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

July 14, 2025

VIA ELECTRONIC SUBMISSION

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Health and Human Services' Request for Information: Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again, Docket No. 2025-08384.

Dear Secretary Kennedy:

On May 14, 2025, the United States Department of Health and Human Services (HHS) published a request for information on the deregulation of its rules and policies to increase efficiency and reduce burden on the healthcare system.[1] This letter constitutes the Office of Advocacy's (Advocacy) public comments to the agency's solicitation which identify rules for consideration to be revised or repealed that are of interest to affected small entities.

Advocacy supports HHS' efforts to identify opportunities to reduce regulatory burdens throughout all sectors of the economy. The Regulatory Flexibility Act (RFA)[2] directs Advocacy to work with federal agencies to minimize the economic impacts of regulations on small entities. HHS' request for information aligns with Advocacy's mission and will help identify deregulatory opportunities designed to provide regulatory relief to small businesses. Advocacy encourages HHS to prioritize responses on any deregulatory ideas proposed by small entities.

I. Background

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

[1] 90 Fed. Reg. 20478 (May 14, 2025).
[2] Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

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 RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] 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.[4] If a rule is not expected to have a significant economic impact on a substantial number of small entities, agencies may certify it as such and submit a statement of the factual basis for such a determination that adequately supports its certification.[5]

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[6] The agency must include a response to these written 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.[7]

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."[8]

B. HHS' Request for Information (RFI)

HHS is seeking "to address regulations that are unnecessary, inconsistent with the law, overly burdensome, outdated, out of alignment with current Executive Orders (EO), or are otherwise unsound." Specifically, HHS is seeking input from a full range of stakeholders, including health care providers and suppliers; state, local, territorial, and Tribal governments; health and drug plans and payers; human services agencies; public health agencies; community and faith-based organizations; long term care facilities; pharmacist and pharmacy associations; health and human services professional organizations; farmers and food producers; patient advocacy groups and organizations; people living with chronic disease and their family members; researchers; health technology organizations; and other businesses.

II. Advocacy's Small Business Concerns

The mission of Advocacy is to give small entities a voice in the regulatory process. To accomplish this goal, Advocacy regularly meets with small entities to discuss the regulations impacting their daily business practices. During the first 100 days of President Trump's

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

administration, Advocacy held 150 meetings with groups representing small businesses. Additionally, Advocacy held roundtables to solicit small entity input on the DOJ, FTC, DOI, and DOT deregulatory efforts. Further, 16 small business manufacturing roundtables were held in nine states, allowing Advocacy to connect with more than 175 small business participants overall.[9] In order to provide HHS with small entity health care perspectives on its RFI for any deregulatory matters ripe for revision or repeal, Advocacy hosted a roundtable for interested small business stakeholders on June 17, 2025. The results of that roundtable and input gathered from other Advocacy outreach efforts to the food, drug, and health care community form the basis for this letter.

To reduce regulatory burdens on small entities, it is important to examine the totality of the regulatory process. As a result of our conversations with small entities, Advocacy's comments contain both general suggestions to improve the regulatory process as well as specific rules which should be targeted for deregulatory efforts.

III. Recommendations to Improve the Regulatory Process

A. Federal Agencies Should Consider the Direct and Indirect Impacts of their Rules on Small Entities.

To understand the true scope of a rule's effects on small entities, federal agencies should consider a broader view of all relevant impacts. For example, the reasonably foreseeable impacts of a rule on small entities could include restrictions on other entities they do business with. A regulation on a supplier, for example, may not only impact that business, but all of the businesses that purchase the supplier's products as well.

IV. HHS Should Examine the Paperwork Burdens it Currently Impose on Small Entities.

Small entities often face a deluge of forms from federal agencies that they must file. The Paperwork Reduction Act (PRA) is meant to minimize the paperwork burden on the public and state, local, and tribal governments[10] and requires the OMB to review and approve agency collections of information.[11] Even with the PRA, the OMB currently has more than 10,900 outstanding information collections requiring more than 11.6 billion hours to complete at an annual cost of almost $203 billion.[12] As of July 13, 2025, HHS and its subagencies have more

[9] U.S. Small Bus. Admin, Off. of Advocacy, *First 100 Days: Cutting Red Tape for Small Businesses* (Apr. 30, 2025), https://advocacy.sba.gov/2025/04/30/first-100-days-cutting-red-tape-for-small-business/.
[10] *See* Paperwork Reduction Act of 1995, 44 U.S.C. § 3501(1).
[11] *See* 44 U.S.C. § 3504(c).
[12] *See* Off. of Info. & Regul. Aff., *Inventory of Currently Approved Information Collections July 13, 2025,* https://www.reginfo.gov/public/do/PRAReport?operation=11 (last accessed July 13, 2025).

than 1,100 active collections of information, resulting in more than 1.7 billion annual burden hours and more than $2.2 billion in annual costs, according to OMB.[13]

Small entities impacted by multiple federal information collections have expressed concerns that they must build significant resources and spend a considerable amount of time on their business plans to ensure forms are completed in a proper and timely manner. Streamlining forms and clarifying the steps small businesses need to take to comply with federal information collection regulations will reduce one of the most common regulatory burdens faced by small entities. Additionally, all agencies should strive to ensure their information collections are not duplicative of other federal agencies. Advocacy encourages all agencies, including HHS, to thoroughly review and streamline existing forms for ease of use for small entities and reduce duplicative paperwork burdens.

V. Specific Deregulatory Actions for Consideration by HHS

Section 601 of the RFA defines small entities as including small businesses, nonprofit organizations that are independently owned, operated, and not dominant in its field, and small government jurisdictions with a population of less than fifty thousand. For regulatory purposes, the Centers for Medicare and Medicaid Services (CMS) interprets this small entity definition as including most hospitals and most other health care providers and suppliers, as that term is used in the RFA. CMS generally concludes that the majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business.[14] As such, HHS typically treats these businesses as all being small entities for RFA purposes. Therefore, Advocacy sought to discuss this RFI with stakeholders that represent a wide-ranging sample of small entities in the health care and food sectors regulated by HHS.

The following is a summary of deregulatory issues Advocacy has discussed with those small health care and food industry-related businesses. The rules in this summary are not comprehensive, as Advocacy speaks with small businesses in various forums to ensure we capture issues that are important to them. Different small businesses in different industries may have opposing viewpoints on rules. Where there is a clear consensus among small businesses, Advocacy advances specific recommendations. In cases where there is no clear consensus, Advocacy presents both sides of the argument and encourages careful agency review and information-gathering via small business outreach. As the voice of small business, and in an effort to inform HHS about real views of small entity stakeholders, some recommendations are based on direct feedback from stakeholders rather than Advocacy's thoroughly analyzed conclusion. In some instances, Advocacy shared feedback verbatim to capture small businesses'

[13] *See* Off. of Info. & Regul. Aff., *Inventory of Currently Approved Information Collections*, https://www.reginfo.gov/public/do/PRAMain (choose "Department of Health and Human Services" from dropdown under "Current Inventory"; then click "Submit") (last accessed July 13, 2025).
[14] *See e.g.,* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes, 90 Fed. Reg. 18002, 18487 (Apr. 30, 2025).

specific concerns and impacts. We plan to be in constant communication with the HHS and raise additional deregulatory issues as they arise in the future.

A. Centers for Medicare & Medicaid Services (CMS)

1. Home Health, Skilled Nursing Facility and Long-Term Care Facility Deregulatory Issues

a) Medicaid Program; Ensuring Access to Medicaid Services (CMS-2442-F).[15]

Many home care stakeholders appreciate the policy goal of ensuring that eligible individuals have access to Medicaid services. Some, however, voiced concern to Advocacy about the impacts associated with this regulation. This rule requires that at least 80 percent of all Medicaid payments for certain Home and Community-Based Services (HCBS) must be allocated to compensate direct care workers (homemaker services, home health aide services, and personal care services). The other 20 percent of payments can be allocated for administrative, overhead, and marketing costs. Small home care agencies have reached out to Advocacy noting that the 20 percent limit for administrative costs is too little to sustain their companies. Further, even for those agencies that could meet the thresholds, they would nonetheless incur record keeping costs to demonstration compliance, meaning that such a requirement levies an administrative burden on every agency in the market. As a result of these impacts, small home care agencies could be forced out of the market. Stakeholders suggest that CMS consider alternative approaches, such as a scaling threshold based on provider size, rural/urban status, risk of closure, and/or an exceptions process for small providers.

State Medicaid representatives are also supportive of the rule's policy to improve Medicaid members access, support, and care. But they report having concerns with the costs for upgrading IT systems, despite the rule's proposal that CMS would contribute 90 percent of the cost to systems upgrades. State stakeholders suggest that a finalized rule will cost significantly more than CMS has estimated and will take more time to implement beyond CMS' proposed one- to four-year time frame for implementation of the various components of the rule. These stakeholders are also concerned about the paperwork burden associated with the proposed rule as it contains significant new reporting and evaluation requirements.

Advocacy recommends this rule be withdrawn and that small entity outreach be conducted to determine if any other alternatives exist that would reduce the impacts of this rule on small businesses.

[15] 89 Fed. Reg. 40542 (May 10, 2024).

b) Civil Monetary Penalty Policy Improvements – 42 CFR § 488.

CMS has the authority to impose civil monetary penalties (CMPs) in healthcare settings that accept federal Medicare and Medicaid payment, including hospitals, home health, hospice, and nursing homes. A CMP is a monetary penalty the Centers for Medicare & Medicaid Services (CMS) may impose against nursing homes for either the number of days or for each instance a nursing home is not in substantial compliance with one or more Medicare and Medicaid participation requirements for long-term care facilities. A portion of CMPs collected from nursing homes are returned to the states in which CMPs are imposed. State CMP funds may be reinvested to support activities that benefit nursing home residents and that protect or improve their quality of care or quality of life. More than $200 million of CMPs were imposed by CMS on nursing homes annually for the past two years (2022 and 2023).

Stakeholders believe that CMS' imposition of CMPs on health care providers varies and disproportionately imposes penalties on nursing homes as compared to other health care settings. Stakeholders suggest that there is little evidence that the imposition of CMPs on nursing homes improves patient quality of care or outcome. Further, CMP notices are often issued too late to serve the stated goal. This means facilities may be punished with CMPs long after they have corrected the deficient practice(s). Most importantly, CMPs divert funds from care and services for residents. Lastly, an additional problem exists when the State Survey Agency delays processing survey information that results in providers accumulating excessive per-day CMP fines, which significantly impacts their revenue.[16]

Nursing home stakeholders recommend the following actions be taken by CMS on the CMP issue:

- Apply CMPs only in cases where the facility fails to submit a plan of correction and/or achieve substantial compliance.
- Allow CMP fines to be used to correct deficient practice(s).
- Establish standards related to survey timeline.
- Eliminate delayed CMP Notifications.
- Establish a State Performance Standards System (SPSS) measure.
- Eliminate the Use of CMPs for Self-Reported Incidents

c) Civil monetary penalties (CMPs) provided for in the FY 2025 Skilled Nursing Facilities Prospective Payment System (PPS) rule should be rescinded.

The reduction of punitive financial penalties will allow nursing homes to better allocate funds to workforce investments and facility improvements. The Social Security Act prohibits facilities from conducting their own Nurse Aide Training and Competency Evaluation Programs (NATCP) for two years if they receive a CMP of more than $12,924. The CMP rule allows for

[16] Current federal regulations require that the State Survey Agency (SSA) conduct a survey of each ICF/IID no later than 15 months after the last day of the previous survey.

the imposition of penalties for per instance and per day fines, which could result in more facilities losing the ability to conduct NATCP programs. Nursing home stakeholders believe that sections of the rule constitute duplicative enforcement. Examples of duplicative enforcement include provisions on CMPs for more than one area of noncompliance and the three-standard-survey lookback period.

Stakeholders recommend that CMS rescind these CMP provisions or make the following recommended revisions:

- Apply CMPs only in cases where the facility fails to submit a plan of correction and/or achieve substantial compliance.
- Allow CMP fines to be used to correct deficient practice(s).
- Establish standards related to survey timeline.
- Eliminate delayed CMP Notifications.
- Establish a State Performance Standards System (SPSS) measure.
- Eliminate the Use of CMPs for Self-Reported Incidents.

d) Discontinue mandatory National Health Safety Network (NHSN) reporting for long-term care facilities and allow voluntary reporting.

Nursing home stakeholders suggest that because the COVID-19 public health emergency has ended, the required weekly reporting on the NHSN platform is no longer necessary. For example, relevant COVID-19 reporting has been incorporated into other systems and programs. Resident level vaccination status includes COVID-19 and influenza and is reported via the Minimum Data Set (MDS), the standardized assessment tool for nursing homes. Respiratory illnesses are reported to many local public health departments. Also, the misalignment between NHSN reporting definitions and ICD-10 coding standards[17] creates inconsistencies and inefficiencies in data reporting. Mandatory NHSN reporting results in duplication of data, causing additional and unnecessary reporting burdens for facilities and should be repealed.

The Centers for Disease and Control Information Collection Request (ICR) for the National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities[18] indicates that the total paperwork collection burden is estimated at 1.7 million hours and has a burden to the public of $102 million per year and a burden to the federal government of $42 million. Advocacy calculates that $28 million is burden of long-term healthcare facilities, with the rest coming from hospitals and dialysis centers.

[17] ICD-10 refers to the International Classification of Diseases and is used by CMS to code and classify them.
[18] Off. of Info. & Regul. Aff., *ICR – OIRA Conclusion of National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities,* https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202502-0920-015 (last accessed July 14, 2025).

e) Remove or modify the 42 CFR § 483.71 Facility Assessment Regulatory Requirement and all guidance associated with the requirement.

Stakeholders suggest that CMS should repeal the § 483.71 Facility Assessment requirement because it has little impact on resident care as compared to the administrative regulatory burden it imposes. Stakeholders believe that the removal of this provision will eliminate unnecessary paperwork burden, resulting in decreased costs to nursing homes.

f) Improve 42 CFR § 488.431 Informal Dispute Resolution (IDR) and § 488.431 Independent Informal Dispute Resolution (IIDR) processes for compliance and fairness.

Nursing home stakeholders suggest the IDR and IIDR processes should be revised to include regulatory clarifications and to adjust timeframes to improve efficiency, transparency, and consistency. IDR and IIDR processes should align with a shorter, such as 60-day, resolution timeframe, which would reduce burdens on facilities by expediting decisions, especially where CMPs are involved. Stakeholders believe that preventing premature uploading of survey results to the CASPER system[19] until dispute resolution would ensure accurate public reporting and minimize reputational and financial impacts on facilities. Also, they recommend that States and CMS should provide facilities with written rationales for final decisions. This would enhance clarity, support accountability, and reduce confusion surrounding disagreement with IDR or IIDR recommendations. Lastly, CMS should improve knowledge requirements for IDR reviewers which would engender trust in the decision-making process.

g) Modify 42 CFR § 483.60 food and nutritional services experience requirements to increase availability of Directors of Food and Nutritional Services.

CMS added to the requirements for the Director of Food and Nutrition Services position at § 483.60(a)(2)(E) as part of the FY 2023 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) rule.[20] The rule would allow a candidate for the Director of Food and Nutrition Services to qualify for employment if they have two or more years of experience in the position of Director of Food and Nutrition Services in a nursing facility setting and have completed a course of study in food safety and management. Stakeholders believe this provision should be expanded to recognize relevant work experience as a qualification. This would help facilities who are struggling to find qualified personnel in food and nutrition services.

Stakeholders recommend that CMS modify § 483.60 as follows: "Has 2 or more years of experience working in food and nutrition services in a nursing facility setting or other healthcare setting and has completed a course of study in food safety and management that includes topics

[19] CMS uses the Quality Improvement and Evaluation System (QIES) as its national reporting database. CASPER (Certification and Survey Provider Enhanced Reports) is part of the QIES.
[20] 87 Fed. Reg. 47502 (Aug. 3, 2022).

integral to managing dietary operations including, but not limited to, foodborne illness, sanitation procedures, and food purchasing/receiving."

h) Medicaid Home and Community-Based (HCBS) Settings Rule

In 2014, CMS issued a rule commonly referred to as the Home and Community-Based Settings (HCBS) rule.[21] The rule required that every state ensure that services delivered to seniors and people with disabilities living in the community, outside of institutions, meet minimum standards for integration, access to community life, choice, autonomy, and other consumer protections. Within the rule, CMS provided guidance that some settings, called "presumptively institutional settings," may have institutional characteristics. If these settings wished to receive Medicaid HCBS funding, they had to prove that they could overcome that presumption and meet all other requirements of the rule. This process is called "heightened scrutiny." Heightened scrutiny is how the federal government makes sure Medicaid HCBS funds only go to settings that are truly community-based, and not to institutional settings which are funded under a different Medicaid program.

According to small home health stakeholders, this language is too restrictive and can easily eliminate many important resident-centered options for seniors and people with disabilities. Thus, it prejudges settings including assisted living units in continuing care retirement communities, Alzheimer's care facilities, and multilevel campuses as being institutional. Such a presumption increases the risk of disqualification from the Medicaid program and deters investment in residential care facilities willing to serve Medicaid beneficiaries, which already are in short supply in most states.

Stakeholders recommend that CMS rescind the following parts of 42 CFR:

- Part 441 - Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.
- § 441.301 - Contents of request for a waiver (b)(4)(vi)(F)(5)(v).
- § 441.530 - Duration, extension, and amendment of a waiver (a)(1)(vi)(F)(2)(v).
- § 441.710 - § 441.710 State plan home and community-based services under section 1915(i)(1) of the Act (a)(1)(vi)(F)(2)(v).

i) Surveying Intermediate Care Facilities.

Home health stakeholders told Advocacy that there are over 5,300 intellectual or developmental disabilities (ID/DD) residences, or Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) serving more than 56,000 residents in the U.S. Virtually all funding for ID/DD residents is covered under Medicaid. Current federal regulations require that the State Survey Agency must conduct a survey of each ICF/IID facility no later than 15 months after the last day of the previous survey. In contrast, hospitals, home health, and hospice settings follow a three-year survey cycle.

[21] 79 Fed. Reg. 2948 (Jan. 16, 2014).

ICFs consistently meeting compliance and quality standards should not be subjected to frequent surveys due to ongoing demonstrated compliance. The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) propose a change to how often ICFs are surveyed based on performance. Those ICFs that perform better on the survey would be surveyed less often (once every 36 months) and others would be monitored more closely. The aim is to optimize resource allocation, reduce the administrative burden on facilities that provide nominal care, and align with CMS and State Survey Agency capacity while maintaining the quality and safety of resident care. This would bring ICFs more in line with the three-year survey cycle available for hospitals, home health, and hospice settings.

According to HHS' Information Collection Request (ICR) for ICF/IID Survey Report Form and Supporting Regulations, this survey costs covered entities $1.3 million per year.[22] According to Advocacy's calculations, decreasing reporting requirements to every three years as requested by the stakeholders would drop costs by 58% or $775,000 annually.

j) Respiratory Illness Reporting Requirements.

As part of the Calendar Year 2025 Home Health Prospective Payment System Rate Update,[23] CMS released new acute respiratory illness reporting requirements for nursing homes, which replaced the requirements at 42 CFR § 483.80 (g). These requirements added data reporting elements, including facility census, resident vaccination status, confirmed resident cases of COVID-19, RSV,[24] influenza, and hospitalized residents with these conditions. CMS estimated that these new requirements would impose $12.6 million in reporting burden on the public.

Nursing home stakeholders suggest that, because the COVID-19 public health emergency has ended, the required weekly reporting on the NHSN[25] platform is no longer necessary and relevant COVID-19 reporting has been incorporated into other systems and programs. Resident level vaccination status includes COVID-19 and influenza and is reported via Minimum Data Set (MDS), the standardized assessment tool for nursing homes. Respiratory illnesses are reported to many local public health departments. This redundant reporting results in duplication of data, causing additional reporting burdens for facilities. Also, the misalignment between NHSN reporting definitions and ICD-10 coding standards creates inconsistencies and inefficiencies in data reporting. They recommend discontinuing the mandatory NHSN reporting and allowing for voluntary reporting.

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[22] Off. of Info. & Regul. Aff., *ICR – OIRA Conclusion of ICF/IID Survey Report Form (CMS-3070G-I) and Supporting Regulations*, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202111-0938-002 (last accessed July 14, 2025).
[23] 89 Fed. Reg. 55312 (July 3, 2024).
[24] Respiratory syncytial virus (RSV).
[25] National Health Safety Network.

k) Payroll Based Journal Reporting.

The Affordable Care Act (ACA) requires nursing homes to electronically submit direct care staffing information (including agency and contract staff) based on payroll and other auditable data. Payroll-Based Journal (PBJ) was created by CMS as a method to collect the staffing data from nursing home providers. CMS publishes the data, combined with census information, to the public, reflecting the level of staffing in each nursing home, as well as employee turnover and tenure. PBJ data is also used to calculate five-star ratings[26] intended to inform consumers of the quality of nursing home care.

Stakeholders reported to Advocacy that CMS' PBJ policies are overly complex, inconsistent, and detract from providing a full picture of facility staffing information to interested persons, including consumers, insurers, and regulators. At present, PBJ policy does not allow providers to submit corrected or missing data for any reason, even when there are unexpected technical issues with the report. Facilities that inadvertently miss the quarterly deadline for submitting staffing data receive the lowest possible score for the corresponding staff turnover measures. Facilities that fail a PBJ audit are faced with a similar reduction in score.

Home care stakeholders believe that the scheduled adoption of PBJ-based measures into the Medicare Skilled Nursing Facility (SNF) Value based Purchasing Program in FY 2026[27] will allow for corrected PBJ data. This will help ensure more facilities have their Medicare reimbursement tied to accurate staffing levels and turnover. The Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) Reconsideration policy and process finalized in the FY 2016 SNF Prospective Payment System[28] provided a reasonable process for nursing facilities to follow and should be used as a model for PBJ reporting. They recommend CMS modify sections of the CMS Electronic Staffing Data Submission Payroll-Based Journal Long-Term Care Facility Policy Manual to establish review and reconsideration processes for nursing homes. CMS should also provide facilities with a preview report, similar to the 1750D PBJ Staffing Data Report, after the final submission is complete for the quarter. This report should flag areas of potential concern and facilities should be provided with at least 14 business days to review and correct the data so that this information, available to residents and families, is accurate and complete. Lastly, CMS should provide facilities with a reconsideration and appeal process like the SNF QRP Reconsideration policy.

[26] Ctr. For Medicare & Medicaid Serv., *Five-Star Quality Rating System*, https://www.cms.gov/medicare/health-safety-standards/certification-compliance/five-star-quality-rating-system (last updated July 10, 2025).
[27] 90 Fed. Reg. 18590 (Apr. 30, 2025).
[28] 80 Fed. Reg. 46390 (Aug. 4, 2015).

l) Rescind the collection and reporting of the Outcome and Assessment Information Set (OASIS) final rule on patients regardless of insurance payers.[29]

Home health representatives request that CMS rescind its decision to lift the suspension of OASIS home health data collection for all insurance payers beginning on July 1, 2025. Home health agencies will need to collect and submit OASIS data for a broader range of patients, including those with non-Medicare/non-Medicaid payer sources and those who self-pay. CMS expects to use this all-payer data to gain a better understanding of the overall quality of care provided by Medicare-certified home health agencies to the patients they serve, regardless of payer source. Stakeholders believe that this decision will result in increased direct and opportunity costs on home health providers as they do not receive any additional reimbursement from payers for the expanded data collection. They also believe that the rule's requirements will disproportionately impact rural providers who face extensive travel to serve patients in underserved areas. The regulation's impact data shows that the regulatory changes will increase the number of assessments providers complete at each timepoint by 30 percent in both estimated hourly burden and clinical costs. They recommend that CMS dataset collection and reporting should be limited to patients for whom the home health provider is receiving payments from Medicare and/or Medicaid. According to the rule, restricting the reporting requirements to Medicare and Medicaid beneficiaries would reduce the total burden by $267 million.

m) Revise regulations for those who may conduct face-to-face encounters and certify patients for home health services to align with the CARES Act provisions.

The 2020 CARES Act[30] included a provision on Improving Care Planning for Medicare Home Health Services Act,[31] which expanded the authority of non-physician practitioners (NPPs), including nurse practitioners, physician assistants, and clinical nurse specialists, to certify eligibility and issue orders for Medicare home health services. Days after the CARES Act was signed into law, CMS published an interim final rule[32] with comment which included regulatory revisions to 42 CFR § 424.22 granting NPPs the authority to certify and order home health services. CMS has yet to issue conforming regulations to reflect statutory flexibility on who may conduct the face-to-face encounter. For example, § 424.22(a)(v)(C) limits the face-to-face encounter to the certifying physician or practitioner for patients admitted from the community. Stakeholders suggest that this provision, and §§ 424.22 and 484.4 requiring NPP collaboration with physicians, contradicts the CARES Act's flexibilities on face-to-face encounters and they should be aligned.

[29] 87 Fed. Reg. 66790 (Nov. 4, 2022).
[30] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116–136 (2020).
[31] Home Health Care Planning Improvement Act of 2015, S. 578, 114th Cong. (2015).
[32] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 90 Fed. Reg. 19230 (Apr. 6, 2020).

n) CMS should allow therapists to perform initial and comprehensive assessments in all therapy cases.

Home health agencies have long advocated for regulatory changes that would allow rehabilitation therapists to perform the initial and comprehensive assessments for all patients when therapy is ordered at the start of care. During the COVID-19 public health emergency, CMS waived requirements outlined in § 484.55(a)(2) and § 484.55(b)(3), thereby allowing rehabilitation skilled professionals to perform the initial and comprehensive assessments when only therapy services were ordered, and nursing services were not required. Home health stakeholders ask CMS to make an existing regulatory modification permanent by amending § 484.55(a)(2) and § 484.55(b)(2) to allow physical therapists (PTs), speech-language pathologists (SLPS), and occupational therapist (OTs), as permitted by statute, to conduct initial and comprehensive assessments whenever therapy services are ordered.

2. Hospital Deregulatory Issues

a) Eliminate or extend the 96-hour average length of stay condition of participation (CoPs) and remove the 96-hour physician certification CoP for critical access hospitals.

Rural health stakeholders told Advocacy that annual lengths of stay and certification requirements are too prohibitive as rural hospitals need flexibility to treat patients as clinically appropriate in a local setting, while adjusting to larger system fluctuations like infectious disease surges and delays in post-acute placement. They believe that this can be accomplished were CMS to eliminate or extend the 96-hour average stay CoP and remove the 96-hour physician certification CoP for critical access hospitals.

b) Allow direct admission to rural hospital swing beds for Medicare patients who do not require acute care but do meet skilled nursing facility requirements at 42 C.F.R. § 409.31.

Rural Medicare beneficiaries would benefit from a direct admission to swing bed care when showing signs of declining health without waiting to deteriorate further, which often results in a costly inpatient admission. This would achieve savings for providers, HHS, and beneficiaries, while supporting patient access to quality care.

c) Remove the 3-day rural hospital stay provision at 42 C.F.R § 409.30 prior to Medicare coverage of a skilled nursing facility stay.

When Medicare was enacted in 1965, it limited coverage in a skilled nursing facility (SNF) under Part A to beneficiaries who had been inpatients in an acute care hospital for at least three consecutive days before their discharge to a SNF.[33] Removing this provision would allow

[33] 42 U.S.C. §1395x(i); §409.30(a)(1).

strained rural hospitals to free up space for other patients and benefit Medicare beneficiaries by allowing transfer to an appropriate facility sooner.

d) Extend the current site neutral payment policy exemption to Medicare-Dependent Hospitals.

Medicare site-neutral payment policies apply to off-campus hospital outpatient departments established after the date for the enactment of the Bipartisan Budget Act of 2015. Rural Sole Community Hospitals (SCHs) are exempted. Rural health stakeholders urge CMS to allow rural Medicare-Dependent Hospitals (MDHs) to be afforded the same exemption from the burdensome site-neutral policies, as MDHs may see even higher patient volumes because they serve as the only point of access to care for their communities.

e) Eliminate mandatory Centers for Medicare and Medicaid Innovation (CMMI) models.

The Center for Medicare and Medicaid Innovation (CMMI), also known as the Innovation Center, was authorized under the ACA to design, implement, and test new health care payment models. Its goal is to address rising costs, improve quality of care, and reduce inefficient spending for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. Rural health care stakeholders urge elimination of recently created mandatory participation requirements under CMMI models for the Transforming Episode Accountability Model (TEAM), Increasing Organ Transplant Access Model (IOTA), and Episode-based Payment Model (EPM). They believe that these models significantly increase costs and go beyond CMS' mandate to test new "innovations." They ask that CMS return to an innovative laboratory of voluntary programs that seek to address affordability, quality and accessibility.

f) Eliminate Inpatient Rehabilitation Facilities (IRFs) Review Choice Determinations (RCD).

The Review Choice Demonstration (RCD) was designed to provide IRFs with flexibility and choice, as well as a risk-based approach to reduce the burden on providers demonstrating compliance with Medicare IRF rules. The RCD program sought to reduce the number of Medicare appeals, improve provider compliance with Medicare program rules, would not result in an alteration of the Medicare IRF benefit, and would not delay care to Medicare beneficiaries. The RCD benefit was implemented to provide intensive rehabilitation therapy in a resource intensive inpatient hospital environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care. To document that each patient for whom the IRF seeks payment is eligible, certain documentation must be provided to CMS. The patient's IRF medical record must document and demonstrate a reasonable expectation that the criteria for medical necessity were met at the time of admission.

The IRF RCD program requires pre-payment review of 100% of all IRF admissions in Alabama and Pennsylvania. The program began in Alabama with 100% prior authorization review of all IRF admissions. Stakeholders assert that the RCD is not providing IRFs with the flexibilities it was designed to create, nor the cost savings. For example, more than 85% of all IRF claims filed during the first year and a half-received approval, and appeals raised the rate even higher. Given these approval rates, it does not appear that the RCD program is reducing stakeholder burden. To the contrary, IRF stakeholders believe that the program is administratively burdensome and unnecessary for them and CMS. As the program is slated to expand to California and Texas soon, stakeholders are concerned that the RCD program will become incorporated into standard practice. Therefore, they suggest that it should be eliminated.

g) Remove the New Maternity Care Hospital Conditions of Participation (CoPs).

Small hospital representatives suggested that CMS should eliminate recently finalized CoPs specific to labor and delivery, prenatal, and post-partum care for newborns and mothers, as the requirements could be counterproductive to CMS' goal of improving maternity care. Specifically, they believe that existing readmission measures have shown little variation between hospitals for several years, providing no meaningful ability to distinguish between good versus poor performers. Therefore, the CoPs offer limited insight into performance differences and should be eliminated.

h) Eliminate the reporting of excessively burdensome and duplicative hospital quality measures.

Stakeholders request that CMS remove or revise hospital quality reporting requirements related to the use of existing patient-reported outcome performance measures (PRO-PMs), structural measures, hybrid measures, and readmission measures. When balanced with the burdensome and costly administrative compliance costs, the quality reporting measures have shown little variation between hospitals. Therefore, the reporting measures do not serve their intended function of distinguishing between good and poor performing hospitals. Stakeholders suggest that CMS utilize a more targeted approach focused on preventable readmissions to gauge hospital effectiveness. Hospital stakeholders also believe that hybrid quality measures, requiring the difficult administrative task of matching patient data between claims and electronic health records, have imposed burdens that outweigh the value of the information collected. They request that CMS eliminate or revise these quality reporting measures.

3. Physician Deregulatory Issues

Physicians and their representatives reported to Advocacy that they are most impacted by Medicare and Medicaid payment rules, administratively burdensome paperwork, and reporting regulations.

a) Evaluate the necessity of administrative provisions that impact physicians.

Physician stakeholders generally recommend that CMS systematically evaluate the needs and impacts associated with administrative requirements imposed on clinicians to determine which regulations can be eliminated or revised without compromising the quality of care, safety, or program integrity. The American College of Physicians refer to a study that showed that physicians and their staff spend 3-5 hours per week on billing and insurance related paperwork, and up to 15 hours per week on quality reporting.[34] Some more recent studies believe this figure is even higher. According to the Medscape Physician Compensation Report for 2023, physicians spend an average of 15.5 hours per week on paperwork and administration.[35] A study done on the costs associated with quality reporting measures estimated that U.S. physician practices spend more than $15.4 billion annually to report quality measures.[36] They ask that CMS adopt a structured approach/framework to ensure that administrative policies support the providers, do not hinder them, and do not negatively affect quality patient care.

Stakeholders suggest that CMS better analyze the impacts of administrative tasks and quality reporting in its Regulatory Impact and Regulatory Flexibility Act analyses that include a standardized assessment of costs, administrative burden, and impact on quality care for existing and proposed regulations. These assumptions should be made available for public comment as regulations requiring administrative tasks shown to negatively impact patient care, clinical judgement, or resulting in increased costs should be revised or eliminated.

b) Physician stakeholders reported being concerned about the structure of the Merit-based Incentive Payment System (MIPS).

Stakeholders believe that CMS treats its performance categories as independent silos, each with separate scoring methodologies. This leads to inconsistencies, undermines integration, and unnecessary complexity of the Quality Payment Program (QPP). Internal medicine stakeholders recommend that CMS simplify and align the quality measurement system to reduce burden and improve patient care. This can be done by prioritizing rigorous performance measures that identify and include the purpose and importance of the measure, a focus on appropriate care, the strength of the clinical evidence, clarity and accuracy of measure specifications, and the feasibility and applicability in clinical practice.

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[34] JULIE ANN SAKOWSKI ET AL., PEERING INTO THE BLACK BOX: BILLING AND INSURANCE ACTIVITIES IN A MEDICAL GROUP., HEALTHAFFAIRS.ORG (2009), https://www.healthaffairs.org/doi/10.1377/hlthaff.28.4.w544?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

[35] Erika Regulsky, *23 Physician Specialties and The Number Of Hours Spent On Paperwork* (June 29, 2023), https://www.billingparadise.com/blog/23-physician-specialties-and-the-number-of-hours-spent-on-paperwork/.

[36] LAWRENCE P CASALINO ET AL., US PHYSICIAN PRACTICES SPEND MORE THAN $15.4 BILLION ANNUALLY TO REPORT QUALITY MEASURES, HEALTHAFFAIRS.ORG (2016), https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1258?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

c) Better align Medicare Advantage and Medicare to reduce burden.

Internal medicine stakeholders recommend that CMS align Medicare Advantage (MA) and traditional Medicare policies to promote transparency and reduce administrative burden. This can be effectuated by working collaboratively with direct Medicare Advantage Organizations to identify, evaluate, and streamline contracting requirements and administrative processes required for clinician participation in MA plans.

d) CMS should revise regulations enforcing the Stark law that prohibits independent physicians from monetizing their intellectual property.

Section 1877 of the Social Security Act[37] prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician's immediate family has a financial relationship unless an exception applies. This is known as the Stark law. The Stark statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (HHS) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. For example, physician intellectual property (IP) (e.g. patents, copyrights, know-how) is often monetized via licensing fees for using technology and royalty payments for products incorporating physician-owned IP. These arrangements can create a "compensation arrangement" under Stark and limit a physician from benefit from entrepreneurial endeavors because any payment (royalty or license) is considered remuneration.

Advocacy was approached by a physician who felt that Stark laws unfairly prohibit physicians from making money on entrepreneurship and monetizing intellectual property. He noted that CMS regulations interpreting the statute created restrictive barriers for independent physicians that do not apply to private equity owed practices or some other organizational structures. He said this skews the incentives for physicians because they can make more money by working for a private equity-backed company or a university, where the institutions capture the value of the physicians' IP rather than the physicians themselves. He suggested, "If primary care physicians could monetize their intellectual property, we would see costs go down. And you would see more independent practices, which many patients prefer. There would be more choice."

4. Nursing Deregulatory Issues

a) "Incident to Billing" (IB) should be eliminated.

Nursing stakeholders believe that IB serves as an impediment for expansion of new nursing businesses. IB occurs when an advanced practice registered nurse (APRN) bills payors under a physician or provider National Provider Identifier (NPI) and is then reimbursed at 100 percent of the Medicare rate instead of at 85 percent. They contend that IB is a significant anticompetitive

[37] 42 U.S.C. § 1395nn.

roadblock for APRNs looking to start their own business, as they would be reimbursed less for the same work performed by other providers. Stakeholders want CMS to remove IB from 42 CFR § 410.26, as this change would level the playing field among all practitioners.

b) Nursing stakeholders want HHS to standardize medical practitioner terms in regulations.

The Code of Federal Regulations (CFR) refers to medical practitioners by different terms depending on where the service is provided and under which federal program the patient is receiving health care coverage. This leads to confusion for both practitioners and administrative staff, as it forces practitioners to not only know where the patient is located, but which program is providing coverage to the patient before they can provide treatment. In the Calendar Year 2024 Physician Fee Schedule proposed rule,[38] CMS declared that instead of using different terms for physicians or APRNs it would use the term "practitioner" for anyone who provides care to patients.

Nursing stakeholders were pleased that CMS made the recommended change in the final rule.[39] However, this definitional change has not become standard practice across the federal government. As a result, there are different rules and regulations depending on which federal department is funding or regulating care. Nursing stakeholders support a standardization of terms across the federal government and the term "practitioner" should be used for all healthcare providers.

c) Nursing representatives encourage HHS to allow for continued use of telehealth.

Prior to the COVID-19 pandemic, telehealth was a very small part of Medicare and was only used in very specific situations. During the pandemic the use of telehealth was expanded, which led to greater access to care. The end of the pandemic returned some of the telehealth rules to their pre-pandemic status, but Congress has continued to extend telehealth flexibilities through the end of this year. 42 CFR § 410.78(b) provides practitioners with the general rules for telehealth, and while there are limitations, there are many services that can be provided on a permanent basis without the need for Congressional action. Relying on and improving § 410.78(b) would reduce the need for waivers and provide practitioners with more tools that they can use to treat their patients on a permanent basis, especially in rural areas.

d) Nursing stakeholders recommend that HHS allow advanced practice registered nurses (APRNs) to practice at the top of their license.

APRNs are highly trained medical practitioners, but there are many states that still do not allow them to practice medicine to the full extent of their license. Full Practice Authority (FPA) allows APRNs to practice at the top of their license, but only 24 to 28 states (depending on the APRN

[38] 88 Fed. Reg. 52262 (Aug. 7, 2023).
[39] 88 Fed. Reg. 78818 (Nov. 16, 2023).

practice area) provide FPA currently. Nursing representatives agree that APRNs and physicians are trained in different ways, and as a result, have different roles in treating patients. FPA does not change the APRN's scope of practice (SOP) in any way. Rather it simply allows these clinicians to practice advanced nursing commensurate with their education and training. HHS should allow APRNs to practice to the full extent of their license.

e) Nursing representatives, including APRNs, nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs), request that HHS eliminate outdated regulations and onerous collaborative agreements and unnecessary supervision requirements.

The specifics for these recommendations are as follows:

- HHS has the authority to provide full practice authority (FPA) to patients who receive healthcare through federal programs, such as Medicare, by creating a program like the Department of Veteran Affairs' (VA) National Standards of Practice, which defines a consistent scope of practice and responsibilities across all VA facilities. Requiring national standards in other care settings, such as facilities that accept Medicare or Medicaid, would allow APRNs to practice at the top of their license while seeing patients covered by federal insurance programs. These standards would only cover patients covered by federal insurance programs and would not require other payers to follow federal rules. Nursing stakeholders pointed Advocacy to data that suggests that the care provided by APRNs to Medicare beneficiaries is comparable to the care provided by physicians.[40] There is also legislation introduced in Congress that would remove many of these barriers,[41] but nursing stakeholders strongly encourage CMS to proactively remove these barriers rather than waiting for Congressional action.

- Stakeholders shared with Advocacy that physician organizations oppose many of these suggested changes, but they argue that modern medicine is built on interprofessional healthcare delivery, and patients should be able to choose which type of healthcare provider they want to see. Recognizing the important role that nonphysician providers play in our healthcare system is becoming increasingly important, as our healthcare delivery system faces real shortages in clinicians available to provide needed healthcare services, particularly in primary care, mental and behavioral health, and in rural/underserved areas. The physician shortage is only expected to grow, and APRNs are trained and ready to help fill care delivery gaps to ensure patients have access to the care they need. However, outdated scope of practice (SOP) laws do not allow APRNs to practice in the settings and manners in which they are needed the most. HHS should allow APRNs to practice at the top of their license, which they are trained and highly qualified to do.

[40] Am. Ass'n of Nurse Prac., *Literature on Quality of Nurse Practitioner Practice*, https://www.aanp.org/advocacy/advocacy-resource/position-statements/quality-of-nurse-practitioner-practice (last visited July 14, 2025).
[41] Improving Care and Access to Nurses Act, S. 575, 119th Cong. (2025).

- Collaborative agreements fulfill a regulatory requirement placed by many states on APRN practice, which require an agreement between a physician and an APRN for either a limited period of time (transition to practice) or by granting them permission to practice. Many of these requirements were relaxed during the COVID-19 public health emergency (PHE) with no negative effect on patient care.[42] Nursing representatives believe that the flexibilities provided during the pandemic should be made permanent. These do not relate to the APRNs' SOP, and there is no evidence to suggest that these collaborative agreements protect patients. Additionally, these transition-to-practice requirements are becoming increasingly difficult to initiate and maintain as primary care physicians and psychiatrists often decline to offer them. Mergers and acquisitions also prevent physicians from signing agreements with APRNs who are not employed by the parent organization, creating additional barriers to nursing practice.

- Supervision requirements are very similar to collaborative agreements and generally require that a physician sign off on an APRN's work. Many states allow APRN practice without unnecessary supervision requirements (NPs can practice in 39 states, CNS' and CNMs can practice in 28 states, and CRNAs can practice in 27 states). During the COVID-19 pandemic, the Trump Administration relaxed these supervision requirements without any evidence that it impacted patient care. Physicians and APRNs can and do collaborate to meet patient and community needs without the need for burdensome collaborative or supervisory agreements. Nursing stakeholders maintain that the supervision requirements that were replaced during the COVID-19 pandemic should become permanent.

f) Nursing representatives from the American Nurses Association (ANA) suggest that CMS reform the Current Procedural Terminology (CPT) and the Relative Value Scale Update Committee (RUC) systems.

Reimbursement for all practitioners is determined through the CPT and the RUC systems. These were created, and are still run, by the American Medical Association (AMA). The AMA has a contract with CMS to determine Medicare payments, and most, if not all, private payers use the CPT system to set reimbursement rates. The ANA is the only nursing organization that has advisors representing nursing in both the CPT (code development) and RUC (code valuation) processes. The ANA believes that while nursing is represented in this process, the nursing sector is not heard equally. Since CPT and RUC are driven by the AMA, often nonphysician provider perspectives are overlooked. This results in a general perception that the payment system is biased towards physicians. As such, CMS has sought comment on rulemaking on the CPT/RUC process and whether it should be replaced with a different payment system. While ANA does not believe that the CPT/RUC process should be replaced with a different payment system, reform is needed.

[42] Brendan Martin et al., *Evaluating the Impact of Executive Orders Lifting Restrictions on Advanced Practice Registered Nurses During the COVID-19 Pandemic*, 14 J. NURSING REGUL. 50 (2023).

ANA believes that the current system must be reformed to better reflect the critical role of nonphysicians in the healthcare delivery system in payment decision-making. While CMS is evaluating the CPT and RUC systems, it should ensure that the process is more inclusive of nonphysicians. This includes having a better balance of physicians to nonphysicians on each of the RUC and CPT panels. This is particularly important as nurse practitioners and PAs continue to meet more and more of the nation's primary care needs. The elevation of nonphysician perspectives in this process is critical to creating more transparency in how payments are determined and ensuring payment rates appropriately reflect how care is provided to patients.

g) Stakeholders suggest that HHS prohibit oversight and control of the nursing practice by non-nursing professionals.

Healthcare, and non-healthcare, professions generally regulate their respective practices and education requirements themselves. However, this is not the case in nursing. Nurses are the only healthcare professionals who do not regulate their own profession, as there are states that require physician representation on nursing boards. This is patently unfair and is not a matter of education. Generally, the stated rationale is to provide objectivity to the nursing board.

Stakeholders posit that nurse licensure should be run by nurses, as they are the only ones who understand the education and training needed to become a nurse. The ANA told Advocacy that they firmly believe that healthcare professionals should regulate their respective professions, and that other healthcare professionals must not be primarily involved in regulating the nursing profession, which generates malincentives. This request should not require the promulgation of any additional regulations. Removing requirements to have physicians sit on nursing boards is a simple reform that would put nursing on par with other healthcare professionals. ANA strongly urges HHS to end all outside regulation of nursing practice and allow them to practice fully within the parameters of their license.

h) Nursing stakeholders ask that HHS forbid the use of non-compete agreements for nurses in Medicare and Medicaid facilities as they are anticompetitive.

Nurses, especially frontline nurses, do not have access to corporate secrets. Therefore, it would seem the reason for nurses to sign non-compete agreements would be to force them to stay in their current job and limit their employment opportunities. This takes nurses out of the free market and artificially caps salaries. Banning non-compete agreements for nurses would raise salaries by increasing competition for nurses who are in demand without decreasing the supply of nurses in the marketplace. Higher salaries and greater employment opportunities would likely draw more people into the nursing profession and could help alleviate the current nursing shortage. Unlike non-compete agreements, representatives suggest that a combination of Health Insurance Portability and Accountability Act non-disclosure agreements can protect patient and business information without imposing additional restrictions on nurses' job mobility.

Distance is not the only unfair element in non-compete agreements. Sometimes these restrictive agreements can last for years, leading nurses to feel that they are either stuck in their current position or they must be retrained in another nursing specialty to seek other employment, which costs them time and money.

5. Pharmacy Deregulatory Issues

a) Reform the Inflation Reduction Act's Medicare Drug Price Negotiation Program.

Pharmacy stakeholders urge CMS to revise the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program (MDPNP).[43] The law provided Medicare with the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. CMS' current approach requires pharmacies to float the costs associated with the IRA's negotiated drug pricing provisions as they are waiting for reimbursements from manufacturers, and leaves pharmacies vulnerable to underwater payments by pharmacy benefit managers (PBMs). This model is also at odds with President Trump's Executive Order, *Lowering Drug Prices by Once Again Putting Americans First*,[44] which called for transparency of the MDPNP. A National Community Pharmacists Association (NCPA) commissioned study on MDPN drugs concluded that the average pharmacy will float the program $11,000 per week, with an estimated annual revenue loss of approximately $43,000 per pharmacy per year.[45] According to the NCPA, this amounts to the average salary of one full-time pharmacy technician. Further, a NCPA survey of its members conducted in January 2025,[46] indicated that approximately 61 percent of independent pharmacists are strongly considering not stocking one or more drugs with prices negotiated under Medicare Part D, while an additional approximately 33 percent have already decided not to stock one or more of the drugs. These statistics are worrisome and suggest that CMS' attempt to reduce prescription drug prices may fail and instead result in shortages.

To remedy these concerns, CMS should evaluate and reform regulations as needed. Stakeholders suggest that CMS modify, plan, and manufacture Maximum Fair Price (MFP) reimbursement policies under the MDPNP by: 1) paying pharmacies no less than the MFP plus a commensurate dispensing fee when providing MFP drugs and 2) not assessing Direct and Indirect Renumeration (DIR) fees on MFP drugs. Further, stakeholders expressed that manufacturers should be required to: 1) effectuate the MFP via the Medicare Transaction Facilitator Data Module (MTF DM) and the Medicare Transaction Facilitator Payment Module (MTF PM); 2)

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[43] Inflation Reduction Act of 2022, Pub. L. No. 117-169.
[44] Exec. Order No. 14,273, 90 Fed. Reg. 16441 (Apr. 15, 2025).
[45] THREEAXIS ADVISORS, UNPACKING THE FINANCIAL IMPACTS OF MEDICARE DRUG PRICE NEGOTIATION: ANALYSIS ON PHARMACY CASH FLOWS (Jan. 2025), https://ncpa.org/sites/default/files/2025-01/January2025-ThreeAxisAdvisors-Unpacking-the-Financial-Impacts-of-Medicare-Drug-Price-Negotiation.pdf.
[46] NAT'L CMTY. PHARMACY ASS'N, REPORT FOR JANUARY 2025 SURVEY OF INDEPENDENT PHARMACY OWNERS/MANAGERS (Jan. 2025), https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf#:~:text=The%20data%20we%20collect%20informs%20our%20advocacy%20and,Inflation%20Reduction%20Act%20Medicare%20Drug%20Price%20Negotiation%20Program.

pay the pharmacy the refund amount Wholesale Acquisition Cost (WAC) minus MFP (the Standard Default Refund Amount, or SDRA), and within 14 days of claim adjudication; and 3) submit to CMS their MFP effectuation plans sooner than September 1, 2025, as pharmacies need to make decisions on PBM/plan contracts earlier.

b) Eliminate Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements.

Pharmacy stakeholders request that CMS strike the amendments to 42 CFR § 423.505 that it finalized in its Calendar Year 2026 Medicare Part D final rule.[47] The rule added paragraph (q) to require that Part D sponsors' network contracts with pharmacies require such pharmacies to be enrolled in the MDPNP's Medicare Transaction Facilitator Data Module (MTF DM). These stakeholders oppose mandatory participation in the MDPNP via PBM/plan contracts that is part of this mandatory requirement. Stakeholders believe this requirement should be eliminated because CMS lacks the statutory authority to tie participation in Part D with participation in the MDPNP.

6. Medical Device Deregulatory Issues

The following medical device representatives' deregulatory recommendations are divided into separate sections on laboratory personnel and training provisions, Medicare reimbursement rules, prior authorization regulations, and general recommendations for HHS.

a) Laboratory personnel requirement provisions that should be revised or eliminated – 42 CFR § 493.

Medical device representatives recommend recission of changes to the laboratory personnel qualifications provisions in the final rule issued by the CMS and the Centers for Disease Control and Prevention (CDC) in 2023 titled, Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories[48] as follows:

(1) 42 CFR § 493.1405(b) – Standard; Laboratory Director Qualifications.

Point-of-care (POC) testing has become a standard of practice in many health care systems, allowing laboratory results to be delivered to the treating health care provider as rapidly as possible. The final rule significantly increased laboratory directors' educational requirements without evidence that such a change was needed. Specifically, the modifications to the medical residency provision emphasizing the requirement for "clinical laboratory training" and requiring two years of experience supervising high complexity testing to qualify for the position of laboratory director will reduce the number of medical doctors who qualify to function as

[47] 90 Fed. Reg. 15792 (Apr. 15, 2025).
[48] 88 Fed. Reg. 89976 (Dec. 28, 2023).

laboratory directors for laboratories associated with their practice. This increase in educational requirements, combined with the existing decline in laboratory professionals, will lead to laboratory closures. It will negatively impact patient diagnosis and care, especially in rural areas, and other locales experiencing health care deserts. Stakeholders suggest that CMS revise or eliminate these qualification provisions to help alleviate these concerns.

(2) 42 CFR § 493.1411(b)(4)(i)(A) - Standard; Technical Consultant Qualifications.

This section of the final rule removed the nursing degree as a qualifying degree to operate as a technical consultant capable of documenting competency to run point of care (POC) tests in moderately complex laboratories essential to critical care and emergency departments. Medical doctor degree holders and Bachelors of Science in nursing should qualify similarly to bachelor's degree holders of chemical, biological, or clinical laboratory science, as was the case under the regulation before the final rule went into effect. No previous issues were identified with individuals holding a nursing degree and this change ultimately reduces the ability of nurses to perform this procedural role in testing. With an existing decline in laboratory professionals, reducing individuals with a Bachelor of Science degree in nursing from operating as a technical consultant limits availability of these professionals. This will lead to overburdened laboratories, which impacts the ability to deliver timely lab results and ultimately impacts patient care.

(3) 42 CFR § 493.1423(b)(7) – Blood Gas Analysis Testing Personnel Qualifications.

Stakeholders recommend rescinding this provision as the change of qualifications for blood gas testing under the final rule ignores standard test qualifications and implements higher education requirements in direct conflict with the preamble to the final rule and the qualifications of emergency medical technicians (EMTs) who perform these POC tests. In the preamble to the final rule, CMS stated, "CLIA allows moderate complexity testing personnel to qualify with a high school diploma or equivalent and documented training of the testing performed prior to reporting patient test results. Individuals who meet the regulatory qualifications for moderate complexity can perform any test categorized by the U.S. Food and Drug Administration as moderate complexity, including blood gases."[49] Yet the final rule reflected a different, higher educational standard for blood gas testing. This heightened requirement has a direct impact on the ability to deliver necessary and life-saving critical care enabled by blood gas testing. EMTs need to run blood gases during critical patient transport, and many are no longer qualified to do so under § 493.1423(b)(7), as revised. Generally, to become an EMT, one needs a high school diploma or equivalent, a CPR certification, a completion of an EMT training program, and to pass the National Registry EMT exam and a state-specific practical exam. A trained, competent, and experienced EMT, whose highest level of completed education is high school, should be allowed to run a blood gas test on a POC device.

[49] *See id.* at 90,013.

(4) 42 CFR § 493.1804(c)(1) - Imposition of Alternative Sanctions.

Stakeholders recommend rescinding the changes under the final rule[50] that allow alternative sanctions to be levied against certificate of waiver (CoW) bearing laboratories as unnecessary, unfair, impractical, and detrimental to patient access to care. The alternative sanctions are financial sanctions for CoW laboratories for improper proficiency testing referrals. According to CMS, this change could decrease the burden for sanctions imposed, "[a]lthough we have no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past." In fact, proficiency testing is not a required process for laboratories only performing waived testing. This change creates new incentives for accrediting organizations to focus regulatory resources on monitoring compliance in waived laboratories, increasing their cost of compliance for processes that are not currently being monitored today. The increase in cost and administrative burden for CoW laboratories will ultimately result in a reduction in their ability to provide necessary patient care. Furthermore, currently there are about 200,000 waived certificates, making effective oversight of this number of laboratories impractical.

(5) 42 CFR § 493, Subpart F – General Administration.

Stakeholders recommend rescinding the changes to Subpart F of Title 42 related to CLIA fees under the 2023 CLIA final rule.[51] In December 2018, CMS increased fees to cover the cost of administering the CLIA program by 20 percent. According to CMS, "The 2018 increase was intended to give CMS time to propose a process through rulemaking to allow for ongoing changes to the CLIA fees. Despite that increase, the level of carryover funding available to cover program expenses is projected to decline continuously. As such, the CLIA program will not be self-supporting by the end of FY 2023 without an additional fee increase."[52] As a result, the final rule imposed an across-the-board fee update of 18 percent. Other changes included a modification to allocate directly from CoW laboratories the cost for the FDA to categorize clinical laboratory tests as waived, and a change to the CLIA fee provisions at Subpart F § 493. CMS claimed these changes would "stabilize the CLIA program."[53] According to stakeholders, these changes will significantly increase the cost to operate laboratories, reducing their viability, especially in CoW laboratories. Stakeholders suggest that there is no evidence that these updates will "stabilize" the program financially, as the repeated increases in fees have not done so previously and only serve to exacerbate the existing consolidation of laboratories. This creates shortages of laboratory professionals and services that impact access to care.

[50] 88 Fed. Reg. 89976 (Dec. 28, 2023).
[51] *Id.*
[52] *Id*.
[53] *Id.*

(6) CMS's Medicare Learning Network Matters related to QW Modifier for CLIA-Waived Tests

The Medicare Learning Network (MLN) provides educational materials for health care providers on CMS programs, policies, and initiatives. These materials include publications, web-based training, and articles. MLN offers weekly Medicare Fee-for-Service email updates and a newsletter. Small medical device stakeholders recommend rescinding the following MLN guidance documents related to CLIA-waived tests approved by the FDA: 1) MM13858, "New Waived Tests," 2) MLN Matters Number: MM13253, and 3) "New Waived Tests." These MLN Matters require that Medicare and Medicaid claims for certain laboratory tests categorized as waived under CLIA must have the modifier "QW" to be recognized as a waived test. This additional paperwork burden is unnecessary and causes delays in reporting usage and reimbursement of CLIA-waived tests on claim forms for laboratory tests that are already FDA approved.

b) Small medical device stakeholders believe that certain Medicare reimbursement, coverage, and coding provisions should be revised or eliminated as follows:

(1) 42 CFR § 405 Subpart B - Medicare Coverage Decisions for Health Care Technology

Small stakeholders recommend rescinding § 405 Subpart B related to Medicare coverage decisions for medical technology, including medical devices, and streamlining the process of reimbursement for FDA-approved Investigational Device Exemption (IDE) studies. The CMS approval process for Medicare reimbursement detailed in § 405 Subpart B contains many redundancies with the FDA approval process. Reimbursement for clinical trials requires both CMS coverage approval and establishment of coding. The process to establish coding can be prolonged and often occurs following coverage approval, contributing to delays in clinical trial access. Combining coding, coverage, and payment assignment into a single process, perhaps at the same time as FDA approval, would eliminate program administrative burden and improve timely trial access. Stakeholders recommend rescission of § 405 Subpart B and the introduction of a more appropriate streamlined process for these Medicare reimbursement decisions.

(2) 42 CFR §§ 412.87 and 412.88 - New Technology Add-On Payments

Multiple medical devices stakeholders suggested that CMS should eliminate the requirements adopted in the Fiscal Year 2024 Inpatient Prospective Payment System (IPPS) final rule.[54] The rule requires that 1) new technology add-on payment (NTAP) applicants must have a complete FDA marketing submission under active review prior to the NTAP application deadline and 2) a marketing authorization must be issued by the FDA no later than May 1 of the fiscal year during

[54] 88 Fed. Reg. 58640 (Aug. 28, 2023).

which the application is submitted. Stakeholder representatives recommend rescinding these provisions, or portions of the same regarding the additional payment for new medical services and technologies used in the inpatient setting as they relate to CMS determinations of new medical services or technologies that are eligible for the new technology add-on payment (NTAP).

Under the current regulations, for a new medical service or technology to be eligible to receive the additional NTAP payment, the medical service or technology must be new, costly, and demonstrate a substantial clinical improvement over existing services or technologies. CMS reviews NTAP applications and decides whether to award these payments on an annual basis. As a general matter, applicants for NTAP must receive FDA marketing authorization for their new medical service or technology. In addition, technologies must either be already FDA market authorized or must have a complete and active FDA marketing authorization request at the time of the NTAP application submission. The application must provide documentation of FDA acceptance or filing to CMS at the time of NTAP application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to the FDA.

These requirements are unnecessarily restrictive and significantly impact patient access and innovation. CMS currently requires documentation of FDA status and FDA marketing authorization on a timeline that is unrealistic, inconsistent with the FDA process, and burdensome for applicants seeking NTAP for innovative and necessary technologies. NTAP applicants are forced to manage great variables in the context of their FDA application process that would otherwise not be necessary but for CMS' NTAP review. Since CMS proposed this policy, industry and other public stakeholders have voiced numerous concerns regarding the fact that this regulation reflects a lack of understanding on CMS' part regarding the FDA process. CMS' timing requirements with respect to FDA documentation are well in advance of, or are inconsistent with, the expected FDA approval date. While CMS dismissed these public concerns in its decision to implement the policy, CMS has since had to revise its requirements twice through sub-regulatory guidance in recognition of its flaws. Meanwhile, there have been at least six NTAP applications since 2023 that have been deemed ineligible by CMS for NTAP. This has resulted in at least a one-year delay of NTAP approval for these new medical services and technologies. These NTAP policies cause significant patient access and cost ramifications for health care facilities. It also limits innovation and U.S. competitiveness.

As an alternative to the current regulatory scheme, representatives recommend that CMS establish a semi-annual or quarterly review cycle for NTAP, like the quarterly cycle used for applications for transitional pass-through (TPT) status under the Medicare Hospital Outpatient Prospective Payment System (OPPS). The TPT process allows for transparent public review but requires less administrative burden as compared to the NTAP process. Under this alternative process, applications would still be submitted to CMS, but through a quarterly sub-regulatory process. The applications could be subject to notice and comment rulemaking in the next applicable Medicare Hospital Inpatient Prospective Payment System (IPPS) annual rulemaking cycle. All applications that are preliminarily approved upon quarterly review would automatically be included in the next applicable IPPS annual rulemaking cycle, while submitters

of applications that are not approved upon quarterly review would have the option of being included in the next applicable IPPS annual rulemaking cycle, or they would withdraw their application from consideration. This process would facilitate a timelier review of applications and would maximize appropriate NTAP approval for purposes of improving patient care and innovation.

Some medical device stakeholders suggested that CMS engage with submitting companies during the New Technology Add-On Payment (NTAP) per application in the review process if additional data or clarification is needed. Mid-review communication would allow CMS to ask for clarifications or additional evidence early, rather than waiting until the proposed rule is released, would improve the quality and completeness of applications, and may accelerate final decision-making and improve alignment between applicant expectations and CMS evaluation criteria.

(3) 42 CFR § 419.66(b)(3): Transitional Pass-Through (TPT) Payments for Medical Devices

Stakeholders recommend rescinding TPT payments for medical devices and the requirement that to be deemed eligible as a device it must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically implanted, inserted, or applied in or on a wound or other skin lesion. The TPT program provides additional payments for new medical devices, drugs, and biologicals used in hospital outpatient settings under the OPPS. This program aims to facilitate access to these innovative technologies by incentivizing hospitals to adopt these innovations by covering the initial costs, while CMS gathers data to determine appropriate future payment rates. This, in turn, increases access to new technologies that might otherwise be too expensive for hospitals to adopt. However, based on the current eligibility criteria,[55] the program is significantly limited to only a minute subset of medical technologies. This technological limitation no longer reflects the current state of technology and should be removed. By limiting the TPT program to inserted or implanted devices, other technologies (such as clinical diagnostic tests) are unable to qualify for pass-through status and therefore face adoption challenges. Technologies currently ineligible are vital for patient care. The costs in terms of improving patient care and stifling innovation due to the current regulation exceed the benefit of minimizing transitional pass-through payments.

c) Small medical device stakeholders suggest that certain prior authorization regulations should be revised or eliminated.

(1) 42 CFR § 419, Subpart I - Outpatient Department Services

Representatives recommend rescinding § 419, Subpart I related to prior authorization for outpatient department services. CMS cites section 1833(t)(2)(F) of the Social Security Act as

[55] 42 CFR § 419.66(b)(3).

authority for the regulations. The section allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered Hospital Outpatient Department (OPD) services." However, CMS has failed to demonstrate that volume increases under OPPS were unnecessary. For example, Medicare claims data clearly demonstrates that the high growth rate of cervical fusions with disc removal in the hospital outpatient setting, cited in CY 2021 OPPS rulemaking[56] as justification by CMS for prior authorization, was the direct result of services migrating from the more expensive hospital inpatient setting of care, and not due to medically unnecessary increases in overall utilization as the result of financial incentives. Requiring prior authorization for the service categories listed at § 419.83, including cervical fusion procedures, is bad policy and results in significant burden to providers and patients. Needless administrative burdens, such as prior authorization, negatively impact patient care and innovation. Prior authorizations can also lead to confusion, frustration, or delays in care for patients.

Certain medical device stakeholders also suggested that CMS should withdraw the information collection request submitted to the Office of Management and Budget proposing the creation of a similar prior authorization demonstration program for Ambulatory Surgical Centers (ASCs).[57]

(2) 42 CFR § 422.122 - Medicare Advantage Program

Medical device stakeholders recommend rescinding prior authorization requirements for Medicare Advantage Plans and all managed Medicare and Medicaid products, as the cost of these requirements outweigh any benefits and are unnecessary considering technological advances. Prior authorization is still mostly a manual process, but technology can automate the process, making it nearly real-time. Stakeholders told Advocacy that most denials from prior authorization are later approved. Prior authorization results in delays to patient care while increasing burden on providers, financial hardships, and higher costs. The prior authorization regulation is outdated and unnecessary.

Certain medical device stakeholders also recommend that CMS terminate the current prior authorization requirements for certain procedures performed in hospital outpatient departments and reimbursed under the OPPS and withdraw the proposal to impose similar requirements for ambulatory surgery centers.

d) Remaining medical device stakeholder deregulatory recommendations for revision or elimination are as follows:

(1) 42 CFR § 414.202 – Definition of Durable Medical Equipment (DME)

Stakeholders recommend revising §414.202 to remove the following two conditions: 1) Items classified as DME after January 1, 2012, that have an expected life of at least 3 years and 2) If it

[56] 86 Fed. Reg. 63458 (Nov. 16, 2021).
[57] 89 Fed. Reg. 12350 (Feb. 16, 2024).

is not useful to an individual in the absence of an illness or injury. The regulation as it currently exists is inconsistent with the underlying statute[58] and no longer reflects the current state of technology. These current conditions are not required by statute, and including them in the regulatory definition sets arbitrary limits on the types of technology that can be considered DME. This unnecessarily restricts new and innovative technology, particularly digital and AI-based technology, from the definition of DME.

(2) 42 CFR § 403.904(c)(8)(ii) and § 403.904(f)(1)(iv) - Open Payments Device Identifier Reporting Requirement

Small business representatives recommend revising the Open Payments regulations to remove the requirement to report device identifiers (DIs) for general and research payments and transfers of value, respectively. This information does not provide meaningful information to the public and can create an inaccurate or misleading picture regarding the payments and transfers of value that are reported by manufacturers to CMS under the Physician Payment Sunshine Act.[59] Interactions that involve a transfer of value related to a device frequently occur in the context of a product line or system, comprised of numerous individual devices that are components and options within that product line or system. Reporting a multitude of DIs per product or system for a single payment record is onerous, may distort or confuse the circumstances of the interaction and associated transfer of value, and does not provide useful information to the public.

(3) Electronic Clinical Quality Measures

Stakeholders recommend that CMS rescind from quality reporting programs the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults Electronic Clinical Quality Measure (eCQM), including for the Hospital Inpatient Quality Reporting (HIQR) Program, Hospital Outpatient Quality Reporting (HOQR) Program, and the Merit-based Incentive Payment System (MIPS). This eCQM is unnecessarily burdensome and based on unsound policy. The eCQM requires facilities to use third-party vendor software to successfully report the data. Typically, eCQMs can be extracted from, or directly reported within, an electronic health record (EHR) system regardless of the EHR vendor. However, eCQMs were not designed for radiology and cannot currently access and consume elements from Digital Imaging and Communications in Medicine (DICOM) objects, so an additional resource is necessary for reporting the measured data. This has created operational challenges for facilities and clinicians and significantly increases the burden of reporting, which eCQMs are intended to reduce. Furthermore, the eCQM's technical specifications and limits for noise and dose compromise image quality and restrict clinicians from making appropriate and necessary adjustments to radiation doses, potentially resulting in inaccurate dosage or misdiagnosis.

[58] The Social Security Act § 1861(n), 42 U.S.C. § 1395x(n).
[59] 42 U.S.C. § 1320a-7h.

(4) Transitional Coverage for Emerging Technologies (TCET) and Coverage with Evidence Development (CED)

Medical device stakeholders recommend that CMS accelerate access for Medicare beneficiaries to novel, safe, and effective medical technologies upon FDA marketing authorization. This includes continuing to move forward with implementation of the TCET program and improvements to the CED pathway. While promising, the limited capacity of TCET (no more than 5 technologies per year) limits the prospects for a timely, predictable path to breakthrough medical devices intended for the diagnosis and/or treatment of life threatening and debilitating conditions. To expand capacity, CMS should eliminate any unnecessary steps to determine or reconsider TCET national coverage and ensure that data collection requirements impose as little burden as possible on patients and providers. Beyond TCET, stakeholders recommend advancing a new accelerated pathway for emerging technologies separate from the existing National Coverage Determination (NCD), CED, and Local Coverage Determination (LCD) pathways. Given FDA's recent initiatives designed to make new and innovative devices available to the public more quickly, Advocacy recommends that CMS review how these stakeholder suggestions can create new opportunities for emerging technologies.

7. Small Independent Health Insurance Agencies' Deregulatory Issues

These CMS deregulatory suggestions were provided by two small independent health insurance agencies. They asked CMS to revise some of the marketing provisions and other regulatory restrictions contained in the Medicare Program: Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program for Calendar Years 2023 (CY 2023)[60] and 2024 (CY 2024)[61] final rules.

Mondry Insurance, LLC told Advocacy that under the CY 2023 and 2024 final rules, small independent agents are held to the same regulatory standard as large Third-Party Marketing Organizations (TPMO). The stakeholder told Advocacy that, "We are a small Mom & Pop insurance agency. Due to the CY 2023 final rule, I have had to purchase a new phone system, and I am required to record and store the phone calls for 10 years. I now pay approximately $5,000 annually. Previously, I was able to run my agency from my cell phone. Now I must have VOIP. In addition, I am required to provide a disclaimer suggesting that clients contact 1-800 Medicare, Medicare.gov, or their local SHIP office for their plan options. I literally advertise for the federal government. Not once does CMS suggest contacting your local agent for help."

Pursuant to the CY 2024 final rule Part D, carriers were allowed to stop paying new and renewal compensation to agents. "For 17 years, I have worked to build my business. I continue to follow the regulations set down by CMS. Every year we get more and more regulations to follow. It now costs me a great deal to run my business and CMS and the insurance carriers feel it is acceptable for me to work for free. Almost without warning my compensation stopped on

[60] 87 Fed. Reg. 27704 (May 9, 2022).
[61] 88 Fed. Reg. 22120 (Apr. 12, 2023).

prescription drug plans. I help clients enroll in these plans daily. We provide service on these plans all year."

"In addition, we review customer's prescription drug plans during the annual enrollment period. This review can mean $1000s in savings to the Medicare beneficiary. This is a valuable service. My compensation was stopped with about a 45-day warning. Most recently, United Healthcare stopped paying compensation on new business effective June 1, 2025. In 2024, I lost $61,000 in compensation. Last year, I lost $40,000 in WellCare compensation alone. This year-to-date, I have lost $12,000 in new growth! I would hope our compensation would be restored. WellCare and Aetna SilverScript allowed agents to enroll clients by the masses in 2023 with their low premium plans. As soon as agents helped clients enroll in those two competitive plans, our compensation was stopped. We are not to steer clients to plans, but this behavior towards agents absolutely triggers churning and steering."

"If compensation will not be reinstated, we should be allowed to charge a fee for our services. Currently, CMS will not allow agents to charge a fee for review. I assume that is because they think we are receiving commissions. There needs to be some allowance for us to be compensated for our research and service work."

Another small insurance stakeholder, Emerald Group Indy, Inc., told Advocacy that the CY 2023 final rule resulted in technical and administrative costs. Emerald has incurred costs for storage and recording phone calls and virtual meetings. A representative of the company expressed to Advocacy the following: "We had to purchase new phone equipment with recording capabilities. Now, I pay monthly data and storage fees for these items. I had to upgrade my Zoom account so that I could record those meetings and store them as well. These expenses are up into the thousands of dollars I am paying each year in order to be compliant. Secondly, as a Third-Party Marketing Organization (TPMO), we are required to provide a disclaimer to essentially advertise for 1-800 Medicare, Medicare.gov, and SHIP. This diverts potential clients to other available resources, leading to a loss of potential revenue and growth for the company."

Emerald voiced similar impacts related to the CY 2024 final rule as they lost compensation from Part D carriers who were no longer required to pay them for new and renewal enrollment of Medicare beneficiaries. According to an Emerald representative, "This has cost my agency approximately $12,000 and I am currently losing YTD on new business approximately $5,000 for Prescription Drug Plans that have been written and not compensated. Even if I could charge the client a one-time fee for a consult, that would lessen the burden of working for completely free."

B. The Office of Civil Rights (OCR)

1. Home health care and hospital stakeholders suggest that the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information at 45 CFR Part 160 and 45 CFR Part 164 should be revised or eliminated.

In January 2025, the OCR issued a proposed rule to modify the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security rule (Security rule).[62] The rule sought to revise existing standards to better protect confidentiality, integrity, and availability of electronic protected health information (ePHI).

Public law 116-321 required HHS to consider a regulated entity's current state of adoption of recognized security practices, or digital maturity status, when enforcing the Security rule. The American Health Care Association (AHCA) suggests that this proposed regulation fails to address or incorporate the legal requirement that CMS scale the requirement to a provider's cybersecurity risk profile and digital maturity, which is contrary to the statute.

The proposed rule is inefficient for both the government and the private sector. The complexity and scope of the requirements establish a burdensome compliance floor for all entities regardless of size or risk profile that would necessitate substantial investments in time, resources, and personnel to achieve compliance. Imposing these regulatory burdens on long term care organizations is onerous, particularly for those with small resident populations located in rural and underserved locations. These facilities face historic workforce challenges and often operate on thin margins. The rule will have an inadvertent and negative impact on these providers and the patients they serve. According to the proposed rule's own analysis, it would place a substantial unfunded mandate on providers of at least $9 billion during the first year and at least $6 billion per year thereafter. For Skilled Nursing Facilities (SNFs), assisted living communities, and Intermediate Care Facilities (ICFs), HHS estimates the costs are $1.04 billion in Year 1 and $694 million per year thereafter.[63] For each establishment, this averages to $10,328 in Year 1 and $7,294 per year thereafter. Stakeholders believe these HHS cost estimates are grossly underestimated. Some of their provider members project the annual costs of this rule will range from $250,000 to $400,000 per organization.[64]

[62] 90 Fed. Reg. 898 (Jan. 6, 2025).
[63] 90 Fed. Reg. 898, 996 (Jan. 6, 2025).
[64] Am. Hosp. Ass'n & Nat'l Ctr. for Assisted Living, Comment Letter on Proposed Modifications to the HIPAA Security Rule to Strengthen the Cybersecurity of ePHI (Mar. 7, 2025), https://www.regulations.gov/comment/HHS-OCR-2024-0020-4575.

C. The Food and Drug Administration (FDA)

1. Pharmacy Deregulatory Issues

a) The FDA should eliminate the proposed rule on demonstrable difficulties for compounding.[65]

The proposed rule established criteria for two lists or categories of drug products that present demonstrable difficulties for compounding (DDC Lists) under certain sections of the Federal Food, Drug, and Cosmetic Act (FFDCA). Drug products or categories of drug products that appear on the DDC Lists cannot qualify for certain statutory exemptions and therefore may not be compounded under § 503A or § 503B of the FFDCA. But according to Congress, the authority is different in these sections. In § 503A, the FDA may bar specific drug products from compounding, a narrow authority focused on individual formulations. In § 503B, the FDA is authorized to restrict both drug products and categories of drugs, a broader power that reflects the scale and manufacturing practices of outsourcing facilities. Despite this distinction, the FDA's proposed regulation applies the broader category-based prohibition to § 503A pharmacies. Stakeholders believe this regulatory approach is not a permissible interpretation of the statute. Section 503A refers only to "drug products," not categories, and makes no provision for banning entire classes of medications. By attempting to impose the § 503B framework into § 503A, the FDA is acting beyond its authority. Therefore, stakeholders urge the FDA not to finalize any rule that exceeds its statutory authority under § 503A and ensure that only individual drug products (not entire categories) may be added to the § 503A DDC List.

b) The FDA should rescind or revise its 2023 Guidance for Industry #256.

Guidance for Industry (GRI) 256 imposes broad restrictions on the use of bulk drug substances in veterinary compounding. Stakeholders believe that this undermines the clinical judgment of veterinarians and unnecessarily restricts access of compounded drugs for animals. If the FDA maintains GFI 256, stakeholders suggest that the agency should revise it into one which improves veterinary practice, appreciates the essential role of compounded medications in animal health, and streamlines the bulk substance nomination process.

c) The FDA should modify the final rule on Nonprescription Drug Products with Additional Conditions for Nonprescription Use.[66]

The FDA created nonprescription drug products with additional conditions for nonprescription use (ACNU) as a new category of over-the-counter drug products. ACNUs can be sold at retail to consumers without a prescription if the product manufacturer implements an additional condition to ensure appropriate self-selection or appropriate actual use, or both, by consumers.

[65] 89 Fed. Reg. 19776 (Mar. 20, 2024).
[66] 89 Fed. Reg. 105288 (Dec. 26, 2024).

This is allowed without supervision by the prescribing health care provider. Consumers must complete a self-assessment process designed by the product manufacturer to screen and determine whether that individual is eligible to purchase the product based on their health.

Pharmacy stakeholders suggest that the final rule increases costs, creates operational difficulties, and imposes additional paperwork burdens on pharmacies. They believe the rule should be revised as follows to make it workable for pharmacies and patients alike:

- Revision 1: Stakeholders recommend that the FDA standardize the ACNU process such that there is a common way for patients to prove that they fulfilled the ACNU. The final rule allows for different manufacturers to establish and deploy varying methods for consumers to complete the self-assessment process to determine their eligibility to purchase a particular ACNU drug. Therefore, each manufacturer may operate ACNU differently, resulting in significant administrative burden for pharmacies as they would need to operationalize and implement sales processes to accommodate a myriad of ACNU requirements. This would also necessitate training salesclerks on these new processes.

- Revision 2: Stakeholders ask CMS to standardize the ACNU self-assessment and to seek pharmacy input in the development of the systems. The final rule will require costly modifications for point-of-sale systems in pharmacy establishments to enter "stop" when asking the patient to provide "proof" that they did the self-assessment and the product is right for them. The systems will also have to add documentation proving the patient provided the self-assessment and showing that the drug was appropriate for them. This scenario creates a heightened administrative burden, as pharmacies would be hesitant to modify their systems without knowing how manufacturers are going to approach the self-assessment.

- Revision 3: Pharmacy stakeholders believe that making prescription and over-the counter medicines available for purchase will likely cause significant patient confusion. Insurance plans may choose to stop covering the prescription version of the drug, which will contribute to greater out-of-pocket costs to patients and create possible medication adherence/access issues. Ideally, the ACNU class of drugs should leverage the expertise of the pharmacist by allowing only state licensed pharmacies to assist the patient with the necessary assessment processes for determining whether a particular medication is appropriate for the individual seeking the therapy.

2. Food Sector Deregulatory Issues

a) Multiple food sector stakeholders voiced concern with the FDA's proposed front of package labeling rule. They suggest that the FDA's assessment of costs is underestimated, and alternative approaches already exist to accomplish the rule's underlying policy.

The Food Industry Association (FMI) suggests that the FDA should consider withdrawing the proposed rule on Front-of-Package Nutrition Labeling (FOPL). The rule would require most packaged foods to display a "Nutrition Info" box on the top third of the front of the package, showing the percent Daily Value for sodium, saturated fat, and added sugars, accompanied by the interpretive markers "High," "Med," or "Low" for each nutrient.

Stakeholders believe that, if finalized, the rule would be burdensome and costly to implement because label redesigns will be needed in most cases. Further, these burdens would be undertaken without evidence of commensurate benefits to consumers, particularly considering the existence of a voluntary front-of-pack labeling scheme that has been widely adopted in the marketplace and with which consumers are familiar.[67] The FDA estimates 322,000 products would undergo FOPL changes.[68] The FDA quantified costs to the packaged food industry from updating labeling to meet the proposed requirements. Annualized costs from relabeling over 10 years would range from $66 million to $154 million at a 2 percent discount rate, with a primary estimate of $105 million per year. Although reformulation of food products is not a requirement or goal of the proposed rule, the FDA quantified the costs of reformulation as the rule may result in some food manufacturers reformulating some food products. The FDA estimated that the annualized costs of reformulation over 10 years would range from $125 million to $377 million at a 2 percent discount rate, with a primary estimate of $227 million. Combined, the FDA estimated the annualized costs of the proposed rule over 10 years would range from $191 to $530 million at a 2 percent discount rate, with a primary estimate of $333 million.[69] The total discounted cost of the proposed rule per entity (including large firms) is approximately $100,253.[70] The FDA estimated that mandatory labeling and voluntary reformulation costs incurred due to the proposed rule would cost roughly $1,030 annually per UPC, or less than a percent of a manufacturer's estimated annual receipts. "If firms choose not to reformulate, total costs annually per UPC are just $326 because voluntary reformulation makes up about 68 percent of total costs."[71]

Stakeholders argue that the labeling costs assumed by the FDA in the proposed rule are underestimated. Based on their experience with the Canadian FOPL requirements, stakeholders

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[67] In 2011 the Food Industry Association and the Consumer Brands Association created a voluntary front of package labeling system that contained nutritional information for the food and beverage industry called Facts Up Front.
[68] U.S. FOOD & DRUG ADMIN., FOOD LABELING: FRONT-OF-PACKAGE NUTRITION INFORMATION: PRELIMINARY REGULATORY IMPACT ANALYSIS, INITIAL REGULATORY FLEXIBILITY ANALYSIS, AND INITIAL UNFUNDED MANDATES REFORM ACT ANALYSIS 22 (Jan 21, 2025), https://www.regulations.gov/document/FDA-2024-N-2910-0130.
[69] 90 Fed. Reg. 5428.
[70] U.S. FOOD & DRUG ADMIN., *supra* note 68, at 52.
[71] *Id*.

reported that that the costs necessary to implement the FDA's rule will be $4,000-$8,000 per label, with the higher end of the range applying where there is a need to update photography and graphics due to the size of the Nutrition Info Box and depending upon the packaging material type. The FDA estimated labeling and reformulation costs at $1,030 per UPC,[72] significantly less than the costs estimated by small stakeholders. The FDA also estimated that covered entities would reformulate approximately 2,000 UPCs (0.5% of all covered UPCs) and the agency estimates the cost of reformulating a single formula at $1 million.[73]

Stakeholders believe that the FDA has likely underestimated the number of reformulations likely caused by the rule. The FDA's estimate of the number of reformulations is based on the number of products with nutrient levels within 1 percent of the FDA cutoffs. Products beyond that range are also likely to reformulate, especially if the FDA thinks customers are going to change their behavior in response to the labels. Also, the FDA assumes that dessert manufacturers will make no reformulations. This assumption is unlikely given desserts' typical nutritional values which this rule is designed to moderate.

Lastly, FMI believes that the proposed FOPL scheme raises significant statutory authority and First Amendment concerns because the FDA lacks the statutory authority to implement mandatory FOPNL. The Federal Food, Drug, and Cosmetic Act (FFDCA) provides the FDA with highly prescriptive instruction as to how the agency is to mandate nutrition labeling and does not include a provision that allows for a mandatory selection of information to be presented separate from the comprehensive nutrition information that includes certain elements specified by Congress.

The Brewers Association (BA) also identified the FOPL rule as being problematic for their industry. The BA noted that most of their products fall under the Department of the Treasury's Alcohol and Tabacco Tax and Trade Bureau (TTB). However, two categories of alcohol beverage produced by their members are outside of TTB's Federal Alcohol Administration Act (FAA) jurisdiction and fall under the primary labeling jurisdiction of the FDA. These are: (a) fermented grain products made without malted barley or without hops, a category that includes most "hard seltzer" products and (b) wines containing less than 7 percent alcohol by volume (ABV), a category that includes most "hard cider" products.

The BA believes that given the split jurisdiction between most alcohol beverage products and the relatively small subset of alcohol beverages subject to the FDA's primary labeling jurisdiction, requiring FOPL on products like hard seltzers and hard ciders would impose significant costs on brewers and would only serve to confuse the public about the nature of these products. The BA estimates that roughly 25 percent of craft breweries produce either hard seltzer and/or hard cider. They believe hard seltzer-type products represent the bulk of affected beverages produced by small breweries. This means that over 2,400 small brewers are potentially directly impacted by the FOPL rule. Accordingly, the BA believes that the FDA should create an exemption of alcohol beverages from a final FOP labeling mandate.

[72] See *id*. at 53.
[73] See *id*. at 20.

In the alternative, BA recommends that any final rule clearly exempts kegged products as virtually all such purchases in bulk are for immediate consumption at the restaurant, bar, hotel, or other on-premises venue where purchased. As such, these bulk purchases are analogous to restaurant sales, to which the proposed FOP mandate would not apply. They also want the FDA to coordinate any final compliance date in the FOP rule with the compliance date of new labeling regulations currently under consideration by the TTB.

The FDA indicates in the proposed rule that it intends to certify in the final rule that the regulation will not have a significant impact on a substantial number of small entities under the RFA. Advocacy suggests that given the cost impact disparity that exists between the FDA and industry and affected stakeholder proffered alternatives, the FDA should not certify the final rule. Also, Advocacy believes that the FDA should continue its outreach with affected stakeholders to identify and analyze any significant alternatives to the rule that may lessen the rule's costs.

b) FDA's Voluntary Sodium Reduction Goals

Advocacy received multiple requests from interested stakeholders on this FDA regulatory initiative. In August 2024, the FDA issued voluntary targets for sodium reduction in foods in the draft guidance, Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods (Edition 2).[74] The guidance contains three-year sodium reduction targets for food categories that are commercially processed, packaged, or prepared in food service establishments. The Meat Institute told Advocacy that the current sodium reduction targets are not achievable across all meat categories, and the FDA failed to recognize either the food safety or the functional role of salt in meat products. They recommend that the FDA must assess actual sodium intake among Americans, (e.g., CDC's National Nutrition and Health Examination Survey) to determine efficacy of Phase 1 targets prior finalizing Phase 2 targets. Current labeling requirements provide the appropriate information so that consumers can make decisions appropriate for their health and lifestyle preferences.

The FMI asks that the FDA's Phase 1 targets should be updated to account for 2023 and 2024 product nutrition data. They also agree that the FDA should determine the efficiency of the Phase 1 targets before they finalize the Phase II targets. This determination should include a publication of the assessment of whether the targets are impacting consumer intake of sodium before proceeding with further targets. FMI argues that the FDA's suggested 3-year goal is insufficient to achieve the Phase II targets given that it takes between 18 and 36 months to complete a single product reformulation. Lastly, they believe that further technologies need to be developed to achieve further sodium reductions in certain food categories.

[74] 89 Fed. Reg. 66727 (Aug. 16, 2024).

c) The requirements of 21 CFR § 118.4(e) should be eliminated.

Each year, the broiler chicken industry produces hundreds of millions of eggs that do not get placed for hatching. Stakeholders believe that these eggs are perfectly edible. For years, they were sent to egg-breaking plants, where they were pasteurized and used to create egg products that, in turn, are used as ingredients in other foods, such as pasta. However, due to an FDA regulation[75] intended to address Salmonella in shell eggs, these hundreds of millions of eggs can no longer be used for human food and, since 2009, are sent for rendering or to a landfill. That regulation, which was intended to address Salmonella Enteritidis in shell eggs, which are not pasteurized, requires eggs to be refrigerated within 36 hours of lay. This is impossible to achieve for hatching eggs because it destroys chick hatchability. A joint FSIS-FDA risk assessment showed that even under extremely conservative assumptions, surplus broiler eggs could be sent for pasteurization with no public health risk.[76] Moreover, if an egg-laying flock tests positive for Salmonella Enteritidis, the shell egg rule allows those eggs to be sent for pasteurization.

As originally proposed, surplus broiler eggs would not have been subject to the shell egg rule, but they were included without advance notice when the rule was finalized. The FDA should exempt surplus broiler hatching eggs from its shell egg rule's refrigeration requirement, allowing these eggs to be sent to FSIS-regulated egg breaking plants for pasteurization. This can be done by adding an exemption to § 118.1 for surplus broiler eggs, when none of the eggs from the farm are intended for use in human food without pasteurization. This change would provide an additional revenue stream with no additional investment, which would disproportionately benefit smaller companies that are less able to absorb the types of costs and losses imposed by the current policy. Removing this restriction would allow a greater supply of shell eggs for product, lowering food costs at a particularly difficult time for the egg industry.

d) The Food Safety Modernization Act (FSMA) Traceability Rule[77]

The FDA delayed this regulation's implementation date by 30 months given the complex nature of the rule. Advocacy spoke with many food industry stakeholders that are concerned that even with the extended time, it will be difficult to achieve compliance, as the rule touches every level of the food supply chain in the U.S. Differing opinions exist among stakeholders as to whether they can comply with the rule within the 30-month extension, but most agree that the rule will be costly, and technically and administratively difficult to implement. For example, stakeholders suggest that the required case-level tracking of foods on the rule's Food Traceability List (FTL) is a key driver of complexity and costs, and they are concerned about how that aspect of the regulation will be implemented. Also, stakeholders recommend that the FDA focus on the food sector education, especially as it relates to small businesses, to ensure that the rule's objectives and benchmarks are being met before the 30-month extension expires. They encourage the FDA

[75] 74 Fed. Reg. 33030 (Jul. 9, 2009).
[76] Regis Pouillot et al., *Assessment of the Risk of Salmonellosis Linked to the Consumption of Liquid Egg Products Made from Internally Contaminated Shell Eggs Initially Stored at 65°F (18°C) Compared with Eggs Stored at 45°F (7°C)*, 83 J. FOOD PROT. 767 (2020).
[77] 87 Fed. Reg. 70910 (Nov. 21, 2022).

to be transparent about its findings on the interoperability of systems within the food supply chain. Stakeholders believe that the agency should collaborate with the industry on its findings. Some stakeholders also suggest that the FDA should seek input from the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), with its long history of working with the industry to trace product efficiently and effectively.

Stakeholders with whom Advocacy spoke made additional recommendations on how the FDA can use the 30-month extension to evaluate provisions they have flagged as burdensome for industry and could be improved with certain flexibilities. These include:

- Provide Additional Flexibility for Lot Code Traceability. The key driver of regulatory complexity and cost in the food traceability rule is its requirement that distributors and retailers track the lot code for each food they handle. Given that modern distribution systems utilize a "just in time" inventory strategy to deliver a complex variety of foods to individual retail stores on a daily basis, this results in a de facto requirement of tracking food to the case level. This aspect of the rule imposes significant costs. One regional supermarket chain estimates that the rule will impact over 8,000 products spanning 500 suppliers. Implementing case-level tracking would cost the company $8 million annually in labor costs. A food distributor estimates that case-level tracking will increase costs by 20 cents for every 100 lbs. of products shipped for labor and inventory control alone. These recurring costs can be avoided with changes to the rule.

  The stakeholders that spoke with Advocacy believe that at a minimum, the FDA should modify the rule to allow retail stores and distribution centers to maintain a range of traceability lot codes included in a shipment, rather than the precise lot codes in a particular shipment. This solution would continue to provide the FDA with the information they are seeking while simultaneously reducing significant costs along the supply chain. Allowing companies to provide a limited range of lot codes would preserve the overall efficiency of outbreak investigations while alleviating the rule's burdens on day-to-day operations at distribution centers and retail stores.

  Given recent advances in artificial intelligence, it is possible for food distributors to algorithmically infer traceability codes. Stakeholders believe that the FDA should allow this as an alternative to the final rule's provisions, provided that their algorithms are adequately evaluated and documented in the distributors' FSMA traceability plan.

- Exempt Intracompany Shipments from the Rule. The food traceability rule requires recordkeeping when foods are shipped between retail stores. These transactions should be exempt from the rule according to stakeholders. The volume of records required for each shipment associated with each product is leading many retailers to evaluate whether they can continue to offer certain products, limiting consumer choice and convenience. In particular, fresh-cut fruits and vegetables, prepared deli salads, and sushi are products often prepared in central kitchens and shipped to sister retail stores. These types of activities happen so frequently that maintaining full records for these foods will be costly

and may cause these healthy, convenient products to be removed from store shelves. Internal company recordkeeping systems are well equipped to trace products through intracompany shipments and requiring traceability records for these transfers adds an immense burden without an identified corresponding benefit to public health. Understanding that choice and convenience are of paramount importance to consumers, the FDA should reduce the regulatory burden imposed on industry by exempting intracompany shipments from the rule's requirements.

- Pilot Test Before Full Implementation. Stakeholders told Advocacy that there is high anxiety in food retail circles that, come enforcement time in 2028, the food supply chain will not be ready. Stakeholders believe that due to complexities surrounding the requirement to track to the lot code for each FTL food, chaos in the food supply chain may ensue. These concerns have led to calls to test the system prior to the enforcement date. Consider this example from a small restaurant chain, who asked:

  > "I was wondering if an electronic invoice from a distributor was enough for recordkeeping. Unfortunately, as of now no distributor lists the lot codes on that invoice, and there is no practical way to assume that we can manually log every lot code off the box that comes in. We don't have dedicated receivers in any location, and for things like fresh fruits and vegetables, there is no lot code printed on, say, a cantaloupe. This is an impossible task for companies like ours."

  Based on questions such as this, stakeholders believe that there is still great confusion and uncertainty surrounding the rule's basic obligations, especially among smaller companies in the food supply chain. Without the benefit of "pilot programs" or other exercises designed to test the inoperability of the rule in the real world, stakeholders are worried about the rule's impact on the food supply chain.

- The FDA Should Amend the Definition of Traceability Lot Code Source Reference. Stakeholders suggest that a burdensome aspect of the rule is the requirement to maintain and pass forward the traceability lot code source reference. The FDA should amend the definition of "traceability lot code (TLC) source reference" to allow companies to identify the person responsible for assigning the TLC, rather than the location where the TLC was assigned. Requiring that entities maintain records with this level of specificity will be logistically burdensome, particularly for entities such as processors, that transform a variety of food products across many locations within one company system. With this change, companies could list a Global Trade Item Number (GTIN) or similar identifier identifying the person responsible for assigning the TLC if the individual is able to identify the TLC source. This amendment would allow the TLC source reference to identify the corporate entity responsible for assigning the TLC, rather than providing the specific location where the TLC was assigned. This is a less onerous requirement for firms operating multiple locations. This change would reduce the burden on industry without inhibiting the FDA's ability to conduct foodborne illness outbreak investigations.

- Protect Confidentiality. There is significant concern from some producers and suppliers, particularly seafood suppliers, around how to protect confidentiality while still providing a TLC source, as there is no alignment across industry on what approach will be used for this Key Data Element (KDE) (e.g. physical addresses, URLs, etc.). Stakeholders would welcome added flexibility by the FDA as it relates to the provision of TLC source/TLC reference, or greater clarity on how suppliers can comply while keeping confidential certain commercial information.

e) Nutrient Content Claims; Definition of Term "Healthy."

The final rule revised the requirements for when the term ''healthy'' can be used as an implied nutrient content claim in the labeling of human food products to help consumers identify foods that are particularly useful as the foundation of a nutritious diet that is consistent with dietary recommendations.[78] Stakeholders suggest that the final rule should be eliminated because it risks consumer confusion and places unnecessary costs on the food industry due to its duplication and inconsistency with other FDA regulations and policies. These include, but are not limited to, the FDA's Front of Package Labeling proposed rule and Sodium Reduction Guidelines.

f) Electronic Recordkeeping Requirements of 21 CFR Part 11.

Food stakeholders recommend that the FDA revoke the electronic recordkeeping requirements in 21 CFR Part 11. The requirements for electronic recordkeeping under Part 11 are designed to ensure the integrity, reliability, and security of electronic records and signatures in the FDA-regulated industries. Provisions require system validation, audit trails, data integrity controls, and electronic signature security. Stakeholders suggest that many of these requirements are unworkable, outdated, and unfairly restrict innovation for those food producers subject to them (e.g., low acid canned food facilities). They also are unnecessary, as demonstrated by the exemptions from compliance with Part 11 already granted to certain food manufacturing facilities.

g) Warning Statement on High Protein Products (21 CFR 101.17(d)(3)).

Stakeholders recommend that the FDA revoke the regulation requiring foods that derive more than 50 percent of their caloric value from protein and that are represented for weight reduction bear a warning statement specifying that the product should be used only as a food supplement. This regulation is outdated and unnecessary based on current dietary practices and guidelines, and compliance costs are not justified by a commensurate benefit to public health.

[78] 89 Fed. Reg. 106064 (Dec. 27, 2024).

h) Salt Substitutes in Standardized Foods.

FMI requests that the FDA prioritize finalizing the proposed rule[79] to amend the standard of identity (SOI) regulations that specify salt (sodium chloride) as a required or optional ingredient and permit the use of salt substitutes in standardized foods. This would reduce the sodium content, provide for efficiencies in rulemaking, and facilitate a small step towards modernization of standardized food. FMI encourages the agency to use a horizontal approach to efficiently modernize the food standards of identity that address the use of salt as an ingredient or that would not otherwise allow for use of a salt substitute and believe doing so would promote innovation and the development of healthier, lower in sodium foods for American consumers.

i) Food Safety Modernization Act (FSMA) Rules Impacting Small Farms.

AJ Richards, founder of From the Farm, a small Wyoming based company that seeks to assist food producers with marketing and improved pricing based on aggregating order quantities, reported to Advocacy several negative consequences of FSMA on small farming businesses:

- High Compliance Costs for Small Farms: The FSMA's Produce Safety rule imposes significant costs, with the FDA estimating that very small farms (under $250,000 in annual sales) could spend up to 6 percent of their revenue on compliance, compared to less than 1 percent for larger farms, straining their limited budgets.[80] The FDA should revise this rule and provide some relief to small businesses.

- Complex Eligibility for Exemptions: FSMA's Tester-Hagan Amendment exempts farms with sales under $500,000 from the produce safety standards, but determining eligibility (based on a 3-year sales average adjusted for inflation) is complex. This creates uncertainty for small farms with limited resources.[81] The FDA should revise this provision to clarify and ease determinations of eligibility for small farms. This will alleviate the uncertainty.

- Excessive Testing Requirements: FSMA mandates extensive water testing, such as Microbial Water Quality Profiles (20 samples over 2–4 years), adding financial and time burdens that small farms struggle to meet compared to larger operations.[82] The FDA should consider revising these regulatory provisions through outreach with small farmers and by entertaining alternatives designed to lessen these burdens.

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[79] 88 Fed. Reg. 21148 (Apr. 10, 2023).
[80] U.S. FOOD & DRUG ADMIN, STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION RELATING TO AGRICULTURAL WATER: FINAL REGULATORY IMPACT ANALYSIS, FINAL REGULATORY FLEXIBILITY ANALYSIS, AND UNFUNDED MANDATES REFORM ACT ANALYSIS, https://www.fda.gov/media/178236/download?attachment (last accessed July 14, 2025).
[81] U.S. Food & Drug Admin, *FSMA Final Rule on Produce Safety*, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety (last accessed July 14, 2025).
[82] U.S. FOOD & DRUG ADMIN, *supra* note 80.

Burdens associated with water testing under FSMA were emphasized to Advocacy by a small farmer, Steve Jarvis, who has been forced out of business due to high FSMA compliance costs. He noted that, "One example I encountered is that I could dig my potatoes, and I had an open-air washing system. No roof over it. We would dig potatoes, wash and load them on the semi. It took only a few hours to wash 10,000 pounds of potatoes and load them onto my semi under FSMA. Inspectors said I had to build a roof system over my washing system. Along with fencing out hogs, I was going to have to spend $180,000 and borrow all that money to stay compliant. That meant that I would have to spend three years of profits to do this. It was over and they said that I could not ship my crates into a grocery store."

- Implementation Challenges: FSMA's compliance deadlines for very small farms overwhelm small producers who lack the staff or expertise to navigate complex regulations, unlike larger farms with dedicated resources.[83] This stakeholder suggests that the FDA provide further compliance flexibilities that will help very small farmers comply with the FSMA regulations.

3. Medical Device Deregulatory Issues

a) According to a recommendation submitted to Advocacy's Red Tape Hotline from a small medical device manufacturer, FDA should provide cost relief from the FDA's Medical Device Establishment fees.

"The FDA requirement to register and pay a fee costs small medical device establishments an enormous amount each year and is greatly hurting small business manufacturers. There is no discount for small businesses, so a small mom and pop niche business is paying the same fee as huge companies such as Johnson and Johnson, Medtronic, etc. Also, the fee increases substantially each year. It is extremely unaffordable as it is $9,280.00 this year. In 2024 it was $7,653.00. Since it increases by a large considerable amount each year, it will soon cause small medical device manufacturers to just close. This fee hinders the really small business's cash flow, profits, and growth. It's very hard to come up with this kind of money to simply register. There are small entity discounts for patent filing, but zero with the Medical Device Establishment registration. Also, simple Class 1 devices that are sold directly to the public should be completely exempt as they were under the medical device tax. At the very least there should be a great discount for small entities based in the USA. Foreign businesses must also pay to register before importing their device and I see no problem with that. Class 1 medical devices can be as simple as a toothbrushes, bandages, bed pans, soap dispensers, orthotics, etc. Please consider at least giving small businesses a deeply discounted rate."

[83] *Id.*

b) The FDA should utilize the authority provided in Section 3054 of the 21st Century Cures Act (CURES Act) to exempt certain devices from the 510(k) requirement.[84]

Section 3054 of the CURES Act exempted most Class I and Class II devices from premarket notification 510(k) requirements. It also required the FDA to identify, within certain timeframes and on a regular systematic cadence, Class I and II devices that are currently subject to 510(k) requirements that no longer warrant a 510(k). These provisions provide for an efficient mechanism to exempt these lower risk devices from the 510(k) requirement. Small medical device stakeholders encourage use of these exemption provisions, which provide for a risk-based, effective use of government regulatory resources and supports innovation for patients.

c) The FDA should utilize the authority provided in Section 707 of the FDA Reauthorization Act (FDARA)[85] to distinctly classify accessories into Class I.

The FDA has accessory classification authority under section 513(f)(6) of the Food, Drug and Cosmetic Act (FDCA), as amended by FDARA Section 707. In 2019, the FDA finalized a list of accessories that it found to be suitable for distinct classification in Class I. In accordance with FDCA § 513(f)(6)(D)(i), the FDA is required to publish a list of accessories to be classified as Class I at least once every 5 years. Stakeholders encourage the FDA to meet its statutory requirements to publish a new Class I accessories list as this would provide small medical device manufacturers with certainty, flexibility and burden relief.

d) Title 21, Chapter I – Point-of-Care (POC) Tests

Stakeholders recommend that the FDA rescind the portion of those regulations that require manufacturers to submit a premarket notification to the FDA for devices that are in vitro devices intended for POC testing, including 21 CFR § 878.9; 21 CFR § 882.9; 21 CFR § 862.9; 21 CFR § 864.9; 21 CFR § 874.9; 21 CFR § 866.9; 21 CFR § 880.9; 21 CFR § 884.9; 21 CFR § 868.9; 21 CFR § 872.9; 21 CFR § 888.9; 21 CFR § 870.9; 21 CFR § 876.9; 21 CFR § 886.9; 21 CFR § 890.9; and 21 CFR § 892.9.25. The value of POC in vitro diagnostic testing, including those tests intended for use in a doctor's office, school, workplace, or the home, was demonstrated during the COVID-19 pandemic and continues to grow today. Significant regulatory hurdles make it extremely difficult for developers of POC tests to succeed. Throughout Title 21, POC tests, which are low-risk and could be launched without FDA review, are subject to FDA review simply because the test is deemed to be intended for the POC setting. Categorically limiting a device simply because it is POC does not support the public health in today's health care environment, and it creates unnecessary regulatory hurdles that stifle innovation.

[84] The CURES Act authority amends Sections 510(l) and 510(m) of the Food Drug and Cosmetic Act.
[85] The FDARA adds section 513(f)(6) of the Food, Drug Cosmetic Act granting FDA accessory classification authority.

e) 21 CFR Part 11 - Electronic Records; Electronic Signatures[86]

Representatives recommend rescinding regulations related to the requirements for validation, audit trails, record retention, and electronic record copying. These requirements date to August 2003 when the FDA announced that it was reevaluating Part 11 and exercising enforcement discretion for a narrower application of Part 11 while retaining the regulation in its entirety. The significant resource expenditures associated with Part 11 were identified by the FDA as the reason for the enforcement discretion. These regulations set forth the criteria under which the FDA considers electronic records to "be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper." Since the regulations were promulgated, the common use of electronic systems (as opposed to paper recordkeeping) has greatly expanded. However, nearly 22 years later, Part 11 remains part of the CFR even though it is outdated and unnecessary.

f) Stakeholders suggest that the FDA should rescind the following 510(k) Premarket Notification draft guidance documents.

- Best Practices for Selecting a Predicate Device to Support a Premarket Notification 510(k): Draft Guidance for Industry and Food and Drug Administration Staff.[87] 21 CFR § 11.1(a) recommends manufacturers select a predicate device that meets certain characteristics to support a 510(k) premarket notice submission. However, there is no statutory basis to make or enforce such recommendations. The draft guidance document also recommends manufacturers disclose information regarding their predicate device selection process in a public-facing 510(k) summary. However, this information is not a required element per 21 CFR § 807.92. The disclosure of information sought by the FDA is irrelevant to the determination of a substantial equivalence determination and may inadvertently result in disclosure of proprietary information.

- The Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff[88] appears to change the definition of an implanted medical device as defined in 21 CFR § 860.3(d). The draft guidance document also includes blanket recommendations that do not consider the risk of the device, which is inconsistent with the FDA's longstanding benefit-risk and "least burdensome" principles.

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[86] This recommendation was also voiced by small food industry representatives. *See supra* Section V.C.2.f.

[87] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, INFUSION PUMPS TOTAL PRODUCT LIFE CYCLE: GUIDANCE FOR INDUSTRY AND FDA STAFF (Dec. 2, 2014), https://www.fda.gov/media/78369/download.

[88] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, EVIDENTIARY EXPECTATIONS FOR 510(K) IMPLANT DEVICES: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 7, 2023), CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, EVIDENTIARY EXPECTATIONS FOR 510(K) IMPLANT DEVICES.

- The Use of Clinical Data in Premarket Notification 510(k) Submissions: Draft Guidance for Industry and Food and Drug Administration Staff[89] includes examples and recommendations related to the use of clinical data in 510(k) submissions. This guidance suggests a deviation from the FDA's statutory standard to demonstrate equivalence towards a premarket approval (PMA) standard in which one must demonstrate safety and effectiveness. This is too burdensome and should be eliminated.

g) FDA Draft Guidance: Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling: Draft Guidance for Industry and Food and Drug Administration Staff should be rescinded.[90]

Small medical device stakeholders recommend rescinding this draft FDA guidance as it is overly broad in scope and will impede device discovery and development. This guidance applies to many device types and it goes well beyond the guidance it is intended to supersede. It includes all premarket submissions, including Investigational Drug Exemptions (IDE) applications without any delineation across the product lifecycle. It is inconsistent with the criteria for IDE applications and contrary to the least burdensome approach Congress directed the FDA to take with respect to medical device premarket evaluation that may delay the marketing of beneficial new products.[91] Lastly, the guidance has created much industry confusion considering its conflicts with the FDA established policies and recognized standards, and it does not reflect a risk-based approach. Stakeholders recommend that the FDA withdraw this draft guidance and instead work with industry and other stakeholders to develop a workable, tailored policy done via establishing standards to develop processes.

h) FDA Guidance: Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the Federal Food, Drug, and Cosmetic Act.

The FDA published the final guidance titled, Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act.[92] This guidance updated the previous version of the guidance, of the same title, issued on November 17, 2023, and finalizes the concurrently issued draft guidance titled, Select Updates for the 506J

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[89] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, RECOMMENDATIONS FOR THE USE OF CLINICAL DATA IN PREMARKET NOTIFICATION [510(K)] SUBMISSIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Sept. 7, 2023), https://www.fda.gov/media/171837/download.

[90] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, EVALUATION OF THERMAL EFFECTS OF MEDICAL DEVICES THAT PRODUCE TISSUE HEATING AND/OR COOLING: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Mar. 15, 2024), https://www.fda.gov/media/177004/download.

[91] *See* U.S. FOOD & DRUG ADMIN., THE LEAST BURDENSOME PROVISIONS: CONCEPT AND PRINCIPLES, GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (Feb. 5, 2019) https://www.fda.gov/media/73188/download.

[92] 90 Fed. Reg. 1152 (Jan. 7, 2025).

Guidance: 506J Device List and Additional Notifications. Small medical device representatives recommend that the FDA rescind this guidance and revise its approach to notice under Section 506J of the federal Food, Drug, and Cosmetic Act (FD&C Act) which covers discontinuance or interruption of device manufacturing during a public health emergency (PHE). Stakeholders also believe that the associated guidance which provided a 506J Device List is confusing and unnecessarily wide in scope.[93]

As an initial recommendation, stakeholders suggest that the FDA should withdraw the guidance and focus solely on Section 506J statutory reporting criteria, not "additional notifications." The expectation for expansive Section 506J reporting, referred to as "additional notifications," beyond a PHE will further strain the supply chain while diverting already critical resources from vital manufacturing and response activities. While the FDA may receive voluntary notifications pertaining to a permanent discontinuation or interruption in the manufacture of a device at any time, this concept should not be included in policy guidance for the industry.

The FDA should revise its 506J Device List to focus on what is truly critical in a given or typical PHE consistent with Section 506J and not focus on key devices for which a positive impact on availability can be made during a PHE. The above approach will result in a patient-centric approach tailored to maximize healthcare in a PHE. Before expanding requirements, outstanding challenges with the current system should be addressed by the FDA. More transparency should be implemented around determinations of product shortages and public listing and delisting. Regulators are still absorbing how to interpret and understand the data it receives. With additional reports, it is likely that regulators will not be able to keep pace with maintaining accurate, actionable data. It could also detract from medical technology manufacturers' efforts, who are supplying the products needed for PHEs and the routine practice of medicine while facilitating new innovations for patients.

i) FDA Guidance: Infusion Pumps Total Product Life Cycle.[94]

This guidance was introduced in 2014 with an expectation that a safety assurance case (SAC) would be submitted with all infusion pump 510(k) submissions. The SAC framework was intended to provide an organized case that the infusion pump adequately addresses hazards associated with its intended use within its environment. However, the SAC framework does not achieve its intended goal to improve safety, and it slows the submission and review of innovative devices.

[93] U.S. Food & Drug Admin., *506J Device List*, https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list (last updated Jan. 6, 2025).
[94] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, INFUSION PUMPS TOTAL PRODUCT LIFE CYCLE: GUIDANCE FOR INDUSTRY AND FDA STAFF (Dec. 2, 2014), https://www.fda.gov/media/78369/download.

j) FDA Cybersecurity Guidance Documents.

Stakeholders recommend that the FDA rescind the following two guidance documents: 1) Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software[95] and 2) Information for Healthcare Organizations about the FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."[96]

These guidance documents, issued in 2005, are outdated, given the significant evolution of the cybersecurity landscape over the past two decades. Medical device cybersecurity has matured and evolved substantially, with more robust expectations through § 524B of the Food, Drug & Cosmetic Act, guidance, and industry best practices. Notably, the FDA's Center for Devices and Radiological Health (CDRH) has already identified these guidance documents for review, revision, or withdrawal as part of its retrospective review process. In addition, there is terminology in these guidance documents that are no longer aligned with the FDA's current cybersecurity guidance, potentially leading to confusion among stakeholders. Moreover, content in these guidance documents has largely been supplemented and replaced by the FDA's more comprehensive premarket and post market cybersecurity guidance documents. Rescinding these guidance documents will help ensure that stakeholders are referencing up-to-date, relevant, and consistent cybersecurity expectations.

k) FDA Draft Guidance: Laser-Assisted In Situ Keratomileusis (LASIK) Lasers – Patient Labeling Recommendations.[97]

Small stakeholders recommend that the FDA rescind this draft guidance and engage in a collaborative effort to develop more appropriate patient labeling recommendations. The draft guidance is problematic in that its approach interferes with the patient-physician relationship, is not balanced, and fails to include both the benefits and risks of LASIK procedures.

l) Stakeholders suggest that the following FDA guidance documents should be rescinded.

Stakeholders believe these guidance documents should be rescinded as the issues have been superseded by other recommendations from the FDA: 1) FDA Guidance: Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations – Premarket

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[95] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, CYBERSECURITY FOR NETWORKED MEDICAL DEVICES CONTAINING OFF-THE-SHELF (OTS) SOFTWARE (Jan. 2005), https://www.fda.gov/media/72154/download.

[96] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Information for Healthcare Organizations about FDA's "Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software"* (Feb. 2005), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-healthcare-organizations-about-fdas-guidance-industry-cybersecurity-networked-medical.

[97] U.S. FOOD & DRUG ADMIN., CTR. FOR DEVICES & RADIOLOGICAL HEALTH, LASER-ASSISTED IN SITU KERATOMILEUSIS (LASIK) LASERS – PATIENT LABELING RECOMMENDATIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (July 28, 2022), https://www.fda.gov/media/160239/download.

Notification 510(k) Submissions;[98] and 2) FDA Guidance: User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide-Guidance for Industry.[99]

m) FDA Guidance: Content and Format of Premarket Notification 510(k) Submissions for Sharps Containers.[100]

Medical device representatives recommend that the FDA rescind this guidance as it contains outdated recommendations. There are recent ISO standards (ISO 23907-1 and-2), both consensus standards recognized by the FDA, that cover many of the same product safety and performance requirements included in the guidance document.

n) FDA Guidance: Commercially Distributed Analyte Specific Reagents (ASRs); Frequently Asked Questions.[101]

FDA should rescind this guidance document as it interprets which products qualify as analyte specific reagents (ASRs) inconsistent with (more narrowly than) the regulatory definition of ASRs at 21 CFR 864.4020(a).

o) FDA Guidance: Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program.[102]

The FDA did not provide an opportunity to comment prior to issuing the pilot as a final guidance, and thus it did not capture input on how to structure the pilot for success. To date, no one has enrolled in the pilot, and the FDA officials have previously indicated that they are considering whether to continue the study. To the extent that the FDA does continue the pilot, the guidance is not needed and should be rescinded.

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[98] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff* (July 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hydrogen-peroxide-based-contact-lens-care-products-consumer-labeling-recommendations-premarket.

[99] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry (Apr. 1, 2003), https://www.fda.gov/media/71135/download.

[100] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers (Oct. 1993), https://www.fda.gov/media/72328/download.

[101] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health & Ctr. for Biologics Evaluation & Research, Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions: Guidance for Industry and FDA Staff (Sept. 14, 2007), https://www.fda.gov/media/71127/download.

[102] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Ctr. for Devices & Radiological Health & Oncology Ctr. of Excellence, Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program: Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff (June 20, 2023), https://www.fda.gov/media/169616/download.

p) FDA Should Defer to The American Association of Tissue Banks New Standards to Reduce the Risk of Transmission of Mycobacterium tuberculosis (MTBC) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);[103] and to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) by Eliminating or Revising Its Recently Guidance Documents.[104]

On January 7, 2025, the FDA issued these guidance documents for immediate implementation. The American Association of Tissue Banks (AATB) issued new standards to address MTBC transmission in human tissue implants that were effective January 31, 2025. The FDA should defer to these standards as "solving" any underlying very small risk of MTBC transmission. Further, the guidance documents will, if implemented as written, unnecessarily reduce the already constrained supply of human tissue for implant by at least 38 percent, which would be catastrophic for patients. Finally, at a minimum, tissues that are processed with processes that remove viable cells should be exempted from these guidance documents because those processes by themselves eliminate virtually any risk of MTBC transmission.

q) Pulse Oximeters for Medical Purposes – Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations.[105]

Despite participating in the update of the ISO 80601-2-61 standard with a world renown group of experts in the technology and social sciences, the FDA has issued a guidance document that intentionally diverges from the draft text of the consensus standard and adds significant regulatory burden in a manner that is inconsistent with the available scientific evidence. The FDA's recommendations for a clinical study are so prescriptive that they appear to be attempting to establish a performance standard through guidance without notice-and-comment rulemaking. The FDA is requesting that manufacturers submit 510(k)s with new clinical data even if there are no changes that require submission of a 510(k) pursuant to 21 CFR 807.81(a)(3). Stakeholders recommend that this issue should be rescinded or revised.

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[103] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Recommendations to Reduce the Risk of Transmission of Mycobacterium tuberculosis (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)* (May 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-reduce-risk-transmission-mycobacterium-tuberculosis-mtb-human-cells-tissues-and.

[104] U.S. Food & Drug Admin., Ctr. for Biologics Evaluation & Research, *Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)* (May 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-reduce-risk-transmission-disease-agents-associated-sepsis-human-cells-tissues-and.

[105] U.S. Food & Drug Admin., Ctr. for Devices & Radiological Health, *Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations* (Jan. 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and.

r) The Recall Communications Pilot.[106]

Stakeholders recommend that this pilot program should be rescinded. Communicating corrective actions that could potentially lead to a recall may be premature and result in unintended consequences, since the impact of the corrective action to the patient or general public has not yet been evaluated by either the company or the FDA, or the decision on whether a recall is needed has not yet been determined. Additionally, there are already statutory requirements within the CFR to address corrective actions, corrections or removals, and recalls. This includes requirements for corrective and preventive actions (21 CFR Part 820.100) to identifying any actions needed to correct and prevent recurrence of nonconforming product, requirements for a manufacturer to submit a written report to the FDA of any correction or removal of a device that is initiated if the correction or removal was to address risk to health posted by the device (21 CFR Part 806.10), and guidance for manufacturers when initiating a voluntary recall (21 CFR Part 7). There is already a time requirement in place. The device company is to submit the report to the FDA within 10 working days from the time the company initiates the correction or removal.

s) Update eSTAR Version 5.1 to Remove Enhanced Technical Screening Text.

The electronic Submission Template and Resource (eSTAR) is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission for the FDA. The FDA has recently updated eSTAR and expanded the nature of their Technical Screening hold to make it more like the Refuse-to-Accept process. This update was inconsistent with the governing guidance document and without announcing that the new version was uploaded to the FDA's website. The enhanced Technical Screening text should be removed.

4. Nursing Deregulatory Issues

Nursing stakeholders request that HHS work with the Drug Enforcement Agency (DEA) to revise proposed rules on special registration.

In the final week of the Biden Administration, DEA released a long overdue proposed rule on special registration for telehealth prescribers of certain controlled substances. While stakeholders appreciate that DEA issued this statutorily mandated rule, the proposal contains many provisions that create new regulatory barriers for nurses and patients.

One example of where the proposed rule may have unintended consequences is requiring at least 50 percent of prescriptions in a calendar month not be Schedule II narcotics. DEA does not offer any reason for this number, and it is illogical. Prescribers may have a different patient mix in a

[106] U.S. Food & Drug Admin., *CDRH Announces Communications Pilot to Enhance Medical Device Recall Program* (Nov. 21, 2024), https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-communications-pilot-enhance-medical-device-recall-program.

given month, or they may have other reasons for not issuing specific prescriptions which could cause them to run afoul of the regulations.

Another regulatory provision that creates an unnecessary burden to practice is requiring that patients and practitioners be physically located within the same state. While representatives understand the intention underlying this provision, they recognize that there are areas of the country where it is very common for residents to cross state lines for work, healthcare, and other daily activities due to geographic proximity and ease of care. Often in these cases, a patient would be unnecessarily barred from continuing to receive care from their established and trusted provider simply because their residence is over a state line. Moreover, the rule allows for no exception, even when the provider is licensed in both the state where they are physically located and the state where the patient resides. Nursing representatives urge HHS to work with DEA to explicitly allow for telehealth prescribing across state lines, provided that the practitioner is licensed to practice in both states where the practitioner and the patient are physically located.

Although these rules fall under DEA, both HHS and the FDA have vast expertise and jurisdiction in the fields of health care access and drug regulation, two barriers posed by these proposed rules. Telehealth prescribers are already operating under a waiver that allows patient access. Therefore, it would not be detrimental to telehealth prescribers or consumers to continue operating under the current waiver until a revised proposed rule can be published. Nursing stakeholders believe that HHS and the FDA should use their influence and work with the DEA to pursue rulemaking that does not create new and unnecessary regulatory barriers or burdens.

5. Premium Cigar Industry Deregulatory Issues

a) Premium cigars should be excluded from the Deeming rule (FDA-2014-N-0189).[107]

In the final Deeming rule, the FDA concluded that there was no justification to exempt premium cigars from the regulation, stating that no evidence supported the premise that they have different usage patterns or lower health risks compared to other cigars. Premium cigar stakeholders believe that the FDA's conclusion is counter to various studies that suggest otherwise. For example, the Alcohol, Tobacco, Tax and Trade Bureau's (TTB) consumption data highlight that premium cigars make up a small percentage of the total cigar market, and this trend has been fairly stable over time. This is consistent with the Population Assessment of Tobacco and Health (PATH) survey data, which show that premium cigar use among adults was 0.6–0.8 percent from 2013 to 2018. Other relevant data on premium cigar demographics and frequency of use highlight the industry position that premium cigars are consumed differently than other types of cigars and cigarettes covered by the Deeming rule.[108] As a result of these studies, small premium cigar stakeholders request that they be excluded from the Deeming rule.

[107] 81 Fed. Reg. 28974 (May 10, 2016).
[108] NAT'L ACAD. OF SCI., ENG'G, & MED., PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS 22, 391 (Steven M. Teutschet al eds., 2022), https://doi.org/10.17226/26421; Catherine G. Corey et al., Little

b) Excluding premium cigars from the Very Low Nicotine rule (FDA-2024-N-5471).[109]

In the proposed Very Low Nicotine rule regarding reducing nicotine yield, the FDA acknowledged the August 9, 2023, court ruling that vacated the FDA's Deeming rule on premium cigars. However, the FDA stated that it has appealed the court's ruling and "will consider any associated impacts with respect to this proposed rule and take additional steps as warranted, including for example, by reopening the comment period and/or issuing a supplemental notice of proposed rulemaking." The 2023 court ruling found FDA's decision to include premium cigars in the final rule to be arbitrary and capricious, and it cited a record of commentary and data to support the position of premium cigar companies. Given the August 2023 court order and other documentary evidence presented supporting the stakeholders' position, stakeholders ask that the FDA exclude premium cigars from the Very Low Nicotine rule.

c) Excluding premium cigars from the Tobacco Product Manufacturing Standards Rule (FDA-2013-N-0227-0066).

In the proposed rule titled, Requirements for Tobacco Product Manufacturing Practice,[110] the FDA established a compliance framework related to the manufacture, preproduction design validation, packing, and storage of all types of finished and bulk tobacco products. The proposed rule would impose significant costs on small businesses without sufficient evidence that the requirements would minimize risks associated with their final products. Although the rule's "umbrella" framework is designed to allow flexibility in the establishment of procedures, major elements of the proposed requirements may not be appropriate for the broad spectrum of covered products, including those that are produced following traditional farming and manufacturing practices.

The small entity analysis in the proposed rule identifies 130 small tobacco manufacturing firms and 1,240 small tobacco wholesalers that will be impacted by the regulation. However, the analysis does not attempt to identify or estimate economic impacts to small tobacco farmers, product designers, retailers, or other indirectly impacted entities. The premium cigar industry commented that the Tobacco Product Manufacturing Standards rule is fundamentally unsound, imposing enormous and inappropriate costs for no public health benefits. The premium cigar industry further asserts that the rule "…should be withdrawn or at least exempt premium cigars (and be fundamentally redesigned to agricultural rather than pharmaceutical products)."

Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012– 2013, 63 MORBIDITY & MORTALITY WEEKLY REP. 650 (2014) https://pmc.ncbi.nlm.nih.gov/articles/PMC4584787/pdf/650-654.pdf.

[109] 90 Fed. Reg. 5032 (Jan. 16, 2025).

[110] 88 Fed. Reg. 15174 (Mar. 10, 2023).

Stakeholders recommend that the FDA do the following:

- Adopt the following definition of "premium cigar" in line with what federal courts have already recognized: a premium cigar is *(1) wrapped in whole tobacco leaf; (2) contains a 100 percent leaf tobacco binder; (3) contains at least 50 percent (of the filler by weight) long filler tobacco (i.e., whole tobacco leaves that run the length of the cigar); (4) is handmade or hand rolled (i.e., no machinery was used apart from simple tools, such as scissors to cut the tobacco prior to rolling); (5) has no filter, nontobacco tip, or nontobacco mouthpiece; (6) does not have a characterizing flavor other than tobacco; (7) contains only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weighs more than 6 pounds per 1,000 units.*
- Exempt premium cigars from inappropriate FDA regulation that was never designed with them in mind.
- Protect small businesses from regulatory costs that serve no meaningful public health purpose.
- Ensure long-term stability for manufacturers, importers, retailers, and consumers alike.

d) The FDA should develop consistent cigar categories and definitions used in research.

Small premium cigar stakeholders recommend that the FDA, in consultation with other federal agencies, develop formal categories and definitions for cigars to be used for research to ensure consistency among studies.

6. Herbal Product/Dietary Supplement Deregulatory Issues

Advocacy heard from small herbal products stakeholders including the American Herbal Products Association (AHPA) that made the following suggestions on the HHS RFI.

a) The FDA should remove the requirements for "written assurances" except where explicitly established by statute.

A set of regulations implementing the Food Safety Modernization Act's (FSMA) Preventive Controls for Human and Animal Foods, Foreign Supplier Verification Program and Produce Safety rules, commonly referred to as the "customer provisions," include specific "written assurance" requirements. These require sellers (farmers and food processors) to obtain from their customers (downstream food processors and distributors) and buyers to obtain written assurances from their vendors on an annual or biannual basis and maintain records of these documents.

The requirement to obtain and maintain annual written assurances from customers is a source of massive industry expense and redundant compliance activity, requiring the production of millions of assurance documents annually. For small entities with limited resources or engaged

with multilayered supply chains, it is impossible to obtain the required assurances. The FDA has announced an open-ended policy of enforcement discretion for these requirements.[111]

The assurance requirements are a prime example of a regulation that imposes significant costs to businesses that are not outweighed by public benefits. The recordkeeping requirements involved are not needed or used effectively. They are especially burdensome upon small businesses high in the supply chain.

The FDA should rescind "written assurance" requirements of the abovementioned customer provisions, except where required by law.

b) The FDA inspectors should cite the specific regulation associated with each observation issued on FDA Form 483.

When issuing an inspectional observations report (Form 483), the FDA has established an internal policy to not cite regulations when reporting objectionable conditions or other violations of applicable law.[112] Although an inspector may disclose the regulatory basis for an observation while onsite, there is no written record of this linkage. As a result, when a firm receives a Form 483, it is often unclear what element of the regulation the FDA considers to be applicable to the observation or deficiency.

This information is necessary for transparency, accurate communication, and ease of rapid compliance by the regulated trade. Clear regulatory references following inspection ensure rapid, accurate, and therefore cost-effective compliance by regulated companies, with particular benefit to small businesses in need of greater guidance on regulatory elements at issue. The FDA previously received and denied a Citizen Petition seeking that the agency formally rescind this policy and thereby revise the Inspections Observations Manual to reflect this change. Any business, especially small businesses, would benefit from receiving as much information as possible about the regulatory basis of each Form 483 observation so that management can clearly understand the basis for the problem and what is required to address it.

The FDA should revise the Inspections Operations Manual (IOM) to require that agency investigators include references to underlying current good manufacturing practice (cGMP) regulations in relation to each cGMP-related observation listed in Form 483s issued to conventional food and dietary supplement facilities.

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[111] Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs; Guidance for Industry; Availability, 83 Fed. Reg. 598 (Jan. 5, 2018).

[112] *See* U.S. FOOD & DRUG ADMIN., INVESTIGATIONS OPERATIONS MANUAL CHAPTER 5 – INSPECTIONS, 42 (2025), https://www.fda.gov/media/166533/download?attachment ("However, do not quote regulations when reporting your observations.").

c) The FDA should exempt very small establishments from 21 CFR Part 111.

In promulgating 21 CFR Part 111 in 2007, the FDA estimated that very small establishments having fewer than 20 employees or less than $1 million in annual sales would incur costs of around $46,000 annually to comply with the rule.[113] Stakeholders believe that this highly conservative estimate understated the burdens of compliance for very small dietary supplement firms, which are subject to more expansive and complex compliance costs when compared with their larger counterparts.

Enforcement of 21 CFR Part 111 on dietary supplement facilities operated by very small firms which are operating in a capacity unlikely to create any public health risk is an undue burden on industry not justified by any putative public health benefit.

The FDA should apply a formal policy of enforcement discretion to regarding 21 CFR Part 111 (as well as 21 CFR Part 117 Subparts C and G, which technically would apply in the absence of Part 111 compliance) on very small firms with less than $250,000[114] in annual sales (based on a 3-year rolling average and adjusted for inflation as aligned with current food regulation), where (a) the firm complies with all local health department regulations; (b) for any purchased ingredients that are processed foods, the firm obtains and reviews the vendor's certificate of analysis for each lot to ensure the ingredient is free from contaminants that may adulterate the finished product; and (c) none of the botanical ingredients used by the firm are listed in Safety Class 2a or Class 3 in the American Herbal Products Association's Botanical Safety Handbook (latest edition).

d) Master manufacturing records should be able to declare a range of batch sizes.

21 CFR § 111.205(a) describes the requirement to establish a written master manufacturing record (MMR), and states: "You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch."

In many cases, the quantity of each component must be accurately recalculated for each batch size to maintain the correct proportions. Also, batch sizes that differ greatly may require use of different equipment or other changes. However, there are other means to ensure quality and consistency of a given product across different batch sizes. Therefore, the requirement to create an MMR for every batch size is cumbersome, impractical, and overly prescriptive. The regulation as currently written at 21 CFR § 111.205(a) to require a separate MMR for each batch size of a dietary supplement is both ineffective and imposes unnecessary costs on certain dietary supplement manufacturers. These burdens are especially punishing to small businesses due to

[113] 72 Fed. Reg. 34,752 at 34,917-18, 34,938.
[114] This threshold is intended to reflect ¼ the value set forth defining "very small firms" at 21 CFR § 117.3.

their general applicability and generation of duplicative overhead costs. Stakeholders recommend that the current 21 CFR § 111.205(a) should be amended as follows:

> You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each lot or batch size, to ensure uniformity in the finished ~~batch~~ product from lot to lot and batch to batch, except that a master manufacturing record may cover a range of lot or batch sizes so long as the (a) relative proportions of all components in the formulation, (b) equipment, (c) in- process specifications, and (d) packaging components used all remain the same for all sizes within the range, and so long as each batch record created from the master manufacturing record is reviewed and approved prior to use by quality control personnel to ensure accuracy and appropriateness. Alternately, in cases where ingredient quantities and other manufacturing parameters vary based on lot size rather than batch size, master manufacturing records may cover a range of batch sizes wherein the lot size is fixed but the number of lots per batch may vary. For packaging operations, a separate MMR is not required for each batch size so long as there are no process parameters that vary based on the batch size.

e) Supplement manufacturers should be allowed to work in a facility with only one employee.

The cGMP rule for dietary supplements at 21 CFR § 111.210(h)(3)(ii) describes instruction requirements in a master manufacturing record. This provision indirectly requires that a minimum of two people are needed to perform certain manual operations that involve the weighing, addition, and verification of the weighing and addition of components in a dietary supplement. This requirement is unnecessarily prescriptive and does not reflect modern automated means by which the weight or volume and the addition of components can be verified.

As current 21 CFR § 111.210(h)(3)(ii) would necessarily require a very small dietary supplement manufacturer with only one employee to hire a second employee on at least a part time or occasional basis, this generates a major cost to no clear benefit. It is inappropriate for this specific regulation to impose requirements that would immediately exclude any firm that employs only one person. Existing language from the regulation of infant formula manufacturing practices is available to address this gap.

Consistent with this detail in the infant formula cGMP rule, AHPA requests that the following amendment replace the current § 111.210(h)(3)(ii):

(ii) For manual operations, such specific actions must include:

> (A) One person weighing or measuring a component and another person verifying the weight or measure; and

(B) One person adding the component and another person or system verifying the addition. This verification shall ensure that the correct component is added during the manufacturing process and that the correct weight or measure of the component is added to the batch.

f) The FDA should discontinue the practice of imposing manufacturing cGMP requirements under 21 CFR Part 111 on "own label distributors."

In the preamble to the rulemaking establishing the cGMP regulation at 21 CFR Part 111, the FDA stated:

> "A manufacturer who contracts with a person to do packaging and labeling, but who later distributes the packaged and labeled product, is ultimately responsible for the dietary supplement it releases for distribution. The manufacturer would be responsible for the cGMP requirements for the operations that it performs, including those related to the release of the product for distribution."[115]

The FDA has cited this preamble to the regulation in warning such companies, referred to colloquially as "own label distributors," that they must comply with various parts of the cGMP regarding products manufactured for them by contract manufacturers, such as maintaining master manufacturing records, batch manufacturing records, raw material testing records, etc. These obligations, however, are not spelled out in the cGMP regulations for any type of distribution company and cannot be implemented by a firm engaged in distribution rather than manufacturing.

This extra-regulatory standard is contrary to 21 U.S.C. 342(g), which states in subparagraph (2) that:

> "*...No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code* (emphasis added)."

The FDA has taken a variety of inconsistent positions regarding the scope of applicability of manufacturing cGMP requirements to such firms. In addition to direct burdens upon such companies, this treatment creates major duplicative documentation burdens, as all applicable manufacturing records and documentation are properly created and held by the partnering manufacturer in such a business arrangement. The FDA's current expansive reading of the preamble to the cGMP rule raises the prospect that the FDA's treatment of "own-label distributors" is not based on the best reading of its underlying statutory authority and indeed violates the associated prohibition. The resulting set of regulatory practices creates significant

[115] 72 Fed. Reg., 34,752 at 34,790.

confusion, cost, and duplicative burden to industry with no public health benefit. Of note, the own label distribution model often serves as a market entry point for small business innovators. The current regulatory approach creates an especially severe burden on these entities.

The FDA should direct the Office of Food Chemical Safety, Dietary Supplements, and Innovation and the Office of Compliance and Enforcement to discontinue the practice of imposing manufacturing cGMP requirements under 21 CFR Part 111 on "own label" distributors until such time as appropriate notice and comment rulemaking has occurred to clearly define such entities and establish such requirements.

VI. Conclusion

Advocacy submits these recommendations in response to HHS' Request for Information on deregulatory issues. Advocacy encourages HHS to evaluate these suggestions from small entity stakeholders and revise or eliminate regulations or guidance documents that are a barrier to small business success. Advocacy looks forward to working with HHS on these issues going forward. 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,

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