



Deregulatory Recommendations for Skilled Nursing Facilities In Response to Department of Health and Human Services Request for Information Published in the Federal Register May 14, 2025

Thank you for the opportunity to submit suggestions for deregulation on behalf of the Ohio Health Care Association (OHCA). OHCA is a statewide trade association representing long-term services and supports providers in Ohio, including skilled nursing facilities (SNFs). SNFs are regulated in a variety of ways by HHS agencies, most notably CMS.

We have a number of deregulatory proposals relating to CMS and other agency regulations or sub-regulatory guidance. They are organized by the questions in the RFI, but not necessarily by priority under each question. We appreciate your consideration of them.

If you have questions or need additional information on our suggestions, please contact me at pvanrunkle@ohca.org or 614-361-5169.

Pete Van Runkle, Executive Director

HHS Questions

What HHS regulations and/or guidance meet one or more of the following seven criteria identified in E.O. 14219? Should they be modified or repealed? What would be the impact of this change, especially the costs and savings?

- * Unconstitutional regulations and regulations that raise serious constitutional difficulties, such as exceeding the scope of the power vested in the Federal Government by the Constitution;
- * Regulations that are based on unlawful delegations of legislative power;
- * Regulations that are based on anything other than the best reading of the underlying statutory authority or prohibition;
- * Regulations that implicate matters of social, political, or economic significance that are not authorized by clear statutory authority;
- * Regulations that impose significant costs upon private parties that are not outweighed by public benefits;
- * Regulations that harm the national interest by significantly and unjustifiably impeding technological innovation, infrastructure development, disaster response, inflation reduction, research and development, economic development, energy production, land use, and foreign policy objectives; or

* Regulations that impose undue burdens on small business and impede private enterprise and entrepreneurship

1. <u>Proposal</u>: Rescind Biden Administration rule expanding civil monetary penalties (CMPs) on SNFs that exceed the statutory framework.

Regulatory reference: FY 2025 SNF payment rule, August 6, 2024 (CMS)

<u>Rationale</u>: CMS implemented the statutory instruction to implement CMPs for survey citations many years ago. Late in the Biden Administration, CMS used the annual Medicare payment rule for SNFs to expand CMPs in several ways, increasing these regulatory penalties beyond the previous, statutorily-based levels.

2. <u>Proposal</u>: Put in place specific reforms to the public-facing 5-Star Quality Rating System (5-Star) to make it more accurately reflect SNFs' quality performance. These reforms should include eliminating the red hand icon, basing overall star rating primarily on quality measures (QMs) instead of surveys, utilizing only the last 2 survey cycles, and eliminating forced distribution of ratings.

Regulatory reference: 5-Star technical users' guide (CMS)

Rationale: 5-Star's original purpose was to give consumers actionable information about SNFs to assist them in the selection process. It is the key feature of CMS's Care Compare website. Over the years, 5-Star has accrued other uses such as constructing managed care networks and establishing metrics for reimbursement. For 5-Star to achieve these goals, it must be as accurate as possible within the limitations of its data sources. Some of the policy choices CMS made when they constructed 5-Star were based more on philosophy than giving the most accurate representation of each facility's performance. Those choices should be reversed through revisions to subregulatory guidance.

The red hand icon denoting an abuse citation is excessively frightening to 5-Star users and includes citations that did not involve actual abuse and situations where the SNF did everything it was required to do and abuse occurred anyway. CMS's QMs (which measure the most important outcomes of SNF care) should be used as the first building block of 5-Star instead of survey results – data instead of opinions. Survey results are inconsistent across and even within states. The QMs are based on data from the minimum data set (MDS) assessment, which is the same everywhere. The choice to use three survey cycles was a mistake that should be reversed. Three survey cycles could encompass 6-8 years, with the oldest survey not being an accurate depiction of the SNF's performance at present. Worst of all is the forced distribution CMS chose, which arbitrarily rates twice as many facilities as one-star vs. five-star, no matter how they actually performed. The forced distribution is an artifact of using survey as the driving factor. QMs are graded against fixed standards, not comparison with other facilities. The

goal should be for all buildings to improve over time. Fixe goalposts provide a better incentive.

3. <u>Proposal</u>: Implement risk-based surveys nationwide and expand participation criteria to include 25% of the SNFs in each state.

<u>Regulatory reference</u>: <u>CMS website</u> reference to risk-based surveys (April 2024, update) (CMS)

Rationale: CMS tested risk-based surveys in 2024. This concept seeks to align the length and intensity of annual surveys with a SNF's performance on a variety of (unpublished) metrics. Risk-based surveys offer great promise for conserving federal and states resources while still meeting statutory requirements for survey frequency and content. By all accounts, the pilot was a success, as the risk-based surveys identified deficiencies when they existed but took much less time and personnel. While an argument could be made that extending risk-based surveys to all facilities would improve government efficiency, implementing the program across the country and expanding the qualifying buildings to 25% instead of 10% in the pilot program would be a big help. This burden-relieving approach should be added to the subregulatory guidance on surveys.

4. <u>Proposal</u>: Rescind Biden Administration changes to State Operations Manual Appendix PP.

Regulatory reference: QSO-25-14-NH (CMS)

<u>Rationale</u>: This late Biden Administration publication exceeds long-standing guidance on many aspects of the Medicare/Medicaid requirements of participation (ROPs) for SNFs, adding more requirements even though the text of the rules hasn't changed. The revision should be rescinded in its entirety.

5. <u>Proposal</u>: Replace the strict liability concept for certain deficiency citations where it appears in the ROPs and replace it with a non-compliance standard.

Regulatory reference: 42 CFR chapter 483, most importantly 42 CFR 483.12 (CMS)

Rationale: No other provider type regulated by CMS has a strict liability standard for citations (because a bad thing happened). Instead, they are governed by a non-compliance standard (the provider did not do something specific required by the regulations). Strict liability results in SNFs being cited and subjected to penalties when they did everything the regulations require, but something bad happened anyway. Revise 42 CFR 483.12 and analogous regulatory provisions to specify that a SNF should not be cited because abuse, neglect, misappropriation, or another negative outcome occurs if the facility has complied with the numerous specific requirements for preventing and responding to the negative outcome.

6. <u>Proposal</u>: Remove provisions categorizing citations for paperwork violations such as failure to report or not having required policies as abuse, neglect, or misappropriation if the violation did not lead to an actual negative outcome.

<u>Regulatory reference</u>: <u>State Operations Manual Appendix PP</u>, particularly F600 et seq. (CMS)

<u>Rationale</u>: CMS lists buildings as having abuse citations when no abuse has occurred, which is damaging to the provider and misleading to the public. The other tags should be characterized as what they are: reporting, policies, etc.

7. <u>Proposal</u>: Revise guidance to stop classifying SNF self-reported incidents (SRIs) as complaints.

Regulatory reference: State Operations Manual Chapter 7 (CMS)

<u>Rationale</u>: The ROPs require SNFs to report allegations or suspicions of abuse, neglect, or misappropriation to the state survey agency (SA), as well as the results of the facility's investigation. These SRIs are denominated and handled as complaints even though they are not complaints. This incorrect designation vastly inflates reported data on complaints against SNFs and costs SAs and providers the time and expense of surveys on SRIs that SNFs are required to investigate themselves.

8. <u>Proposal</u>: Remove requirement to investigate complaints against SNFs that are frivolous or repetitive.

Regulatory reference: State Operations Manual Chapter 7 (CMS)

Rationale: CMS guidance calls for SAs to investigate all complaints against SNFs and to triage them in terms of severity of the allegations. The triage process determines when the investigation will take place, not whether the complaint requires investigation. As a result, SAs and providers waste resources on investigations of frivolous complaints, complaints alleging inconsequential issues, and repeated complaints where the complainant slightly changes the allegation. In the case of SAs, this time would be better spent doing annual surveys or revisits to verify correction of deficiencies. In the case of providers, this time would be better spent providing care. The subregulatory guidance should be clarified to allow SAs not to investigate these complaints.

9. <u>Proposal</u>: Prohibit states from having more stringent standards for special focus facilities (SFFs) than CMS does and include QMs in determining SFF status.

Regulatory reference: SFF subregulatory guidance, October 21, 2022 (CMS)

Rationale: CMS created the SFF program in 1998 to identify the poorest-performing SNFs in each state (according to survey results) and require greater scrutiny of those facilities, ultimately leading to termination from Medicare/Medicaid if they do not improve. The SFF subregulatory guidance sets timeframes for improvement or termination. Given that SFF is a federal program, CMS should revise its guidance to prevent states from interfering with the federal regulatory scheme, which happened in Ohio. In addition, the criteria for designating SNFs as SFFs should include performance on QMs as well as on surveys.

10. <u>Proposal</u>: Eliminate schizophrenia audits conducted by Myers and Stauffer under contract with CMS and remove the "six-month rule" from subregulatory guidance defining an appropriate schizophrenia diagnosis.

<u>Regulatory reference</u>: <u>QSO-23-05-NH</u> and Resident Assessment Manual <u>errata sheet</u> (CMS)

<u>Rationale</u>: These audits implemented by the Biden Administration, layered on top of the already-onerous survey process, are overkill. They can result in facilities receiving significant penalties for good-faith and clinically-appropriate prescriber behavior and cause certain individuals to be denied access to long-term care. The survey process is sufficient to address residents who are being harmed by inappropriate medications. The subregulatory guidance should be rescinded and the audit program stopped. In addition, the subregulatory guidance should be revised to remove the requirement for 6 months of documentation of persistent behavior issues. It is often impossible to obtain documentation that far back for individuals newly admitted to a SNF.

11. <u>Proposal</u>: Delay the nursing staff turnover measure for SNF Value-Based Purchasing (VBP) until at the earliest FY 2028, utilizing date from FY 2023 and 2024.

Regulatory reference: Final SNF payment rule for FY 2024, August 7, 2023 (CMS)

<u>Rationale</u>: CMS adopted this measure for FY 2026 in the FY 2024 SNF payment rule. The measure looks at baseline FY 2021 and reports to FY 2022, when COVID was still having a heavy impact on SNF staffing.

What regulations should we reconsider as we look to achieve some of the policy objectives outlined in Executive Order 14212, "Establishing the President's Make America Healthy Again Commission," to focus on reversing chronic disease?

1. Proposal: Rescind requirement for SNFs to utilize enhanced barrier precautions.

<u>Regulatory reference</u>: <u>Subregulatory guidance</u> requiring SNFs to comply with EBP guidelines (CMS/CDC)

<u>Rationale</u>: Another Biden Administration initiative, the requirement for SNF personnel to wear gowns and gloves to provide care to residents with wounds or invasive medical devices, regardless of whether they have multi-drug-resistant infections, is excessive. The requirement is costly, administratively burdensome, and most importantly, negatively affects resident dignity and peace of mind.

2. Proposal: Rescind vaccination reporting requirements applicable to SNFs.

Regulatory reference: 42 CFR 483.80(g); FY 2024 SNF payment rule (August 7, 2023) (CMS/CDC)

Rationale: Originally a COVID-era requirement for SNFs to report cases and vaccination rates to the National Healthcare Safety Network (NHSN), an offshoot of CDC, the Biden Administration made it permanent and expanded it to include other respiratory infections. The ROPs never before required reporting to NHSN. The Biden Administration also made vaccination reporting part of the Quality Reporting Program (QRP), which penalizes non-compliant SNFs with a 2% Medicare rate cut. Both the ROP section and the QRP reporting requirement should be rescinded.

3. Proposal: Rescind educate-and-offer requirements for COVID-19 vaccine.

Regulatory reference: 42 CFR 483.80(d)(3) (CMS)

<u>Rationale</u>: Another holdover from COVID, the requirement for SNFs to provide periodic education to residents and employees about the COVID vaccine and offer the vaccine to them is obsolete and should be rescinded. Documenting education, offering, and responses is administratively burdensome.

4. Proposal: Rescind COVID-19 health care personnel (HCP) guidelines.

Regulatory reference: HCP guidelines, May 8, 2023 (CDC)

<u>Rationale</u>: The ROPs incorporate CDC guidelines as mandatory, and SNFs are cited for not following them. CDC has not updated the HCP guidelines to reflect current practice for two years, unlike what they did with guidance for the general public. The HCP guidelines should be repealed, making the general guidance the applicable standard for SNFs.

For more general deregulatory consideration under E.O. 14192, are there additional HHS regulations and/or guidance that:

- * Are confusing or unnecessarily complicated;
- * Require an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively;

- * Impose requirements on the wrong individual or group;
- * Carry excessive penalties;
- * Are conflicting (examples include but are not limited to conflicts between HHS and State regulations, public and private sectors);
- * Impede access to or delivery of care or services;
- * Impede efforts to innovate
- * Are obsolete; and/or
- * Otherwise interfere with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans? Should they be modified or repealed?

What would be the impact of this change, especially the costs and savings?

1. <u>Proposal</u>: Rescind Biden Administration rule and related subregulatory guidance on ownership/additional disclosable party disclosure by SNFs.

<u>Regulatory reference</u>: <u>Final reporting rule</u>, November 23, 2023, and <u>subregulatory guidance</u> (CMS)

Rationale: This Biden Administration rule and subregulatory guidance that elaborates on the rule's requirements place enormous new reporting burdens on SNFs and additional processing responsibilities on the Medicare administrative contractors that review Medicare revalidation applications. The rule implemented provisions from the Affordable Care Act that were unused throughout the remainder of the Obama Administration and the first Trump Administration. Both the rule and subregulatory guidance should be rescinded while the statute is reviewed for potential repeal or amendment.

2. <u>Proposal</u>: Rescind Biden Administration rule imposing payment transparency requirements on states and SNFs.

Regulatory reference: Minimum staffing rule, May 10, 2024 (CMS)

<u>Rationale</u>: Another late Biden Administration regulatory move, this provision landed in an unrelated rule on minimum staffing in SNFs. The minimum staffing standards were vacated by two federal district courts for exceeding CMS's statutory authority, but the payment transparency requirements were not. They should be rescinded because they create extensive new reporting burdens for both SNFs and states.

3. <u>Proposal</u>: Replace Biden Administration Medicaid access rule with a requirement that states demonstrate to CMS that their existing rates for all Medicaid services are sufficient to provide access to quality care, using a process and criteria similar to those in the access rule for rate cuts greater than 4%.

Regulatory reference: Final Medicaid access rule, May 10, 2024 (CMS)

Rationale: The Medicaid access rule was another late Biden Administration regulatory effort. This rule included a variety of problematic provisions but did not address the primary purpose of 42 USC 1396 (a)(30)(A), which requires Medicaid rates that are sufficient "to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." The rule does require enhanced CMS review of state proposals to cut provider rates by 4% or more. The access rule as it currently exists should be replaced with a requirement that states demonstrate to CMS that their existing rates for all Medicaid services are sufficient to provide access to quality services, using a process similar to the access rule requirements for rate cuts greater than 4%.

4. <u>Proposal</u>: Revise the requirements for the SNF Payroll-Based Journal (PBJ) to allow a correction period for PBJ data and count all time worked.

Regulatory reference: PBJ policy manual (CMS)

Rationale: CMS developed the PBJ system to obtain data measuring staffing levels in SNFs. All SNFs in the country must report PBJ data quarterly to CMS. The data are used for a variety of purposes, most notably to determine the staffing star in 5-Star and to inform surveyors inspecting SNFs about staffing levels. PBJ has two major flaws that distort the data and can result in significant negative consequences for SNFs. First, there is no period for correcting errors or omissions in reported data. Other data submission requirements typically allow a correction period. Second, CMS mandates that SNFs underreport actual hours worked by limiting salaried employees to 40 hours and requiring deduction of a 30-minute meal period whether taken or not. These two flaws should be corrected through revisions to the subregulatory guidance.

5. <u>Proposal</u>: Clarify that the requirement for written notice of discharge from a SNF to ensure does not apply if the discharge is voluntary on the part of the resident.

Regulatory reference: 42 CFR 483.15(c)(3) (CMS)

Rationale: Recent changes to State Operations Manual Appendix PP removed language distinguishing between resident-initiated and facility-initiated discharges and specifying that the requirements for notifying residents and the state ombudsman did not apply to resident-initiated discharges. This change to the subregulatory guidance increases useless paperwork and opens facilities up to citations. However, the revised guidance conforms to the current regulatory text, which does not distinguish between voluntary and involuntary discharges. The rule should be revised to limit the notice requirements to involuntary discharges.

6. <u>Proposal</u>: Amend sub-regulatory guidance on the physician certification statement for SNF care to ensure the Medicare General Information, Eligibility and Entitlement Manual is consistent with the Medicare Program Integrity Manual.

<u>Regulatory reference</u>: <u>Medicare General Information, Eligibility and Entitlement Manual;</u> Medicare Program Integrity Manual (CMS)

Rationale: Medicare denies SNF claims when the provider doesn't explicitly state that the patient needs continuation services in a SNF setting. However, there is no prescribed form or statement that CMS requires physicians to use. SNFs are supposed to be able to supplement the certification with medical records. But initial reviewers deny, we have to appeal, and then 5 years later they overturn in ALJ. It is administratively burdensome, on both sides. The Medicare Program Integrity Manual chapter 6, section 6.3 states that no specific procedures or forms are required for certification and recertification statements and the provider may adopt any method that permits verification. However, in the Medicare General Information, Eligibility and Entitlement Manual Chapter 4 CMS prescribes more specific guidance on certification statements for SNF services. This has led to confusion and erroneous denials by the MACs. CMS should update the General Information Manual to be consistent with the Program Integrity Manual.

What alternative approaches could be taken to achieve or accomplish the same goal with a lesser burden? For example, are there less burdensome approaches that are used by other entities such as State governments or private companies that could be adopted by HHS to achieve its goal with less burdensome requirements? What would be the impact on costs and savings?

Covered in responses to other questions.

Are there HHS regulations, guidance, or reporting requirements that are rooted in outdated technology? Can new technologies be leveraged to allow for rescinding or updating these policies? What are the cost implications?

1. <u>Proposal</u>: Withdraw Biden Administration proposal to amend HIPAA cybersecurity regulations.

<u>Regulatory reference</u>: <u>HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information</u> (OCR)

<u>Rationale</u>: The Biden Administration's proposed HIPAA cybersecurity rule, which has not been finalized by the Trump Administration, would be extremely burdensome and costly to health care providers. The rule would mandate numerous activities that previously were considerations that providers could adopt or not depending on their own circumstances. Instead, the proposal would create a one-size-fits-all set of requirements

that do not meaningfully take into consideration the size, complexity, and sophistication of different health care providers across the country and the risk of disclosure of protected health information. For large providers such as urban hospital systems, compliance with the proposed requirements would be extremely burdensome. For small providers who do not have information technology departments familiar with the concepts in the proposed rule, the cost of compliance could put them out of business. OCR should withdraw the proposal and, if updating the rule is deemed necessary, convene a stakeholder process to find solutions that appropriately balance information security with compliance burdens for different types and sizes of providers.

Are there HHS regulations, guidance, or reporting requirements that are inconsistent with Executive Orders 14151, 14154, 14168, and 14213 or others issued by the President? Should they be modified or rescinded to make them consistent?

1. <u>Proposal</u>: Rescind the rule requirement for SNFs to designate an infection preventionist.

Regulatory reference: 42 CFR 483.80(b) (CMS)

Rationale: The ROPs require every SNF to have an effective infection control program that meets prescribed standards. SNFs are cited for deficiencies and potentially subjected to penalties if they do not follow the standards, especially if infections result from the failures. It is not necessary for the federal government to create a new role in a SNF – the infection preventionist – and dictate their qualifications, responsibilities, and work hours. It is sufficient to mandate that the SNF designate someone to be responsible for the infection control program and to judge the outcomes: whether infection control procedures are followed and infections prevented.

2. Proposal: Rescind SNF facility assessment requirement.

Regulatory reference: Minimum staffing rule, May 10, 2024 (CMS)

Rationale: As with item 3 above, this requirement was included in the minimum staffing rule but not addressed by the court decision vacating the staffing standards. Also like item 3, this requirement should be rescinded. Facility assessments are an unnecessary administrative burden. Each SNF is required to follow a detailed administrative process to develop a plan for staffing the building. SNFs already are required to provide sufficient staffing to meet the care needs of their residents. Mandating the process that every facility must follow to determine staffing needs, complete with who must be involved and specific factors that must be considered, results in more paperwork and takes facility personnel away from providing care.

3. Proposal: Remove the requirement for a certified dietary manager (CDM).

Regulatory reference: 42 CFR 483.60(a)(2)(E) (CMS)

<u>Rationale</u>: This requirement is burdensome for SNFs, particularly in rural areas, as CDMs are hard to come by. CMS provided temporary relief during COVID, but that relief has expired. It should be updated and made permanent. The rule should be revised to read, "Has 2 or more years of experience working in food and nutrition services in a nursing facility setting and has completed a course of study in food safety and management that includes topics integral to managing dietary operations including, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving;"

4. <u>Proposal</u>: Remove the long-term care experience requirement to lead a nurse aide training and competency evaluation program (NATCEP).

Regulatory reference: 42 CFR 483.152(a)(5)(i) (CMS)

Rationale: The regulation requires a NATCEP course to be under the general supervision of a RN who has two years of experience, one of which must have been in long-term care. This overly prescriptive requirement makes it difficult to find primary instructors for NATCEPs, especially in career centers and community colleges, at a time when all efforts need to be directed to expanding the caregiving workforce to respond to the rapidly growing senior population. NATCEP involves training nurse aides, not nurses, and has a specific, mandated curriculum. The long-term care experience requirement should be removed from the regulation to expand the pool of potential NATCEP instructors.

"The training of nurse aides must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care facility services;"