U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

November 2, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: **Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting (CMS–3442–P)**

Dear Administrator Brooks-LaSure:

On September 6, 2023, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule entitled, "Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting."[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments on the proposed rule.

Advocacy shares CMS' desire to advance policies aimed at improving the quality of care for the nation's seniors and acknowledges the difficulties CMS faces in balancing the policy goal of establishing stronger staffing requirements against the practicalities of implementation and costs. However, Advocacy is concerned that this rule may have unintended consequences that negatively impact long-term care facilities and other related providers, the vast majority of which are small businesses. These impacts are particularly troublesome at a time when there is a real shortage of qualified nurses and other nursing home caregivers in the United States, especially in rural areas.

CMS certified[2] in the Regulatory Flexibility Act (RFA) section of the rule that this proposal will not have a significant impact on a substantial number of small entities. CMS projected that the rule's cost impacts on long-term care facilities' annual earnings would not exceed the agency's metric of "significant impact," which equates to 3-5% of covered entities' annual revenue.

[1] 88 Fed. Reg. 61352 (Sept. 6, 2023).
[2] 5 U.S.C. §605(b).

Advocacy believes that CMS should revisit its decision to certify this rule under the provisions and requirements of the RFA because the factual basis underlying the certification may underestimate the regulation's impacts and costs to small entities.

Advocacy has learned from multiple small long-term care facilities (LTCFs) and their representatives that the costs of this rule will have detrimental economic impacts on their businesses. Also, these LTCFs argue that it will be extremely difficult and expensive to comply with this rule's provisions as there is a nursing shortage in the U.S. that makes it problematic for them to retain and/or employ nurses and patient caretakers. Taken together, these concerns indicate the rule will impose significant costs on LTCFs that will likely exceed CMS' cost projections.

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA) that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The Regulatory Flexibility Act (RFA),[3] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.[5] Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau, the Occupational Safety and Health Administration, and the Environmental Protection Agency to conduct special outreach efforts through a review panel.[6] The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.[7] If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.[8] The agency must provide a statement of factual basis that adequately supports its certification.[9]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[10] The agency must include a response to these written

[3] Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[4] Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).
[5] 5 U.S.C. § 603.
[6] *Id.* § 609.
[7] *Id.*
[8] *Id.* § 605(b).
[9] *Id.*
[10] Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).

comments in any explanation or discussion accompanying the final rule's publication in the Federal Register unless the agency certifies that the public interest is not served by doing so.[11]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[12]

B. The Proposed Rule and its Provisions

The proposed rule would establish minimum staffing standards for long-term care facilities to ensure safe and quality care. In addition, the rule would require states to report the percent of Medicaid payments for certain Medicaid-covered institutional services that are spent on compensation for direct care workers and support staff. CMS proposes requiring a registered nurse (RN) to be on-site 24 hours per day and 7 days per week to provide skilled nursing care to all residents in accordance with resident care plans. The agency also proposes individual minimum staffing type standards, based on case-mix adjusted data for RNs and nurse assistants (NAs), to supplement the existing "Nursing Services" statutory requirements. CMS also specifies that facilities must provide, at a minimum, 0.55 RN hours per resident day (HPRD) and 2.45 NA HPRD. RN and NA staffing can never be lower than these proposed minimum standards, and if the acuity needs of residents in a facility require a higher level of care, a higher RN and NA staffing level will also be required. CMS expects that a total of 12,639 additional RNs and 76,376 additional NAs will be needed to meet the proposed rule's requirements.[13]

Section 605(b) of the RFA permits the head of the agency to certify that the rule will not have a significant impact on a substantial number of small entities. The certification must be accompanied with the factual basis underlying the certification.[14] Also, pursuant to section 605(b), if a certification is used, an agency may avoid the requirements of publishing initial and final regulatory flexibility analyses (IRFA), which would include a discussion of significant, burden-reducing alternatives.[15]

CMS certified pursuant to the RFA that this rule will not have a significant impact on a substantial number of small entities.[16] As its measure of significant economic impact on a substantial number of small entities, CMS uses a change in affected entities' revenue of more than 3 to 5 percent.[17] CMS' factual basis for the certification asserts that the rule's costs are estimated to be between 2.30 percent (3% discount rate) and 2.42 percent (7% discount rate) of

[11] *Id.*
[12] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).
[13] Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 88 Fed. Reg. 61377, 61352 (Sept. 6, 2023).
[14] 5 U.S.C. §605(b).
[15] *Id.* §603.
[16] 88 Fed. Reg. at 61,426.
[17] *Id.*

LTCF's revenues. These estimated costs fall below the agency's 3 to 5 percent significance threshold."[18] Therefore, CMS did not draft an IRFA.

C. Stakeholders Affected by this Rule Argue that CMS Took a One-Size-Fits-All Approach to this Regulation that will Negatively Impact Long-Term Care Facilities.

LTCF providers and their representatives approached Advocacy, asking that we review the potential impacts associated with this rule. They also provided our office with documents and studies written by interested parties to this regulation. Those stakeholders were concerned that CMS' approach to improving nursing home care took a one-size-fits-all approach that would prove detrimental to the industry. As evidence, they cited multiple concerns about any unintended consequences attendant with the proposal's staffing requirements at a time when the U.S. is facing an unprecedented nursing and nursing home staffing shortage. They suggest that the nursing home staffing regulation comes at a time when the need for nursing home services by baby boomer Medicare beneficiaries is expected to continue rising during the upcoming years.

Congress created Advocacy to be the voice of small business in the federal government. As part of this mandate, Advocacy is charged with informing federal rulemaking agencies about regulatory matters of concern to small entities. Pursuant to this mission, Advocacy presents the following concerns on behalf of stakeholders in the LTCF space.

a) The Rule's Requirements are Currently Unfunded.

Stakeholders are significantly concerned with the fact that this rule's requirements are completely unfunded. They submit that they cannot be expected to absorb or pass along, the billions in costs projected by CMS in this rule. Stakeholders believe that further economic analysis is needed and that LTCFs should be engaged on how to make funding and compliance with this rule more manageable.

b) There is a Nursing Shortage that will Make Compliance with the Rule Problematic.

Massachusetts Senior Care explained to Advocacy that CMS drafted this regulation using a one-size-fits-all approach therefore it does not take into consideration the size of the facility, the acuity of the patients treated on a facility-by-facility basis, or the different specialties of care provided by LTCFs. They believe that CMS should improve its analysis as to how this rule is to be implemented.

Stakeholders suggest that because of staffing shortages, it will be difficult, if not impossible for them to comply with the rule's mandates. According to the U.S. Bureau of Labor Statistics, "there are roughly 235,900 fewer health care staff working in nursing homes and other long-term care facilities compared to March of 2020."[19] Further, they referred Advocacy to a Kaiser Family

[18] *Id.* at 61,425.
[19] U.S. Bureau of Lab. Stat., *Occupational Outlook Handbook: Registered Nurses* (Sept. 6, 2023), https://www.bls.gov/ooh/healthcare/registered-nurses.htm#tab-6.

Foundation (KFF) study[20] that concluded that it would be difficult for the majority of LTCFs to meet the rule's requirements as currently proposed. The study concluded that, among all nursing facilities, fewer than 1 in 5 could currently meet the required number of hours for registered nurses and nurse aides, which means over 80% of facilities would need to hire nursing staff. Ninety percent of for-profit facilities would need to hire additional nursing staff compared with 60% of non-profit and government facilities.

Further, the nursing shortage is more acute given that LTCFs compete with hospitals, which are also experiencing a bedside nurse hiring shortage. The Nurse Journal notes that "COVID-19 has highlighted the gaps in healthcare and created an increasing demand for bedside nurses. In the United States, it is projected that 1.1 million nurses are needed to replace retiring nurses by 2022. Globally, the need is closer to 13 million."[21]

Given these stakeholder concerns and the belief that CMS' economic cost estimates are understated, Advocacy encourages CMS to better analyze the rule's potential impacts on small entities as it finalizes this rule.

c) The Rule Fails to Address the Root Causes of Issues in the Long-Term Care Facility Industry.

Stakeholders argue that a mandate to increase the quality of LTCFs' staff does not resolve many of the fundamental issues that LTCF providers face and the rule seeks to correct. These issues are related to broader structural issues facing the entire healthcare industry. Stakeholders pointed Advocacy to a CMS contracted study by Abt Associates (Abt) which concluded that no single staffing level would guarantee quality care, although the report estimated that higher staffing levels would lead to fewer hospitalizations and emergency room visits, faster care, and fewer failures to provide care.[22]

According to a Maine consortium of health providers, Maine has been grappling with a decline in access to long-term care, with seventeen facilities shutting down or transitioning to lower levels of care since the start of 2020. The root causes are primarily underfunding and the persistent staffing shortage, both of which will be even more acute should the proposed rule take effect.[23]

---

[20] Kaiser Fam. Found., *What Share of Nursing Facilities Might Meet Proposed New Requirements for Nursing Staff House?* (Sept. 18, 2023), https://www.kff.org/medicaid/issue-brief/what-share-of-nursing-facilities-might-meet-proposed-new-requirements-for-nursing-staff-hours/.

[21] Gayle Morris, *Post-Pandemic Nursing Shortage: Effects on Aspiring Nurses*, NURSE JOURNAL (OCT. 3, 2023), https://nursejournal.org/healthcare-review-partners/gayle-morris/.

[22] ABT ASSOC., NURSING HOME STAFFING STUDY: COMPREHENSIVE REPORT 121-22 (June 2023), https://kffhealthnews.org/wp-content/uploads/sites/2/2023/08/Abt-Associates-CMS-NH-Staffing-Study_Final-Report_-Apndx_June_2023.pdf.

[23] Me. Health Care Ass'n et al., Comment Letter on Proposed Rule on Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting (Sept. 6, 2023), https://www.regulations.gov/comment/CMS-2023-0144-15032.

Maine Veteran's Homes (MVH) told Advocacy that it has struggled with employment vacancies as high as 160 openings for RNs, LPNs, and CNAs. To address this shortage, they have hired temporary labor. The temporary labor costs grew from a negligible amount before the pandemic to $8.6 million in FY2023. Last year, MVH had to invest over $4.4 million in wage increases just to remain competitive in the market. While MVH is starting to rebound from the COVID-19 pandemic, if this rule is implemented, they will again find themselves with extraordinary wage inflation and likely be forced to increase the use of temporary labor to remain open which will result in unsustainable financial losses. MVH stated that reimbursement rates are already lagging in the industry and most homes have experienced year-over-year net losses.

The rule's reliance on defining nursing facilities as "urban" versus "rural" may place an increased burden on rural providers. CMS should ensure that the disparity between how those terms is statistically defined will not serve to prejudice how rural LTCFs are treated in the rule.

Stakeholders voiced concern that the rule does not encourage, or is silent, the use of licensed practical nurses (LPNs) and other key staff. Nursing facilities across states employ a substantial number of LPNs and rely on these professionals to support patients, veterans, and seniors alike. Given the importance that LPNs currently play in providing care, stakeholders want CMS to reevaluate this omission. Improving this aspect of the rule will lessen the burden on covered LTCFs.

d) The Hardship Exemptions Proposed by CMS are Too Burdensome to be Useful.

CMS did provide for hardship exemptions designed to help impacted small entities comply with the rule's requirements. Stakeholders told Advocacy that the proposed exemptions were too burdensome and too limited to be useful. They noted that the hardship exemption would apply only under limited circumstances. For example, to qualify for a one-time waiver from the mandate, LTCFs would need to first be cited for non-compliance, then would need to demonstrate to state surveyors a good faith effort to hire and a financial commitment to hiring. They believe that the hardship process should not be punitive but should serve to help small LTCFs comply with the rule, resulting in meeting staffing levels and better patient health care outcomes.

Stakeholders also voiced concerns with a provision that allows for a hardship exemption where the workforce is unavailable, or the facility is a least 20 miles from another LTCF. Stakeholders suggest that the 20-mile requirement seems to be arbitrarily set and does not allow for the potential that multiple LTCFs may need to seek the exemption because of staffing shortages.

e) The Rule's Enforcement Actions are too Severe.

Stakeholders are extremely worried about their legal exposure should this rule be finalized. They believe that the regulation's enforcement actions (referred to as remedies in the rule) are too severe. Noncompliance with the rule could lead to citations on small LTCFs based on violations of Medicare's Conditions of Participation. This could result in the termination of the provider

agreement, denial of payment for all Medicare and/or Medicaid individuals by CMS, and/or civil money penalties. This legal exposure could lead to unintended consequences that the rule is designed to correct. For example, LTCFs could deny or restrict access to care for Medicare beneficiaries seeking nursing home care, especially in rural areas.

D. Advocacy believes that CMS should have performed an initial regulatory flexibility analysis (IRFA) in lieu of its certification given the disparity between the rule's description of impacts and stakeholders' belief that costs have been underestimated.

CMS notes that the vast majority (95%) of the health care sectors covered by this rule are small entities.[24] Section 603 of the RFA was designed by Congress to require federal regulatory agencies to analyze the impacts of their regulations on small entities. The promulgating agency is required to draft an IRFA when the rule is expected to have a significant impact on a substantial number of small entities. The analysis should identify the small entities regulated, the costs of the rule on those entities, and any alternative approaches that would reduce the impacts on those small businesses while allowing the agency to maintain its policy objectives.[25]

In this case, CMS certified the rule, but the factual basis underlying the RFA certification could be improved. CMS estimated that almost all skilled nursing facilities (NAICS 6231) and intellectual and developmental disabilities facilities (NAICS 6232) are small entities, as that term is used in the RFA.[26] However, the rule is expected to have an impact on other LTCFs that also rely on nurses. Therefore, CMS should have included those sectors in its factual basis. Some of these impacted sectors are:

- Residential Mental Health and Substance Abuse Facilities (NAICS 62322)
- Continuing Care Retirement Communities and Assisted Living Facilities for the Elderly (NAICS 6233)
- Continuing Care Retirement Communities (NAICS 623311)
- Other Residential Care Facilities (NAICS 62399)
- Services for the Elderly and Persons with Disabilities (NAICS 62412)

Had CMS performed an IRFA, it would have allowed for a clearer understanding of the regulation's impact on these LTCFs and nursing sectors.

In addition, CMS' analysis provides cost impacts on the affected health care sectors in estimated annual average cost terms. However, costs analyzed on a per small entity basis would make it easier to understand the rule's true impact. Based on the CliftonLarsonAllen (CLA)[27] and Kaiser Family Foundation (KFF)[28] studies on this issue, CMS' estimated average annual costs ($3.7

[24] 88 Fed. Reg. at 61,425.
[25] 5 U.S.C. §603.
[26] 88 Fed. Reg. at 61,425.
[27] CLIFTONLARSONALLEN LLP, CMS PROPOSED STAFFING MANDATE: IN-DEPTH ANALYSIS ON MINIMUM NURSE STAFFING LEVELS (Sept. 2023), https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/CLA%20Staffing%20Mandate%20Analysis%20-%20September%202023.pdf.
[28] Kaiser Fam. Found., *supra* note 20.

billion at a 7% discount rate and $3.9 billion at a 3% discount rate) may be underestimated.

CMS used fiscal year (FY) 2021 wage estimates to determine the cost of complying with staffing requirements—i.e., hiring full-time registered nurses and nurse assistants. However, when analysts at CLA used FY 2023 wage estimates, they found that the costs were $6.8 billion, which is over 50% higher than CMS' estimates.[29] When applying CMS' discount rates of 3% and 7% respectively, the updated cost estimates are $6,601,941,748 and $6,355,140,187. If the revenue from 2017 is an accurate estimate for 2021, updated revenue for small entities in NAICS codes 6231 and 6232 would represent 3.9 - 4.1% of revenue which falls within CMS' measure of economic significance for RFA purposes. Therefore, CMS would have not been able to certify the rule using its own measure of significance criteria and the agency may have decided to prepare an IRFA. Had CMS performed an IRFA, it may have determined that because of the rule's expected impact on small LTCFs, alternatives existed that could lessen the regulation's impact on those businesses beyond those discussed in the rule.[30]

CMS acknowledged that it heard from LTCFs concerned with the complexities and costs of complying with this rule, especially during a post-COVID-19 nursing shortage.[31] Appropriately, CMS discussed some of its regulatory options and alternative approaches in the rule.[32] But CMS concluded that LTCFs regulatory concerns were outweighed by the benefits of increasing nursing staffing to improve care in long-term care facilities. Advocacy understands that CMS provided covered entities with extended compliance deadlines,[33] but stakeholders believe that even with these elongated timelines it will be difficult to comply with the rule's provisions.

The RFA requires the promulgating agency to consider and discuss alternatives designed to reduce the impacts of the rule on small entities. Had CMS performed an IRFA, the costs associated with compliance may have led CMS to adopt additional alternatives that would have reduced the rule's burdens on affected LTCFs. This in turn would have mollified some of the concerns voiced by the stakeholders.

E. Conclusion

Advocacy encourages CMS to take the affected small entities' concerns outlined above into consideration as it finalizes this rule. Advocacy also encourages CMS to revisit its analysis that concluded that this rule will not have a significant impact on a substantial number of small entities given the uncertainty supporting the costs associated with this regulation.

---

[29] CLIFTONLARSONALLEN LLP, *supra* note 27, at 14.
[30] Section 603(c) of the RFA requires the promulgating agency to describe any significant alternatives that minimize the impact of the rule on small entities. This discussion is to be included in RFA section of the rule, not solely in the Regulatory Impact Analysis, as was done by CMS.
[31] 88 Fed. Reg. at 61,419.
[32] *Id.*
[33] *Id.* at 61,354.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Linwood Rayford at (202) 205-6533 or by email at linwood.rayford@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Linwood L. Rayford, III
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Richard L. Ravesz, Administrator
Office of Information and Regulatory Affairs