SENIOR CARE PHARMACY COALITION

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November 6, 2023

Submitted via Electronic Filing

Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

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

Dear Administrator Brooks-LaSure:

The Senior Care Pharmacy Coalition ("SCPC") appreciates the opportunity to provide comments on the September 6, 2023 Proposed Rule issued by the Centers for Medicare & Medicaid Services ("CMS"), entitled *Medicare and Medicaid Programs: Minimum Staffing Standards for Long Term Care Facilities and Medicaid Institutional Payment Transparency Reporting* (the "Proposed Rule"). Respectfully, we believe that the Proposed Rule, while well-intentioned, is the wrong policy at the wrong time, and could well limit access to nursing facility care for Medicare and Medicaid beneficiaries, undermine the overall quality of care and services for long-term care (LTC) facility residents, and threaten the financial viability not only of LTC facilities, but also of LTC pharmacies.

SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 80% of all independent LTC pharmacies. Our members serve one million residents daily in skilled nursing facilities and assisted living communities across the country.[1] SCPC is committed to assuring that Medicare beneficiaries who need LTC receive high quality care and services, including LTC pharmacy services, not only in LTC facilities, but in whatever setting they reside.

LTC facilities contract with LTC pharmacies to satisfy the pharmacy services requirements of participation for skilled nursing facilities (SNFs) participating in Medicare and nursing facilities

[1] This figure is based on pre-pandemic facility occupancy rates. Our members also serve an increasing number of individuals with LTC needs, including Medicare beneficiaries, living in community settings and at home.

(NFs) participating in Medicaid.[2] In addition, LTC pharmacies must meet Part D service criteria. CMS State Operations Manual characterizes LTC pharmacy services as "an integral part of the care provided to each nursing home resident." This is not surprising, since LTC facility residents rely on prescription drugs and the specialized and clinical services LTC pharmacies provide, with residents averaging 12 prescriptions per year.[3] Given the importance of prescription drugs and LTC pharmacy services to the quality of care LTC facility residents receive and given the precarious economic position of LTC pharmacies due to unrelated changes in federal policy discussed below, our insights and concerns regarding the Proposed Rule merit close consideration.

There are three key elements of the Proposed Rule:

- A requirement that each facility have a registered nurse (RN) on-site 24/7/365. Current regulations require that each facility have an RN on-site eight hours per day.
- A requirement that each facility provide 0.55 hours per resident day (HPRD) of RN care. Current regulations require each facility to provide nurse staffing sufficient to meet the needs of each resident.
- A requirement that each facility provide 2.45 HPRD of certified nursing assistant (NA) care.

The Proposed Rule emphasizes that these requirements establish a floor not a ceiling and includes various additional requirements to prevent LTC facilities from using the minimum staffing standards to avoid hiring additional nursing staff to meet the needs of the residents. Given the complex chronic health care needs, multiple impairments in activities of daily living, and prevalence of cognitive impairments in the LTC resident population, it is likely that the Proposed Rule would require substantially greater increases in nurse staffing levels than the proposed minimum staffing standards would require.

There are four reasons we urge CMS not to finalize the Proposed Rule: (1) there is an inadequate available workforce to meet the proposed staffing requirements; (2) Medicaid reimbursement is inadequate to pay for the proposed staffing requirements; (3) it is insufficiently flexible and unduly complex when overlaid on existing state nurse staffing requirements; and (4) it will result in countervailing unintended consequences that will undermine overall quality of care for residents in LTC facilities and that threaten the economic viability for significant subsets of the LTC facility and LTC pharmacy markets.

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[2] 42 U.S.C. § 1395i-3 (pertaining to SNFs participating in the Medicare program) and 42 U.S.C. § 1396r(b)(4)(a)(iii) (pertaining to NFs participating in the Medicaid program). Based upon these statutory requirements, CMS has promulgated extensive regulations establishing detailed requirements of participation for SNFs under Medicare and NFs under Medicaid. 42 C.F.R. §§ 483.1-483.95.

[3] ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need 5 (July2021).

Inadequate Available Workforce

While most providers in the health care sector have recovered from the COVID-19 pandemic, the LTC sector has not. LTC facility occupancy remains well below pre-pandemic levels, due largely to shortages of available nursing staff.[4] LTC facilities must hire an additional 150,000 employees – RNs, licensed practical nurses (LPNs), and NAs among them – just to return to pre-pandemic staffing levels, yet LTC facilities have been unable to find workers to fill these positions.[5] The need for post-acute skilled nursing facility care and for long-stay nursing facility care remains high, yet the shortage of nursing staff willing to work in LTC facilities unquestionably has impeded the ability of LTC facilities to serve this need. Since 2020 more than 500 LTC facilities have closed, many due to the inability to find nursing staff. Given these challenges, it is unfortunate but understandable that 93% of LTC facilities currently would not satisfy at least one of the minimum staffing standards in the Proposed Rule.[6]

To meet the proposed minimum staffing requirements, LTC facilities would have to hire an additional 102,000 nurses, including 18,000 RNs and 84,000 NAs.[7] It is unlikely that enough nurses willing to accept positions in LTC facilities are available, and the pool of RNs in the nursing profession is expected to decline sharply soon. By 2027, 900,000 RNs are expected to leave the nursing profession.[8]

The Proposed Rule completely discounts the essential role LPNs play in providing quality nursing care to LTC facility residents, since the proposal does not include LPN staffing. Ignoring the 170,000 LPNs working in LTC facilities across the country is dismissive of their essential contributions to resident care and will result in greater demands on RNs to perform tasks well within the expertise and scope of licensure of LPNs but which are beyond the expertise and scope of licensure for NAs. One crucial example is that LPNs are authorized to pass medications to residents, but NAs generally are not authorized to do so.[9]

CMS omits LPNs from the proposed minimum staffing standards based largely on a report the agency commissioned from Abt Associates, particularly the statement that "[t]there is no

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[4] https://www.kff.org/coronavirus-covid-19/issue-brief/nursing-facility-staffing-shortages-during-the-covid-19-pandemic/.

[5] AHCA SURVEY: NURSING HOMES LIMITING, TURNING AWAY RESIDENTS DUE TO WORKFORCE SHORTAGE, June 15, 2023 available at https://www.healthleadersmedia.com/post-acute/ahca-survey-nursing-homes-limiting-turning-away-residents-due-workforce-shortage#:~:text=55%25%20of%20nursing%20home%20providers,to%20hire%20and%20retain%20staff; *see also* *https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/SNF%20Survey%20Mid-Year%202023.pdf*.

[6] *See* CLA Analysis, available at https://www.ahcancal.org/News-and-Communications/Fact-Sheets/FactSheets/CLA%20Staffing%20Mandate%20Analysis%20-%20September%202023.pdf.

[7] Id.

[8] https://www.ncsbn.org/news/ncsbn-research-projects-significant-nursing-workforce-shortages-and-crisis (referencing April 2023 survey).

[9] In a handful of states, NAs may pass medications following completion of specialized training.

consistent relationship of quality and safety with LPN staffing. There is negative correlation between LPN and RN staffing, indicating that nursing homes with higher LPN staffing levels tend to have lower RN staffing levels."[10] Of course, no consistent relationship does not mean that there is correlation. Indeed, the Abt report acknowledges that increasing licensed nursing staffing – including both RNs and LPNs – is related to better care: "[s]imulation modeling results show that the percentage of delayed or omitted clinical care decreases appreciably with increased licensed nurse (RN, LPN) staffing levels."[11] Abt also includes both LPN staffing and total nurse staffing (RNs, LPNs, and NAs combined) among the options discussed in the report, all of which argues against excluding LPNs altogether.

The "negative correlation" between LPN and RN staffing itself does not warrant any particular inference or conclusion regarding LTC facility behavior, although the discussion in the Proposed Rule intimates that facilities inappropriately rely on LPNs rather than RNs. A more likely explanation is that, in the face of RN shortages, effective use of LPNs within the scope of their licensure is an appropriate use of nursing training and skills to effectively care for residents. If accurate, this suggests that failure to include LPNs in the proposed rule could undermine both the efficiency and effectiveness of nursing facility care, thereby undermining rather than improving quality.

The Proposed Rule argues that facilities ask LPNs to perform tasks outside the scope of their licensure and training and therefore LPNs should not be included in the minimum staffing standards. Interestingly, CMS relies on the Abt report for this conclusion, yet ignores the fact that the Abt report also states that facilities also ask NAs to perform tasks outside the scope of their legal authority. The former is not a reason to exclude LPNs from minimum staffing standards, just as NAs should not be excluded from minimum staffing standards as well.

Residents in LTC facilities need – and benefit from – various nursing services, and therefore benefit from care rendered by RNs, LPNs, and NAs within the scope of their training, licensure, or legal authority. Some resident care tasks are within the scope of authority for both RNs and LPNs or LPNs and NAs such that facilities need the operational flexibility to assign tasks to RNs, LPNs, or NAs based on staff availability. If facilities use nursing staff beyond the scope of licensure or legal authority, then the facility currently is subject to oversight and penalty, and such inappropriate use should not be the basis to exclude LPNs from minimum staffing standards.

The fact that facilities use both RNs and LPNs in a coordinated manner underscores the importance of staffing flexibility given the realities of the labor market and gives credence to a standard that recognizes total nursing hours, not just hours by nursing discipline, is essential to any staffing standard. Yet the Proposed Rule states:

[10] Abt Associates, Nursing Home Staffing Study Comprehensive Report vii (June 2023) (Abt Report).
[11] Id. at xi.

> [T]otal licensed nurse staffing standards may ensure adequate levels of licensed nurse staffing and allow nursing homes the flexibility to substitute nurse type for example LPN/ LVNs for RNs, or NAs for LPN/LVNs, but may result in compromising the safety and quality of care. Multiple studies have found no evidence of a consistent relationship of quality and safety with LPN staffing.[12]

Although the proposed rule asserts that there are "multiple studies," the only reference in the Proposed Rule to support this statement is the Abt report, which in turn does not cite "multiple studies" in support of its statement that there is no consistent relationship between quality and safety and LPN staffing. Rather, it bases this statement on its own "multivariate analysis."[13] This is an inadequate basis on which to adopt staffing standards that will profoundly impact the way care and services are provided to residents in LTC facilities.

It will be impossible for facilities to recruit the RNs and NAs needed to meet the minimum staffing proposal. Further, the failure to include LPNs or a total nursing hours standard exacerbates the workforce challenges while limiting facility options to assure adequate staffing. Given these realities, we urge CMS not to finalize the Proposed Rule.

Inadequate Reimbursement

CMS estimates that it would cost LTC facilities more than $4 billion per year, or $40 billion over ten years, to meet the minimum staffing requirements in the Proposed Rule. Clifford, Larson, Allen (CLA) estimates the annual cost to be $6.8 billion, $68 billion over 10 years, to meet the minimum staffing requirements.[14] Since the proposed minimum staffing standards represent a floor not a ceiling, and given the acuity of LTC facility residents, it is likely that implementation costs will be higher than these estimates if facilities are to staff at the levels required by the Proposed Rule, which often will exceed the minimums.

The Proposed Rule does not include any funding to assist facilities in implementation. LTC facilities are still suffering from the economic devastation of the pandemic, with 59% of facilities reporting negative operating margins in 2021.[15] In other words, more than 50% of LTC facilities operate at a loss now, yet the Proposed Rule would require these facilities to spend an additional $4 billion each year with no additional funding. Given that nearly all LTC facility revenues are from the Medicare and Medicaid programs, facilities have no ability to raise revenues to offset increased costs absent increased Medicare and Medicaid payments, a reality the Proposed Rule simply ignores.

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[12] 88 Fed. Reg. 61352 at 61357, citing the Abt Report.
[13] Abt Report at 112.
[14] CLA, CMS Proposed Staffing Mandate: In Depth Analysis on Minimum Nurse Staffing Levels at 6 (September 2023).
[15] CLA, SNF Cost Comparison and Industry Trends Report (October 2022).

While there may be resources that could be reallocated to add nursing staff, it is unlikely that there are resources sufficient to meet the proposed minimum staffing standards without shifting resources away from other services required for quality resident care and safety. As MedPAC noted during its October 2023 public meeting, the Proposed rule represents a "brute force" test of the hypothesis that there is enough money in the system to pay for the proposed minimum staffing standards.[16] A "brute force" test is an ill-advised approach to improving care for LTC facility residents.

The implications are varied but should have been considered in the Proposed Rule. Some facilities will find the resources to meet the minimum staffing standards, but potentially by trade-offs that undermine care in other ways. Some facilities will meet the minimum staffing standards by reducing occupancy, thereby reducing access to LTC facility services for the millions of Americans who need them. Some will simply close their doors, further limiting access to needed care. As an illustration of the access problem the Proposed Rule could create, if facilities met the minimum staffing proposal by reducing occupancy, over 275,000 current residents – or more than 25% of LTC facility residents – would be denied access to care.[17] Regardless of which option an individual facility chooses, however, patients will be denied access to care and the economic viability of a financially unstable sector will continue to deteriorate.

Given the risk to access, quality of care, and financial viability of a crucial element of our health care delivery system, we urge CMS to abandon its brute force test to determine whether there are sufficient resources already in the system to fund the proposed minimum staffing standards.

Insufficient Flexibility and Undue Complexity

As noted above, by limiting the proposed staffing standards to two disciplines, excluding LPNs, and eschewing a total nursing metric, the Proposed Rule imposes an inflexible framework on facility staffing decisions that unduly limit the facility's ability to assure adequate staffing to meet resident needs in a manner consistent with overlapping scopes of authority for RNs and LPNs and that likely will result in unintended consequences that undermine resident care in areas separate from nursing. Forty-five states and the District of Columbia have their own minimum staffing requirements,[18] all of which differ from the proposed minimum staffing standards, and these requirements typically are conditions of facility licensure such that facilities will have to remain in compliance with the state-level standards while simultaneously complying with the proposed federal standards.

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[16] https://www.mcknights.com/news/medpac-members-rip-brute-force-test-of-staffing-mandate-ponder-consequences-and-possible-gaming/.

[17] CLA, CMS Proposed Staffing Mandate: In Depth Analysis on Minimum Nurse Staffing Levels at 18 (September 2023).

[18] The Proposed Rule states that 38 states and the District of Columbia currently have minimum staffing standards, 88 Fed. Reg. at 61356. In fact, 45 states and the District of Columbia have such standards. UCSF, NURSING HOME STAFFING STANDARDS IN STATE STATUTES AND REGULATIONS (2008), available at https://www.justice.gov/sites/default/files/nursing_home_staffing_standards_in_state_statutes_and_regulations.pdf.

The result likely will be chaotic. Facilities, on a state-by-state basis, will have to determine staffing algorithms that allow them to comply with disparate federal and state staffing requirements. State requirements may include minimum hour requirements for all nursing disciplines, total nursing hour requirements, or some combination of both. With federal requirements limited to only two nursing disciplines, it is likely that, in many jurisdictions, facilities will have to add more nursing staff than necessary to meet federal requirements, thus increasing the workforce and inadequate funding pressures described above. This phenomenon could accelerate both reduced access to care and greater financial challenges for facilities simultaneously, underscoring the brute force nature of the Proposed Rule and the substantial risk to Medicare and Medicaid beneficiaries if the underlying hypothesis regarding resources available in the system proves to be wrong.

It is noteworthy that state minimum staffing rules take sector economics more sensibly into account. Medicaid pays for the care most LTC facility residents receive, and state Medicaid payments for LTC facility care vary widely, from a low of $170 per day to $400. Since 75-80% of facility residents are Medicaid beneficiaries, Medicaid reimbursement directly determines the resources a facility has available to hire nursing staff. Not surprisingly, states with higher Medicaid rates tend to have higher minimum staffing standards, while those with lower Medicaid rates tend to have lower staffing standards. The Proposed Rule does not recognize the reality of Medicaid funding and its impact on the ability of facilities to hire nursing staff.

Given the inflexibility of the Proposed Rule and the complexity it would add to facility operations, we urge CMS not to finalize the proposal.

Unintended Consequences

As noted above, the Proposed Rule could well have unintended consequences, including reduced access to LTC facility care, operational tradeoffs that could impact non-nursing services, deepening economic instability for facilities, and facility closures. Of particular concern to SCPC and its members is the potential impact on LTC pharmacy services and on LTC pharmacies themselves. Our comments will focus on the unintended consequences for LTC pharmacies and their secondary impact on facility residents.

The Medicare and Medicaid Pharmacy Services Requirements of Participation obligate participating LTC facilities to assure that residents receive the prescription drugs and related pharmacy services appropriate to their medical needs. LTC facilities generally contract with off-site LTC pharmacies to dispense and deliver those medications and to provide the related pharmacy services. CMS defines LTC pharmacy in regulation and lists the core services a pharmacy must provide to qualify as a LTC pharmacy in guidance.[19] One LTC pharmacy generally

[19] 42 U.S.C. § 1395i-3 (pertaining to SNFs participating in the Medicare program) and 42 U.S.C. § 1396r(b)(4)(a)(iii) (pertaining to NFs participating in the Medicaid program). Based upon these statutory requirements, CMS has promulgated extensive regulations establishing detailed requirements of participation for SNFs under Medicare and NFs under Medicaid. 42 C.F.R. §§ 483.1-483.95.

dispenses medications and provides related clinical and specialized pharmacy services for all residents in a facility.

The Proposed Rule is likely to undermine reimbursement for LTC pharmacy services. First, it is likely that the Proposed Rule will reduce facility occupancy. Fewer residents mean less beneficiary access to LTC pharmacy services. Since the economic viability of LTC pharmacies correlates closely with the economic viability of LTC facilities, LTC pharmacies already are in a precarious financial position since they too have not fully recovered from the impact of the COVID-19 pandemic. In addition, the American Rescue Plan Act of 2021 changed the methodology used to calculate drug manufacturer rebates in the Medicaid program, which in turn has precipitated substantial reductions in insulin prices across all markets. Insulin is frequently prescribed for many LTC facility residents. While SCPC and its members strongly support lower drug prices for consumers, we note that neither the 2021 change in Medicaid rebates nor the drug price negotiation provisions of the IRA account for the adverse consequences on pharmacies, particularly LTC pharmacies. The Proposed Rule would add even greater economic challenges for LTC pharmacies. These combined financial pressures risk loss of LTC pharmacy capacity, since many LTC pharmacies may be forced to limit the facilities they serve or cease operations altogether. Such an outcome would operate to the detriment of LTC facility residents and others who need LTC but live in community settings. Unintended consequences such as the adverse impact on LTC pharmacies and the patients they serve should be sufficient reason not to implement the Proposed Rule.

We also note that LTC pharmacies are at risk from the unintended consequences of the Medicare drug price negotiation provisions of the Inflation Reduction Act. Earlier this year, CMS announced the ten Part D drugs that will be subject to negotiated prices beginning January 1, 2026. Eight of these drugs are used heavily in the LTC resident population and account for a significant percentage of LTC pharmacy revenues and margins. While a thorough discussion of the likely impact of these price changes is beyond the scope of these comments, the salient point is that LTC pharmacies, which have yet recovered from the economic impact of the pandemic, face significant financial pressure from policy-driven reductions in drug prices and the financial pressure those changes place on Part D Plans. The Proposed Rule would add financial pressures from LTC facilities as they shift expenses away from prescription drugs and pharmacy services and toward nurse staffing. This likely will have unintended and potentially adverse impacts on resident access to prescription drugs and related LTC pharmacy services, which concomitantly would undermine the quality of care.

The unintended consequences of the Proposed Rule could reduce access to care, exacerbate the current financial instability of the LTC sector including both LTC facilities and LTC pharmacies, and could force resident care tradeoffs that would thwart the goal of the Proposed Rule to improve the quality of care for LTC facility residents. The risk of such unintended consequences should offer sufficient basis not to finalize the Proposed Rule.

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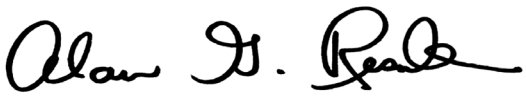
We respectfully submit that, while well-intentioned, the Proposed Rule would not accomplish its intended purpose, would threaten the economic viability of LTC facilities and LTC pharmacies, would restrict access to LTC facility care, and ultimately would undermine rather than enhance quality care for facility residents. We therefore urge CMS not to finalize the Proposed Rule.

Thank you for consideration of these comments and we welcome any questions or follow up that you may have. Please feel free to contact me at arosenbloom@seniorcarepharmacies.org or (717) 503-0516 if we can provide any additional information.

Respectfully submitted,



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