Joint Consumer Comments on Revised Policies Regarding Immediate Imposition of Federal Remedies

November 22, 2017
Division of Nursing Homes
Survey and Certification Group
Center for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Revised Policies regarding the Immediate Imposition of Federal Remedies-FOR ACTION (S&C: 18-01-NH)

Submitted electronically: dnh_triageteam@cms.hhs.gov.

Dear David, Karen, Evan, Lisa, and CMS colleagues,

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, we have conducted policy studies and analyses of nursing home laws, standards and their implementation. In addition to our work on systemic nursing home issues, we work closely with residents, families and their advocates to improve care.

Overview of Comments

Our organizations appreciate that the Centers for Medicare & Medicaid Services (CMS) is allowing the public to comment on the proposed revisions to Chapter 7 of the State Operations Manual. Nevertheless, we strongly oppose the changes indicated in the Survey and Certification Letter published on October 27, 2017 (S&C: 18-01-NH). In guidance issued just

last year (S&C: 16-31-NH), CMS expanded the bases for the immediate imposition of remedies, including Civil Money Penalties (CMPs), at facilities cited for certain deficiencies and which represent some of the poorest performing facilities in the country. Our organizations are discouraged to now see CMS attempting to reverse its own guidance in favor of the nursing home industry's demands, to the detriment of nursing home residents. Therefore, we would like to take this opportunity to reiterate and expand upon our previous comments submitted in July of 2017.

Proposed § 7304 – Mandatory Immediate Imposition of Federal Remedies

We are troubled that the proposed guidance describes the purpose of federal remedies as "encourage[ing]" facilities to take "the initiative and responsibility for continuously monitoring their performance and to promptly achieve and sustain and maintain compliance with federal requirements." We take issue with the word "encouraging," which undermines the Secretary's duty and responsibility to effectively enforce the requirements of federal law and reflects AHCA's March 9 letter to former Secretary Price objecting to the "out-of-control" use of CMPs.[1] Under the Nursing Home Reform Law, federal remedies serve goals of deterrence as well as prospective correction.

The Nursing Home Reform Law describes the "duty and responsibility" of the Secretary "to assure that requirements which govern the provision of care in skilled nursing facilities under this subchapter, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys."[2] The purpose of enforcement is protecting residents and making sure that public money is effectively and efficiently spent.

The Institute of Medicine's 1986 report, *Improving the Quality of Care in Nursing Homes*, is the legislative history of that law. Chapter 5, "Enforcing Compliance with Federal Standards" (copy attached in 3 documents) begins with the observation, "Even with improved regulatory standards and a more effective survey process, it is unlikely that quality of care and quality of life for residents in marginal or substandard nursing homes will improve unless compliance with the standards is effectively enforced."[3] Advocates for residents concur strongly with that observation and have always supported effective enforcement to protect residents.

The IoM Committee on Nursing Home Regulation conducted a considerable amount of original research in developing its recommendations. When the IoM asked state survey agencies about the state sanctions they use, it found:

Thirty-seven stated that particular sanctions seemed to be effective because they

- affect the income of the provider (20)
- can be implemented quickly (7)
- give the provider unwanted publicity (5), and
- can be used to remove the operator (4).

Nineteen states listed obstacles to the successful use of sanctions. Obstacles included

- administrative and legal time delays in implementation (11),
- administrative problems (3)
- fear of harm to residents (transfer trauma, service cutbacks to pay fines, and so on) (4), and
- insufficient impact on the provider's income (2).[4]

The IoM Committee wrote, "Intermediate sanctions adopted by the federal government and the state should operate so that they can be invoked promptly and be serious enough to the provider to deter violations as well as encourage immediate response."[5] It also wrote specifically about fines:

For a fining system to be effective, it is essential that the administrative and legal delays be avoided by prompt, short hearings, that the fines be graduated according to seriousness, duration, and repetition of the violations, and that fines be used to deter further violations. All fines should be large enough to be more costly than the money saved by the violation. Fining systems should be versatile enough to allow correction of less-serious violations, but immediately punish life-threatening violations.[6]

The enforcement system we have today suffers from the same problems that the IoM identified and that the 1987 Reform Law was intended to correct. In many ways, the current system reinstated the prior system (e.g., facilities are frequently given an opportunity to correct and are sanctioned for failure to correct, not for noncompliance). The enforcement system is slow (the appeals system still takes years and during appeals, Nursing Home Compare does not report CMPs that are under appeal, so publicity about federal fines is deferred) and fines, as imposed, are generally low and, as collected, even lower.

Proposed § 7304.1 – Criteria for Mandatory Immediate Imposition of Federal Remedies Prior to the Facility's Correction of Deficiencies

We are disturbed by CMS's proposal to revise § 7304.1. The proposal would severely impact CMS's ability to take any meaningful enforcement against the poorest performing facilities in the country. The proposed guidance also creates a false distinction between immediate jeopardy (IJ) with harm and immediate jeopardy without harm that does not exist in the nursing home regulations.

Under the current guidance, CMS requires Regional Offices (ROs) to impose remedies, without offering the opportunity to correct, when certain types of deficiencies are found. ROs must immediately impose remedies when there is (1) a citing of immediate jeopardy (scope and severity levels J-L); (2) deficiencies of substandard quality of care (SQC) that are not considered immediate jeopardy; (3) any G-level deficiency for quality of care, quality of life, and resident behavior and facility practices; (4) deficiencies of actual harm or above (G-L) on the current and last standard survey or between the current and last standard survey; and (5) when a Special Focus Facility (SFF) has at least an F-level deficiency during the current health survey or at least a G-level deficiency during the current Life Safety Code Survey. The current

guidance also provides a table explaining what remedies must follow each of the four criteria. For instance, a finding of immediate jeopardy shows that CMPs must be imposed in addition to other remedies.

CMS's proposal significantly revises the criteria for the immediate imposition of remedies. The new guidance proposes that there must be an immediate imposition of remedies when there is (1) immediate jeopardy; (2) any SQC deficiency cited as actual harm (G-I) but that results "injury, harm, or impairment;" (3) deficiencies of actual harm or above (G-L) on the current and last standard survey or between the current and last standard survey; and (4) when a Special Focus Facility has an F-level deficiency or above (except F812, F813 or F814 deficiencies) during the current health survey or a G-level deficiency or above during the current Life Safety Code Survey. Furthermore, the proposed guidance has removed the table linking each of the criteria to specific remedies (see below for our comments on the selection of remedies).

CMS's proposed changes to the criteria for the immediate imposition of remedies will have a profound effect on enforcement. First, the proposed guidance makes a distinction between immediate jeopardy where there is "serious injury, harm, impairment or death" and immediate jeopardy where there is no "serious injury, harm, impairment or death but the likelihood is present." In the latter case, CMS will not require CMPs. However, Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) decisions have consistently ruled against facilities that argued immediate jeopardy did not exist because there was only the likelihood of serious harm. For example, in *Avalon Place Trinity*,[7] the facility argued that immediate jeopardy could not be cited when the incident did not meet the elements of harm, immediacy, and culpability that are set out in the SOM, Appendix Q. The appellate panel responded by emphasizing that "[a]n IJ finding may be based on the actual occurrence or the likelihood of serious harm."[8]

Nursing Home Compare data over the last three inspection cycles show that immediate jeopardy citations continue to account for less than two percent of all citations.[9] Making a false distinction between immediate jeopardy with harm and immediate jeopardy without harm is particularly concerning when one considers how infrequently surveyors cite to immediate jeopardy (no matter the numerous studies over the last 20+ years showing that surveyors tend to under cite deficiencies).[10] More importantly, this false distinction goes against the definition of immediate jeopardy in the federal regulations, which encompasses all situations that pose actual or potentially life-threatening harm, death, and serious injury or impairment, and undermines the enforcement system.[11]

In *Kizer v. County of San Mateo*,[12] the County operated a nursing home and was cited with a state equivalent of an immediate jeopardy deficiency after the death of a resident. The County argued that maintaining a high standard of care for nursing homes, as required by California's Long-Term Care, Health, Safety, and Security Act of 1973, did not necessitate CMPs because alternative enforcement was available to residents through civil action. The California Supreme Court firmly rejected the position that private post-injury litigation is an adequate substitute for public pre-injury enforcement.

“[r]elying on the threat of a personal injury lawsuit to impose compliance with health and safety regulations defeats the very purpose of the statutory scheme, i.e., preventing injury from occurring . . . [b]ecause these patients are “at the mercy of the facility, the inspection, citation, and penalty system established by the Legislature is necessary to ensure that they receive quality care.”[13]

CMS’s proposed guidance loses sight of the fundamental purpose of a regulatory system—preventing harm. The reason for having an enforcement structure is to prevent injury from ever occurring through a process of inspection, citation, and imposition of penalties. Therefore, residents do not have to be harmed by an immediate jeopardy deficiency before CMPs are imposed against a poorly performing nursing home.

Second, CMS should not exempt Special Focus Facilities with F-812, F-813, or F-814 deficiencies from the criteria. By definition, SFFs are the poorest performing nursing homes in the country and require “special focus” to ensure that resident rights are being protected. The F-tags mentioned in the proposed guidance deal specifically with food safety requirements, from where a nursing home’s food is sourced to how food is stored and disposed. These are important regulatory requirements for any nursing home to follow and are unquestionably linked to resident well-being; nursing home residents are not less susceptible to food borne illnesses, like salmonella and E. coli, than the general public.

Proposed § 7304.2 – Effective Dates for Immediate Imposition of Federal Remedies

We are dismayed that CMS has chosen to allow per day CMPs to be lowered when an immediate jeopardy is removed. Current guidance provides that remedies cannot be rescinded once they are imposed. More specifically, CMS notes that a “CMP must be imposed and be in effect, irrespective of when the IJ is removed, unless otherwise rescinded as a result of legal proceedings.”[14] Additionally, the current language notes that this guidance applies to past noncompliance.

The proposed revisions state that all remedies must be imposed until a nursing home is determined to be in substantial compliance, which may occur prior to an on-site revisit. In regards to immediate jeopardy citations, CMS proposes to lower per day CMPs “when the survey agency has verified that the IJ has been removed.” CMS has also removed any language connecting past noncompliance to this section and, specifically notes in § 7304, that ROs will have discretion in determining whether to apply the immediate imposition of remedies to past noncompliance at all.

CMS’s proposal goes against long-standing policy that noncompliance is considered to continue until the facility has demonstrated (as opposed to “determined to be” in) substantial compliance. This determination usually occurs upon an on-site revisit, according to § 7317. The proposed guidance creates an assumption that CMS will lower per day CMPs for immediate jeopardy deficiencies prior to a revisit. This begs the question as to why CMS would

allow CMPs imposed in response to the worst deficiencies to be lowered while allowing remedies for lower level deficiencies to remain in effect. There is no reason to treat immediate jeopardy CMPs any differently than other remedies.

Lastly, the immediate imposition of remedies and their effective dates should continue to be applied to past noncompliance. Current guidance specifically calls for the immediate imposition of remedies for past noncompliance when there is immediate jeopardy, and unambiguously notes that "CMS strongly urges States to recommend the imposition of a civil money penalty for past noncompliance cited at the level of immediate jeopardy."[15] CMS has provided no reasonable basis for proposing that the immediate imposition of remedies should no longer apply to past noncompliance, especially given the fact that CMS's policy for nearly a decade has been to favor the most severe penalty for such deficiencies. Deficient nursing homes should not be given a pass on enforcement simply because deficiencies occurred between inspection periods.

Proposed § 7400.3 – Selection of Remedies

We are alarmed by CMS's proposed revisions to § 7400.5, as it relates to the imposition of immediate remedies and to the selection of remedies for other scope and severity levels. CMS's proposal removes language linking scope and severity levels to specific remedies. We believe further clarification is needed to determine whether this revision would allow ROs to have complete discretion in choosing remedies, regardless of what the scope and severity level is, as the revision implies. As discussed below, such a revision would violate federal regulations and severely mislead ROs.

Under the current guidance, CMS notes that "specific levels of seriousness correlate with specific categories of enforcement responses." Accordingly, ROs are required to select enforcement remedies, above those statutorily required, based on the scope and severity of a facility's deficiency. To assist in this effort, the guidance provides a scope and severity matrix that lays out each scope and severity level (A-J) and its corresponding category of remedies (categories 1-3), as established by 42 C.F.R. § 488.408. For instance, the matrix indicates that a citation for a G-level (actual harm) deficiency requires a category 2 remedy, which includes denial of payments and the lower range of CMPs.

CMS's revisions seemingly removes any language connecting scope and severity levels to any specific remedy. Instead, CMS wants to "encourage the provider to achieve and sustain substantial compliance." To aid in this objective, the proposed guidance clarifies that remedies should be selected according to what "will bring about compliance quickly . . . consider[ing] the extent to which the noncompliance is the result of a one-time mistake, larger systemic concerns, or an intentional action of disregard for resident health and safety." This point is illustrated by revisions to the scope and severity matrix which no longer includes the corresponding remedy categories. On its face, the proposed guidance creates an assumption that a citation for a G-level deficiency, for example, results in the use of any remedy in any category that a RO chooses, in violation of current federal regulations. Yet, if CMS's objective

is to simply allow ROs the ability to choose any remedy within a specific category, that raises the question as to why CMS felt the need to revise this section at all since there would be no change other than adopting an industry-friendly tone.

If CMS is revising the guidance on the selection of remedies to provide ROs complete discretion without notice and comment rulemaking as required by the Administrative Procedure Act (APA), the outcome will violate the law and not benefit nursing home residents. Endless reports spanning decades illustrate that nursing homes are not being properly cited for resident harm and are not being properly penalized for harm. A 2017 report by the Long Term Community Care Coalition found that 95 percent of cited deficiencies on Nursing Home Compare were found to be "no harm."[16] According to the Government Accountability Office (GAO), not only are deficiencies under-cited at a "no harm" level (A-F), but "missed deficiencies at the potential for more than minimal harm level (D-F) were considerably more widespread" than other scope and severity levels."[17] As research has shown time after time, a "no harm" citation does not actually mean that a resident was not harmed.

When facilities are cited at a "no harm" level, those facilities are almost never financially penalized through denial of payments or CMPs. Yet, financial penalties are an essential tool in enforcement by obliging facilities to improve resident care or lose money. The lack of financial penalties may explain why a LTCCC report found that 42 percent of nursing homes have been cited three or more times for the same deficiency over the last three inspection cycles.[18] The underlying cause of such repeat deficiencies may be the result of the weaker remedies found in category 1—directed plan of correction, state monitoring, and directed in-service training—that the current scope and severity matrix points to when deficiencies are categorized as "no harm." Inappropriately allowing ROs the discretion to choose any remedy in taking an enforcement action against a nursing home greatly increases the risk that more category 1 remedies, most commonly correction plans, will be used in remedying a deficiency where "actual" harm or immediate jeopardy has been cited.

Additionally, the Center and LTCCC firmly believe that resident harm is rarely a "one-time mistake." By voluntarily participating in Medicare and Medicaid, nursing homes take on the duty to provide each resident services that will allow him or her "to attain or maintain the highest practicable physical, mental, and psychosocial well-being."[19] Therefore, even when one resident is harmed in an isolated incident, that one incident is still a deficiency. Many ALJ and Council decisions have underscored this simple concept.

The deficiencies discussed in *Avalon Place Trinity* involved an 80 year old resident who died from injuries he sustained due to the facility's neglect.[20] Despite a documented risk of falls and a need for staff assistance, a nurse aide let the resident use the bathroom by himself. When the nurse aide returned to the resident's room, she found the resident "with his face on the floor and blood pooling around his head."[21] The resident died as a result of his injuries. Citing its corporate director of clinical systems, the facility argued that jeopardy could not be cited when the deficiency was based on one incident involving a single resident. The panel observed that the ALJ "is not required" to defer to the facility employee's definition of "pattern" deficiencies.[22] The panel further noted that, given the evidence, there was no legal error in

finding immediate jeopardy "even though only one resident suffered fatal injuries."[23]

Similarly, in *Community Care of Rutherdford County, Inc.*,[24] a resident was diagnosed with medical conditions that made him at risk for falls. The staff members of the facility noted that the resident required extensive assistance with bed mobility and transfers. The evidence showed that the facility failed to provide the assistance that the facility itself found necessary. The facility argued that the failure to meet the resident's needs was a "one-time mistake that was promptly corrected."[25] The ALJ determined that such a line of argument amounted to the facility "conced[ing] the failure to provide the resident with that which he needed."[26]

We urge CMS to reconsider its revisions to § 7400.5. If CMS wants to revise this section with the goal of changing federal regulations, CMS must use notice and comment rulemaking as required by the APA. If CMS is revising this guidance to alter its tone, it should be done with the recognition that the interests of nursing home residents are paramount. Finally, we call on CMS to remove any mention of "one-time mistake" from the proposed guidance; it devalues the enforcement structure and contradicts decades of ALJ decisions.

Conclusion

We urge CMS to clarify all questions raised by S&C: 18-01-NH before making any final changes to the guidance and to adequately respond to the concerns of all the residents who may be severely harmed by the proposed guidance. Our organizations strongly encourage CMS to consider the needs of nursing home residents before making changes to its guidance now and in the future. In this regard, we ask when CMS will adequately address "no harm" deficiencies, which account for 95 percent of all citations on Nursing Home Compare.[27] Given that CMS is willing to address the needs of the nursing home industry with proposed guidance that deals with less than two percent of all deficiencies, we urge CMS to give equal attention and treatment to "no harm" deficiencies, which have the biggest impact on resident care and quality of life.

Sincerely,
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[1] Letter from AHCA & NCAL to Former Secretary Price (Mar. 9, 2017), http://www.ihca.com/Files/Comm-Pub/AHCA-Final-Price-Ltr-3.9.17.pdf.
[2] 42 U.S.C. §§ 1395i-3(f)(1), 1396r(f)(1), Medicare and Medicaid, respectively.
[3] IoM Report 146.
[4] *Id*.
[5] *Id.* at 165.
[6] *Id.* at 166.
[7] No. A-16-108, Decision No. 2819 (Sep. 15, 2017), https://www.hhs.gov/sites/default/files/board-dab-2819.pdf.
[8] *Id.* at 34 (emphasis in original); *see also The Hilltop on Main*, Docket No. C-15-2111, Decision No. CR4801 (Mar. 2, 2017). https://www.hhs.gov/sites/default/files/alj-cr4801.pdf?language=en ("[I]t was only by chance that he [the resident] was not seriously injured or killed as a result of one of those unobserved elopements . . . [the] immediate jeopardy noncompliance justifies a CMP in the middle-to-high range . . . .").
[9] Nursing Home Compare data for the last three inspections show that surveyors cited a total of 337,693 deficiencies. 5,835 of those deficiencies have a scope and severity level of J-L. 5,835 divided by 337,693 equals 1.727901 percent; *see generally* Nursing Home Data Compendium 2015 Edition, CMS, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf (illustrating that citations for actual harm and immediate jeopardy deficiencies accounted for 3.2 percent of all citations).
[10] *See* Richard J. Mollot, *Safeguarding NH Residents & Program Integrity: A National Review of State Survey Agency Performance*, LTCCC (2015), http://nursinghome411.org/national-report-safeguarding-nursing-home-residents-program-integrity/ ("The State Survey Agencies, and CMS itself, have a history of under-identifying nursing home deficiencies and, the those deficiencies that they do identify and cite, too often fail to adequately identify when those violations harm or endanger residents."); *see also Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses*, GAO (May 2008), https://www.gao.gov/assets/280/275154.pdf ("GAO reports since 1998 have demonstrated that state surveyors, who evaluate the quality of nursing home care on behalf of CMS, sometimes understate the extent of serious care problems in homes because they miss deficiencies . . . A substantial proportion of federal comparative surveys identify missed deficiencies at the potential for more than minimal harm level or above.").
[11] 42 C.F.R. § 488.1.
[12] 806 P.2d 1353 (1991).
[13] *Id.*
[14] State Operations Manual, Chapter 7, § 7304.2, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c07.pdf.
[15] *Id.* at § 7510.1.
[16] Richard J. Mollot & Rediet Demissie, *The Identification of Resident Harm in Nursing Home Deficiencies: Observation & Insights,* LTCCC (2017), http://nursinghome411.org/identification-of-resident-harm-in-nursing-home-citations/.

[17] *Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses*, GAO (May 2008), https://www.gao.gov/assets/280/275154.pdf.
[18] Richard J. Mollot, *Chronic Deficiencies in Care: The Persistence of Reoccurring Failures to Meet Minimum Safety & Dignity Standards in U.S. Nursing Homes*, LTCCC (2017), http://nursinghome411.org/nursing-homes-with-chronic-deficiencies/.
[19] 42 U.S.C § 1395i–3(b)(2).
[20] *Avalon Place Trinity*, No. A-16-108, Decision No. 2819 (Sep. 15, 2017), https://www.hhs.gov/sites/default/files/board-dab-2819.pdf.
[21] *Id.* at 6.
[22] *Id.* at 33.
[23] *Id.* at 34.
[24] No. C-09-595, Decision No. CR2173 (Jul. 6, 2010), https://www.hhs.gov/sites/default/files/static/dab/decisions/alj-decisions/2010/cr2173.pdf.
[25] *Id.* at 11.
[26] *Id.*
[27] Richard J. Mollot & Rediet Demissie, *The Identification of Resident Harm in Nursing Home Deficiencies: Observation & Insights,* LTCCC (2017), http://nursinghome411.org/identification-of-resident-harm-in-nursing-home-citations/.