf&utm\\_term=031718&alert=article&redirect=true](https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2674245?utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jamainternalmedicine&utm_content=olf&utm_term=031718&alert=article&redirect=true).

<sup>53</sup> *Id.*

<sup>54</sup> See, e.g., Bell CL et al., *Malnutrition in the nursing home*, Current Opinion Clinical Nutrition and Metabolic Care (Jan. 2015), <https://www.ncbi.nlm.nih.gov/pubmed/25394167> (noting that “approximately 20% of nursing home residents had some form of malnutrition”).

the palatability and safety of resident food services are longstanding concerns. For instance, a New Jersey nursing home was cited after the surveyor found that the facility's dietary staff "failed to demonstrate knowledge of the proper procedure for cooling of cooked meats . . . ." <sup>55</sup> The surveyor reported that the violation "resulted in an immediate jeopardy situation for substandard food preparation and improper cooling . . . ." The surveyor noted that the dietary staff had were "ServSafe certified."

As with many of the other requirements, professional oversight of food and nutrition services is necessary because, in the absence of specific requirements, too many facilities will flout even basic standards of hygiene and nutrition. As CMS notes in its current proposal, the 2016 final rule already included provisions to reduce burdens. <sup>56</sup> Given the prevalence and persistence of this problem, CMS should retain and enforce current requirements for food and nutrition services, not weaken them.

### Administration

**The requirement that facilities conduct a facility-wide and emergency preparedness assessment on an annual basis should be maintained to address longstanding and widespread deficiencies and vulnerabilities that result in resident harm, including avoidable injuries and deaths, every year.**

Current regulations require each facility to conduct a facility-wide assessment as necessary but, at a minimum, every year to determine "what resources are necessary to care for its residents competently during both day-to-day operations and emergencies." <sup>57</sup> The facility assessment must address factors such as the number of residents, the care needs of residents, and staff competencies. <sup>58</sup> According to CMS's Interpretative Guidance in the SOM, "[t]he regulation outlines that the individualized approach of the facility assessment is the foundation to determine staffing levels and competencies." <sup>59</sup>

Citing provider burden and micro-management of business, CMS now proposes to allow facilities to conduct a facility-wide assessment every two years, rather than every year. <sup>60</sup> CMS also proposes to remove the requirement as it relates to emergencies, §483.70(e)(3), citing the requirements elsewhere that facilities develop an emergency preparedness plan. <sup>61</sup>

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<sup>55</sup> Statement of Deficiencies for Millville Center, CMS, <https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.html?ID=315243&SURVEYDATE=05/18/2018&INSPTYPE=STD&profTab=1&Distn=6779.7&state=NJ&lat=0&lng=0&name=MILLVILLE%20CENTER>.

<sup>56</sup> CMS notes that "[t]he October 2016 final rule extensively revised the requirements related to food and nutrition services, including a burden reducing requirement that allows a resident's attending physician to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing a resident's diet to the extent allowed by state law. In addition, the October 2016 final rule established qualifications for a director of food and nutrition services when a dietitian is not employed by a facility full-time." 84 Fed. Reg. at 34,744.

<sup>57</sup> *Id.* at § 483.70(e).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> 84 Fed. Reg. at 34,745.

<sup>61</sup> *Id.*

Revising the regulations to allow nursing homes to conduct facility-wide assessments every two years, instead of annually, and without an assessment of what resources are needed during emergencies, is extremely dangerous. For example, 12 children died at a nursing home in New Jersey after an outbreak of the adenovirus. The surveyor cited the facility for failing to properly follow the facility assessment requirements. The surveyor noted that the facility “failed to evaluate resident population and identify the resources needed to provide the necessary care and services required for residents during . . . [the] outbreak.”<sup>62</sup> The surveyor added that “the failure placed the facility's other residents [those that did not die or not transferred to a hospital] in immediate jeopardy of contracting adenovirus infections, with the likelihood to cause serious harm, impairment, or death.” At the time of these deaths, the emergency preparedness requirements were already in effect.

CMS must not rollback facility assessments for the sake of reducing so-called provider “burdens.” The deaths at the New Jersey nursing home demonstrate the importance of conducting thorough and frequent assessments of what resources are needed to properly care for residents every day.

## QAPI

**We strongly support CMS’s decision to keep provisions §483.75(a)(1) through (4) in this section and urge CMS to retain the other important provisions for a QAPI program in the current regulations.**

Facilities have long been expected to conduct ongoing reviews of their own performance, particularly in respect to identified problems. Nevertheless, serious problems are persistent and widespread in the industry, resulting in resident harm, humiliation, and, too frequently, unnecessary pain and death. GAO, OIG, and other reports have all indicated that substandard care, even when cited by CMS or a state agency, too often is not effectively addressed by facilities. LTCCC’s 2017 analysis of federal data found that an astonishing 42% of nursing homes have what we call chronic deficiencies (repeated violations for the same safety standard three or more times in the three years covered on Nursing Home Compare).<sup>63</sup>

The QAPI program, as required by the Affordable Care Act and laid out in the 2016 final rule, institutes a set of expectations for evaluation and action that are highly flexible in respect to the needs of individual facilities yet responsive to key areas that are essential to resident safety, dignity, and the appropriate use of the public funds that pay for the majority of nursing home care.

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<sup>62</sup> Statement of Deficiencies for Wanaque Center for Nursing & Rehabilitation, CMS, <https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.html?ID=315229&SURVEYDATE=11/17/2018&INSPTYPE=STD&profTab=1&Distn=6755.3&state=NJ&lat=0&lng=0&name=WANAQUE%20CENTER%20FOR%20NURSING%20%26%20REHABILITATION%2C%20THE>.

<sup>63</sup> Richard J. Mollot, *Chronic Deficiencies in Care: The Persistence of Recurring Failures to Meet Minimum Safety & Dignity Standards in U.S. Nursing Homes*, LTCCC (2017), <https://nursinghome411.org/nursing-homes-with-chronic-deficiencies/>.

CMS now proposes to delete all of the specific requirements set out at §483.75(b)(1)-(4) (which describe the design and scope of a QAPI program); §483.75(c)(1)-(4) (which describes program feedback, data systems, and monitoring); and §483.75(d)(2) (which describes systematic analysis and systemic action). In essence, CMS is proposing that there be virtually no enforceable standards for QAPI and that facilities be completely free to define QAPI however they chose. Under the proposed rule, QAPI becomes a completely hollow requirement, mandated by law but totally lacking in substance. CMS's sole rationale for gutting the program is "some industry stakeholders" view that the 2016 rule was "inflexible and too detailed."<sup>64</sup>

For example, under §483.75(b), CMS is proposing to leave the introductory paragraph, which states that "[a] facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility," and to remove what it refers to as "detailed requirements." The requirements here simply state that the program must be designed in such a way that it: "(1) Address all systems of care and management practices; (2) Include clinical care, quality of life, and resident choice; (3) Utilize the best available evidence to define and measure indicators of quality and facility goals...; and (4) Reflect the complexities, unique care, and services that the facility provides."<sup>65</sup> These so-called detailed requirements are, in fact, essential to ensuring that the QAPI is meaningful and has a chance of being effective in encouraging much-needed quality improvement. They should, therefore, be retained.

### **Infection Control**

In the proposed rule, CMS cites the same statistics about infections that it cited in its 2016 rule: "[i]nfection is the leading cause of morbidity and mortality among the 1.7 million residents of United States nursing homes;"<sup>66</sup> residents experience 1.6 to 3.8 million infections in nursing homes each year; almost 388,000 residents die each year from infections; and nursing home infections cost between \$673 million and \$2 billion annually.<sup>67</sup> The 2016 rule also cites 150,000 hospitalizations of residents annually as a result of infections.<sup>68</sup>

The appallingly high number of cases of infections – and resulting deaths – in U.S. nursing homes every year indicates that infections are a problem of catastrophic proportions, for which a vigorous response is necessary. Recognizing the enormous harm and cost of nursing home infections, CMS's 2016 rule substantially strengthens facilities' obligation to address infections through an infection prevention and control program, under the direction of an infection preventionist (IP). The rule requires that the infection preventionist work at least "part-time" in the facility.

CMS now proposes that the term "part-time" be deleted and replaced by a requirement that the IP devote "sufficient" time to infection prevention and control. An IP is responsible for each facility's infection prevention and control program and it is absolutely crucial that every facility have an IP in the facility on, at least, a part time basis. The proposal to reduce this requirement to

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<sup>64</sup> 84 Fed. Reg. at 34,737, 34,745.

<sup>65</sup> 42 C.F.R. § 483.75(b).

<sup>66</sup> 84 Fed. Reg. at 34,737, 34,746.

<sup>67</sup> 84 Fed. Reg. at 34,737, 34,746.

<sup>68</sup> 81 Fed. Reg. at 68,688, 68,808.

“sufficient” is, in fact, insufficient to address this shocking problem, based on the industry’s historical inability to adequately address it on its own, the industry’s historically inadequate interpretation of “sufficient” in respect to care staffing as a whole, and the acute danger this problem poses for residents and their families. In addition, the fact cited by CMS that most of the numerous infection control deficiencies cited in the US “were at the D level, which means that they were isolated cases but represented a potential to do more than minimal harm” speaks to the need for a strengthened, rather than weakened, response to this problem. The failure of state survey agencies to adequately identify when residents experience harm or immediate jeopardy is well-documented.

For example, the New Jersey nursing home where 12 children died after an outbreak of the adenovirus had repeated infection control violations. In 2017 and 2018, state surveyors found infection control violations involving poor hand hygiene and sterilization.<sup>69</sup> Yet the facility was permitted to operate, without meaningful enforcement by either the state agency or CMS, until circumstances turned tragic for those children and their families.

Given the widespread and ongoing problems with infection prevention and control in nursing homes across the country, CMS should be strengthening these requirements rather rolling them back. Mandating facilities to have a part-time IP is the minimum that CMS should expect to ensure that infection prevention and control policies are properly implemented.

### **Compliance and Ethics Program**

**The existing compliance and ethics program requirements should be maintained to ensure that nursing homes implement vigorous and effective protocols to address the persistence of violations of residents’ rights and crimes against residents.**

Though there are strong standards to protect nursing home residents, far too often they face serious violations of residents’ rights, civil rights, and, even, protections against crime. To address this, compliance and ethics rules require nursing homes to have “a program of the operating organization that . . . [is] designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations . . . and in promoting quality of care.”

CMS’s proposal to do away with these specific requirements undermines the very purpose of the statutorily required compliance and ethics program and, if adopted, would eliminate accountability for abuse, neglect, and crimes against residents. In addition, given that the requirements have yet to go into effect, rolling them back at this time is without any real

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<sup>69</sup> Statement of Deficiencies for Wanaque Center for Nursing & Rehabilitation, CMS (May 15, 2017), <https://www.medicare.gov/nursinghomecompare/inspectionReportDetail.html?ID=315229&INSPTYPE=STD&SURVEYDATE=05/15/2017>; Statement of Deficiencies for Wanaque Center for Nursing & Rehabilitation, CMS (Aug. 20, 2018), <https://www.medicare.gov/nursinghomecompare/inspectionReportDetail.html?ID=315229&INSPTYPE=STD&SURVEYDATE=08/20/2018>.



justification in respect to verifiable facility “burden.” We urge CMS to retain these substantive, enforceable requirements and not to replace them with a meaningless paper exercise.

## **Physical Environment**

### **A. Life Safety Code**

**Current Life Safety Code fire safety requirements should be maintained to ensure that present and future residents are protected against a danger that CMS itself has recognized as a serious concern for residents.**

In its 2016 final rule, CMS adopted the 2012 edition of the National Fire Protection Association (NFPA) 101 (81 F.R. 26871), also known as the Life Safety Code (LSC). One of the mandatory references in the LSC is NFPA 101A, Guide on Alternative Approaches to Life Safety, also known as the Fire Safety Equivalency System (FSES). CMS now proposes to allow existing LTC facilities (those that were Medicare or Medicaid certified before July 5, 2016) that have previously used the FSES to determine equivalent fire protection levels, to continue to use the 2001 FSES mandatory values when determining compliance for containment, extinguishment, and people movement requirements.

Fire safety is a serious concern for nursing home residents and one that has been long acknowledged by CMS. It is simply unacceptable to put current and future residents in unnecessary and avoidable danger by allowing nursing homes to use outdated safety standards. The current LSC codes should be maintained.

### **B. Resident Rooms and Bathrooms**

**The benefits of single or (at most) double rooms with bathrooms are universally acknowledged. CMS should retain the requirement that newly constructed, re-constructed, or facilities first certified after November 28, 2016, accommodate no more than two residents in a bedroom and that newly constructed and facilities first certified after November 28, 2016, equip each resident room with its own bathroom that has a commode and sink.**

In the proposed rule, CMS recognizes that current “physical and environment requirements address valid health and safety concerns.”<sup>70</sup> CMS notes that not only does having more than two residents in a room infringe on each resident’s right to privacy and dignity, it also “creates issues related to infection control and safety.”<sup>71</sup> CMS similarly notes that “rooms without bathrooms increases risks related to falls, quality of care, and infection control.”<sup>72</sup> Lastly, and importantly in respect to CMS’s stated objective of reducing provider “burden” while maintaining resident safety and dignity, CMS acknowledges that the “2016 final rule responded to [nursing home industry] commenters’ concerns that the proposed rule was too burdensome.”<sup>73</sup> In fact, the 2016

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<sup>70</sup> 84 Fed. Reg. at 34,749.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

rule avoided placing any potential burden on nursing homes by providing that only newly built or licensed facilities would be subject to these standards.

Given the acknowledged concerns about resident health, safety, and dignity, the public has a right, at a minimum, to expect that newly licensed facilities – regardless of the nature of the previous business at the location – will reflect current standards and expectations related to environmental safety and the human dignity of the elderly and disabled individuals who reside in our nation’s nursing homes.

### **Informal Dispute Resolution**

The Reform Law requires that states and the Secretary make public information, including Statements of Deficiencies, within 14 calendar days after the information is made available to the facility.<sup>74</sup> CMS should not contravene this statutory requirement by allowing facilities to invoke informal dispute resolution as a means of delaying the public’s access to this important information.

Current guidance in CMS’s *State Operations Manual* states that survey results (nursing home inspection reports) should not be uploaded to the Certification and Survey Provider Enhanced Reports (CASPER) system before the resolution of any state or independent informal dispute resolution (IDR). CMS is now proposing to codify this guidance in the regulation, reasoning that “entering the survey results before the dispute processes have been completed may negatively affect a facility’s Five Star quality rating on Nursing Home Compare.”

CMS must not allow facilities to invoke IDR in an attempt to hide negative inspection reports and keep their star ratings inflated for a few more months. Dr. Kate Goodrich (Director, Center for Clinical Standards and Quality and CMS Chief Medical Officer) previously noted, “CMS urges all Americans to consult their physician, family, and Nursing Home Compare before choosing a nursing home for their loved ones.” As Dr. Goodrich’s statement acknowledges, Nursing Home Compare is the premier resource that residents and families use when choosing a nursing home.

CMS’s decision not to require facilities to post survey results immediately means that consumers nationwide are using information that is potentially outdated and misleading. Residents and families should have access to all relevant information concerning a nursing home’s quality and safety, even if that creates additional work for facilities and states. The Reform Law requires that states and the Secretary to make public information including statements of deficiencies within 14 calendar days after the information is made available to the facility.<sup>75</sup> Informal dispute resolution (IDR) cannot delay formal enforcement.<sup>76</sup> If a facility prevails at IDR, then the deficiencies are removed from the Statement of Deficiencies.<sup>77</sup> The current guidance in the State

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<sup>74</sup> 42 U.S.C. §§ 1395i-3(g)(5)(A)(i), 1396r(g)(5)(A)(i), Medicare and Medicaid, respectively.

<sup>75</sup> 42 U.S.C. §§ 1395i-3(g)(5)(A)(i), 1396r(g)(5)(A)(i), Medicare and Medicaid, respectively.

<sup>76</sup> 42 C.F.R. § 488.331(b).

<sup>77</sup> *Id.* § 488.331(c).

Operations Manual (SOM) plainly conflicts with the statute and should be removed from the SOM and not incorporated into the rules.

### **Civil Money Penalties: Waiver of Hearing, Reduction of Penalty Amount**

**CMS should not give nursing homes that face a penalty for substandard care or resident abuse and neglect an automatic 35% discount in the amount of a civil money penalty, unless they waive, in writing, the right to an administrative appeal.**

CMS should not make it easier for facilities to reduce CMPs when they have been found to have violated the minimum standards of care. State surveyors already identify the majority of nursing home violations (more than 95 percent) as not causing any harm to residents. As a result, generally speaking, less than five percent of identified violations have even the potential of resulting in a fine. In the absence of a meaningful financial penalty, nursing homes may have little incentive to correct the underlying causes of resident abuse, neglect, and other forms of harm.

CMS offers no rationale for the proposed change, other than saying that “the constructive waiver process would meet the needs of most facilities facing CMPs.”<sup>78</sup> CMS anticipates annual savings of \$1,108,226 for facilities and annual savings of \$125,886 to CMS.<sup>79</sup>

CMS’s decision to allow facilities to constructively waive hearing rights and still retain the 35 percent CMP reduction will only further reduce already weak enforcement of the standards of care and undermine resident health, safety, and well-being. CMS must not allow facilities to reduce CMPs without any effort or evidence that the cited violation does not warrant the original CMP amount.

### **Conclusion**

The proposed rule would roll back critical resident rights and protections. Several of the proposals, such as those related to the administration of antipsychotic drugs and infection control and prevention would, undoubtedly, result in harm to hundreds of thousands of vulnerable residents every year. Others, such as the proposed changes to the behavioral health requirements, will exasperate dehumanizing conditions for both residents and care staff.

CMS’s sole justification for most of the changes proposed in this deregulatory package is reducing burden on nursing homes. This justification violates CMS’s long-standing statutory duty to protect residents and ensure appropriate federal spending. Given the universally acknowledged need to improve care and safety for our nation’s nursing home residents, our organizations call on CMS to cease efforts to deregulate the nursing home industry and, instead, fully implement the 2016 final rule as written.

Thank you for your consideration.

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<sup>78</sup> 84 Fed. Reg. at 34,737, 34,751.

<sup>79</sup> *Id.* at 34737, 34761-34762.

Sincerely,

Center for Medicare Advocacy

Long Term Care Community Coalition

DRAFT