APhA
American Pharmacists Association

July 14, 2025

[Submitted electronically to www.regulations.gov]

The Honorable Robert F. Kennedy, Jr.
Secretary
United States Department of Health and Human Services (HHS)
200 Independence Avenue SW
Washington, DC 20201

RE: Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again [AQRH-2025-0001]

Dear Secretary Kennedy,

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to HHS's request for information, "Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again." APhA shares HHS's goal of ensuring that health care providers, including pharmacists, can focus on improving the health of the American people by preventing and treating chronic diseases. With this goal in mind, as HHS "is planning the largest deregulatory effort in the history of the Department," APhA recommends the following deregulatory actions to help HHS promote greater utilization of pharmacists to maximize efficiency within the health care system and drive down costs.

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including—but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

President Trump has issued two executive orders promoting deregulation. The first, "Unleashing Prosperity Through Deregulation" (E.O. 14192), issued on January 31, 2025, "directs agencies to eliminate 10 regulations for each new regulation issued ("10-for-1"), and that deregulation leads to significant cost savings."[1] The second, "Ensuring Lawful Regulation

[1] Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again, 90 Fed. Reg. 20478, 20479 (May 14, 2025). Available at: https://www.federalregister.gov/d/2025-08384/p-10.

and Implementing the President's 'Department of Government Efficiency' Deregulatory Agenda" (E.O. 14219) issued on February 19, 2025, states that "the policy of the Trump Administration is to focus the executive branch's limited enforcement resources on regulations squarely authorized by constitutional Federal statutes and commence the deconstruction of the overbearing and burdensome administrative state."[2] This executive order explicitly provides that "agencies are required to identify and report to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget on regulations in one or more of the following categories: (i) [u]nconstitutional regulations and regulations that raise serious constitutional difficulties, such as exceeding the scope of the power vested in the Federal Government by the Constitution; (ii) [r]egulations that are based on unlawful delegations of legislative power; (iii) [r]egulations that are based on anything other than the best reading of the underlying statutory authority or prohibition; (iv) [r]egulations that implicate matters of social, political, or economic significance that are not authorized by clear statutory authority; (v) [r]egulations that impose significant costs upon private parties that are not outweighed by public benefits; (vi) [r]egulations that harm the national interest by significantly and unjustifiably impeding technological innovation, infrastructure development, disaster response, inflation reduction, research and development, economic development, energy production, land use, and foreign policy objectives; and (vii) [r]egulations that impose undue burdens on small business and impede private enterprise and entrepreneurship."[3] In complying with these orders and promoting the Making America Health Again movement, Secretary Kennedy has stated that "making sure that providers and caretakers focus on preventing and treating chronic diseases instead of having to do unnecessary or burdensome paperwork and otherwise comply with Administrative burdensome requirements with no clear health benefit," would be an "important component," of HHS's deregulatory efforts.[4]

To assist HHS's efforts to "produce cost savings, increase efficiency, and stoke health and economic innovation through deregulation," APhA provides the following answers to the proposed questions within the RFI:

Question 1: What HHS regulations and/or guidance meet one or more of the following seven criteria identified in E.O. 14219? Should they be modified or repealed? What would be the impact of this change, especially the costs and savings?

Centers for Medicare and Medicare Services (CMS)

Medicare Drug Price Negotiation

In response to the CMS's May 12, 2025, draft guidance for the Medicare Drug Price Negotiation Program, APhA submitted comments recommending that CMS support pharmacies by ensuring prompt and adequate payment under this program, especially for those anticipating material cash flow concerns, and reconsider mandating pharmacy participation in the program.

[2] *Id.*

[3] *Id.* Available at: https://www.federalregister.gov/d/2025-08384/p-12.

[4] *Id.* Available at: https://www.federalregister.gov/d/2025-08384/p-11.

The mandatory participation of pharmacies in this program, along with the payment and reimbursement processes outlined in this draft guidance, imposes an undue administrative burden on small businesses and may impede patient access to care, particularly in rural and other areas lacking access to any other health care providers.

Prior to the publication of this draft guidance, "CMS finalized in rulemaking a requirement that Part D plan sponsors, starting in contract year 2026, include in their pharmacy agreements provisions requiring the pharmacy to be enrolled in the MTF DM [Medicare Transaction Facilitator Data Module]."[5] CMS noted within its draft guidance "that small pharmacies that rely primarily on prescription revenue to maintain business operations would face material cashflow pressures due to the shift from payment by the Part D plan sponsor to a combination of Part D plan sponsor payment plus a potentially lagged MFP [maximum fair price] refund."[6] Additionally, CMS provided that it is "concerned" about the potential of these cash flow concerns and has taken inadequate action to ensure that patients will have continued access to their local pharmacies and pharmacies will not close due to this burdensome regulation. In response to the commentators who raised this issue to CMS in prior comment periods, CMS stated that it plans to ask pharmacies to self-identify during enrollment if they "anticipate[] having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day MFP payment window."[7] CMS then plans to share that information with Primary Manufacturers, which will be required to include an approach to mitigate such cash flow concerns within their MFP Effectuation Plans. However, this strategy does not solve the problem at hand, as it does not ensure that pharmacies experiencing cash flow concerns will be able to participate in the approaches created by the Primary Manufacturers or those suggested by CMS[8] within the draft guidance. In addition, CMS also imposes additional administrative burdens on the pharmacy, including managing and operating inventory in a specified manner, and leaves many unknowns regarding pharmaceutical wholesale chargebacks (e.g., reimbursement concerns). The solution to this problem is for CMS to prefund the program; however, CMS has made it clear within this draft guidance that it will not prefund the program, forcing community pharmacies to float ongoing costs.

APhA has raised concerns with CMS in previous comments[9] that mandating plan sponsors, including pharmacy benefit managers (PBMs), to include in their pharmacy contracts a

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[5] Chris Klomp, Draft Guidance on the Medicare Drug Price Negotiation Program, Centers for Medicare & Medicaid Services, 71 (2025). Available at: https://www.cms.gov/files/document/ipay-2028-draft-guidance.pdf.

[6] *Id.* at 73.

[7] *Id.*

[8] *See id.* at 77.

[9] *See* APhA Comments to CMS Regarding Medicare Transaction Facilitator for 2026 and 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10912), APhA (Apr. 25, 2025). Available at:

requirement for pharmacies to be enrolled in the MTF DM will force pharmacies to take unsustainable financial losses. Pharmacies are already struggling due to unsustainable reimbursement rates from PBMs, often far below the cost of dispensing these medications, including a minimum of 3% below the cost of dispensing brand medications. This mandate imposes an undue burden on small businesses, which will further harm pharmacies and likely lead to additional closures.[10] As such, APhA recommends that pharmacy participation be voluntary to avoid being subject to underpayment reimbursements from PBMs. If CMS continues to mandate pharmacy participation, it would run directly afoul of the noninterference clause in section 1860D-11(i) of the Social Security Act. APhA notes that CMS has cited this clause as the reason for its inability to protect pharmacies from underwater reimbursements made by the PBMs but points out that CMS is likely "interfering" here by requiring that any contract between the plan sponsor or its PBM and a pharmacy include a provision requiring a pharmacy to be enrolled in the MTF DM, which is not based on the "best reading of the underlying statutory authority."

APhA also supports CMS, not pharmacies, funding the costs associated with the Medicare Transaction Facilitator Payment Module (MTF PM), as any additional financial burdens placed on pharmacies will lead to more pharmacy closures, further limiting patient access to their medications and pharmacist-patient care services. As CMS's recent response to Congress states, CMS only "encourages" Part D plans to improve compensation to pharmacies and states that while, "[e]nrolling in and using the MTF is free for pharmacies and does not place any requirement on them to actually dispense selected drugs under the Part D program."[11] APhA urges CMS to avoid a situation where community pharmacies will be unable to stock or dispense these medications. The current framework and approaches offered by CMS are insufficient. If CMS continues with this framework, APhA encourages CMS to ensure the implementation process and related protocols and procedures work smoothly once required. Any problems with the rollout or administration of the MTF PM will incur costs for pharmacies and pose additional burdens, as they will have to divert staff time and financial resources to address issues that arise during the transitional period.

NCD for PrEP for HIV

In late 2024, APhA sent a letter to CMS regarding the informal guidance related to the Final National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV), which stated that Medicare-enrolled pharmacies would be

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https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=FhUCsGiE6nw%3d. *See also* APhA Comments to CMS Regarding Medicare Price Negotiation Program Draft Guidance, APhA (June 26, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=yijpw7jX3j8%3d.

[10] Ruichen Xu, et al., *Mapping U.S. Pharmacy Closures January 2014 to March 2024*, University of Pittsburgh (May 14, 2024). Available at: https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e.

[11] Letter from Dr. Mehmet Oz, Administrator, U.S. Department of Health & Human Services to The Honorable Earl L. "Buddy" Carter, U.S. House of Representatives (June 23, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=Pu5zcdIsSlU%3d.

unable to bill for HIV PrEP items and services prescribed by pharmacists. CMS required that prescribers of HIV PrEP enroll in Medicare Part B, which pharmacists are not permitted to do as ordering or referring providers. However, there is no legal basis for this exclusion, as it infringes on a state's authority to define and regulate the practice of pharmacy and medicine, is not required by statute for ordering providers of "additional preventive services" including HIV PrEP to be enrolled in Medicare, and is not based on the correct interpretation or the "best reading of the underlying statutory authority." CMS's position appears to be based on confusion regarding authorization to bill for those services and authorization to prescribe those services. CMS's stated rationale for not permitting pharmacists to order HIV PrEP items and services billed to Medicare Part B is that pharmacists are not included in the definition of "eligible professional" under Section 1848(k)(3)(B) of the Social Security Act. That term is defined by statute as: "(i) A physician, (ii) A practitioner described in section 1842(b)(18)(C), (iii) A physical or occupational therapist or a qualified speech-language pathologist, and (iv) Beginning with 2009, a qualified audiologist." Section 1842(b)(18)(C), in turn, describes "practitioners" as "(i) A physician assistant, nurse practitioner, or clinical nurse specialist, (ii) A certified registered nurse anesthetist, (iii) A certified nurse-midwife, (iv) A clinical social worker, (v) A clinical psychologist, (vi) A registered dietitian or nutrition professional, (vii) A marriage and family therapist, and (viii) A mental health counselor." This is clearly an example of "[u]nconstitutional regulations and regulations that raise serious constitutional difficulties, such as exceeding the scope of the power vested in the Federal Government by the Constitution," as medicine, and in this instance, pharmacists' scope of practice is determined by the states, not CMS. Not only does this policy infringe on state authority to define and regulate the practice of pharmacy and medicine, but no statute or regulation requires ordering providers of "additional preventive services" such as HIV PrEP to be enrolled in Medicare, and CMS has not engaged in the requisite notice-and comment rulemaking process to implement such a requirement. Furthermore, such a requirement would amount to arbitrary and capricious action on the part of CMS, as prescriber enrollment is not always required in other similar situations, particularly in the case of drugs used for HIV PrEP that were previously billed under Medicare Part D.

In the case of HIV PrEP items and services, the pharmacy would be enrolled through supplier billing to Part B, and the pharmacist would serve as the ordering/referring/prescribing practitioner. Section 6405(a) and (b) of the Affordable Care Act require ordering practitioners to be enrolled in Medicare for purposes of ordering Durable Medical Equipment, Prosthetics/Orthotics & Supplies (DMEPOS) items, and home health services. Section 6405(c) of the Affordable Care Act also gives CMS discretion to extend the enrollment requirement to all other categories of items or services covered by Part B. Relying on this authority, CMS adopted regulations in 2012 requiring practitioners who order imaging, laboratory testing, and specialist services also to be "eligible professionals" enrolled in Medicare. In other words, under Section 6405 of the Affordable Care Act and 42 CFR § 424.507(a), pharmacists, who are not "eligible professionals" under Section 1848(k)(3)(B) of the Social Security Act, are not permitted to order or refer items or services in the following Medicare benefit categories: DMEPOS items, home health services, and imaging, laboratory testing and specialist services.

HIV PrEP items and services, however, fall into a different Medicare benefit category of "additional preventive services" in accordance with the NCD. Although Section 6405(c) of the Affordable Care Act authorized CMS to extend the provider enrollment requirement to orders or referrals of items and services under any Medicare benefit category, including "additional preventive services," CMS chose to extend the enrollment requirement only to imaging, laboratory testing and specialist services via the formal rulemaking process (in addition to statutory enrollment requirement for DMEPOS items and home health services). Accordingly, APhA urges CMS to permit Medicare-enrolled pharmacies to bill for HIV PrEP items or services that have been prescribed by pharmacists in states that legally authorize pharmacists to prescribe these items.

Signature Requirements

Regarding signature requirements for specific Medicare claims, APhA notes that certain requirements may be overly burdensome, impede access to care, and not aid in the agency's goal of preventing fraud and abuse. Two examples of where an additional signature requirement may not be necessary are the beneficiary's signature on Medicare Part B reimbursement claims under 42 CFR 424.32 and 42 CFR 424.36 and the beneficiary's signature for in-person pickup of Medicare-covered items under 42 CFR 414.57(c)(12). APhA encourages CMS to revise or rescind these signature requirements and any other requirements deemed unnecessary or ineffective in preventing fraud or abuse that provide no benefit to CMS and take time away from pharmacists, pharmacy technicians, and student pharmacists from providing patient care.

Substance Abuse and Mental Health Services Administration (SAMHSA)

While HHS and SAMHSA are not directly involved in enforcing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, the agencies do share regulatory oversight of practitioners and interests of preventing drug misuse with the Drug Enforcement Administration (DEA). Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, practitioners are generally required to conduct an in-person medical evaluation of patients before issuing a prescription for a controlled substance.[12] This statute defines telemedicine as "the practice of medicine in accordance with applicable Federal and ***state law*** [emphasis added] by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42."[13] Pharmacists do have the authority to prescribe controlled substances under state law. Thus, the preceding phrase "and state law" negates the "other than a pharmacist" language and is likely inapplicable to the state-governed practice of medicine. However, the interpretation of this

[12] Public Law 110-425, 122 Stat. 4820 (2008). Available at: https://www.govinfo.gov/content/pkg/PLAW-110publ425/pdf/PLAW-110publ425.pdf.

[13] 21 U.S.C 802(54). Available at: https://www.govinfo.gov/content/pkg/USCODE-2023-title21/pdf/USCODE-2023-title21-chap13-subchapI-partA-sec802.pdf.

statutory definition varies across agencies and within rules. An example of this can be observed by comparing the DEA's delay of final rules titled "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients." In the "Continuity of Care via Telemedicine for Veterans Affairs Patients" final rule, a footnote on this definition explicitly and appropriately states, "This definition of telemedicine does not exclude a pharmacist functioning as a mid-level practitioner authorized to prescribe controlled substances."[14] The "Expansion of Buprenorphine Treatment via Telemedicine Encounter" final rule does not contain this explicit exception within a footnote.[15] As such, APhA encourages SAMHSA to promote the most accurate or "best reading of the underlying statutory authority," which is that pharmacists can practice telemedicine in accordance with state law, because, as stated above, the practice medicine is determined by the states, which is a constitutional issue this RFI specifically seeks to remedy, and directly impacts pharmacists' ability to provide care to their patients.

In addition, under the Mainstreaming Addiction Treatment (MAT) Act and Medication Access and Training Expansion (MATE) Act as part of the Consolidated Appropriations Act of 2023, Congress eliminated the DEA's "X" waiver registration requirement. Within this law, Congress delegated to the Assistant Secretary of Mental Health and Substance Use at SAMHSA the ability to approve additional training organizations for DEA registrants. The statute provides that in addition to the practitioner being authorized by the state to dispense controlled substances, the practitioner must complete at least 8 hours of training related to the treatment and management of patients with opioid or substance use disorders.[16] The statute then lists organizations that can provide this training; however, it excludes training specifically tailored to pharmacists.[17] Congress's intent was not for this to be an exhaustive list based on the "or any other organization approved or accredited by the Assistant Secretary for Mental Health and Substance Use or the Accreditation Council for Continuing Medical Education" language.[18] SAMHSA "has elected not to undertake" the process of approving specific training organizations.[19] SAMHSA's decision not to seek out specific training organizations tailored to pharmacists amounts to SAMHSA not acting in accordance with the actual or "best reading of the underlying statutory authority." Currently, pharmacists requiring this training must utilize training developed by organizations representing physicians, physician associates, nurse

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[14] Continuity of Care via Telemedicine for Veterans Affairs Patients, 90 Fed. Reg. 6524, 6524 (Jan. 17, 2025). Available at: https://www.federalregister.gov/d/2025-01044/p-23.

[15] Expansion of Buprenorphine Treatment via Telemedicine Encounter, 90 Fed. Reg. 6504, 6505 https://www.federalregister.gov/documents/2025/01/17/2025-01049/expansion-of-buprenorphine-treatment-via-telemedicine-encounter#footnote-11-p6505.

[16] Public Law 117-328, 136 Stat. 4459 (2022). Available at: https://www.govinfo.gov/content/pkg/PLAW-117publ328/pdf/PLAW-117publ328.pdf.

[17] *Id.*

[18] *Id.*

[19] *Recommendations for Curricular Elements in Substance Use Disorders Training*, Substance Abuse and Mental Health Services Administration (Apr. 24, 2023). Available at: https://www.samhsa.gov/substance-use/treatment/statutes-regulations-guidelines/mate-act/curricular-elements-training#_edn2.

practitioners, or nurses. SAMHSA's inaction is inhibiting the ability of pharmacists to receive high-quality pharmacy-focused training options to provide the best care for patients with opioid use disorder.

Further, the statute uses the terms "dispense" and "prescribe" within different sections, which has caused confusion. The statute defines a "practitioner" to be someone who "(i) is licensed under State law to prescribe controlled substances; and (ii) is not solely a veterinarian."[20] Within the provision related to the training requirement, it states that practitioners that are not physicians who are "legally authorized by the State to dispense controlled substances under schedule II, III, IV, or V and [are] dispensing such substances within such State in accordance with all applicable State laws," must meet the training requirements.[21] While DEA is tasked with enforcing this requirement, APhA asks SAMHSA to promote the accurate interpretation of the "best reading of the underlying statutory authority," which is that pharmacists only dispensing controlled substances do not need to take this additional training requirement given the definition of practitioner and the fact that the congressional intent of the statute conflicts with the "dispensing" verb utilized within this particular section.

Question 2: What regulations should we reconsider as we look to achieve some of the policy objectives outlined in Executive Order 14212, "Establishing the President's Make America Healthy Again Commission," to focus on reversing chronic disease?

President Trump's "Establishing the President's Make America Healthy Again Commission" executive order provides that "[i]t shall be the policy of the Federal Government to aggressively combat the critical health challenges facing our citizens, including the rising rates of mental health disorders, obesity, diabetes, and other chronic diseases."[22] Further, it states that to achieve this goal, "executive departments and agencies [] that address health or healthcare must focus on reversing chronic disease."[23] During President Trump's first administration, he issued "Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors," which called for the removal of Medicare program requirements that are "more stringent than applicable Federal or State laws require and that limit professionals from practicing at the top of their profession."[24] The Reforming America's Healthcare System Through Choice and Competition report from HHS, the Department of the Treasury, and the Department of Labor also echoed this call by promoting the creation of policies that remove unnecessary barriers to

[20] Public Law 117-328, 136 Stat. 4459 (2022). Available at: https://www.govinfo.gov/content/pkg/PLAW-117publ328/pdf/PLAW-117publ328.pdf.
[21] *Id.*
[22] Establishing the President's Make America Healthy Again Commission, 90 Fed. Reg. 9833, 9834 (Feb. 19, 2025). Available at: https://www.federalregister.gov/d/2025-02871/p-8.
[23] *Id.* Available at: https://www.federalregister.gov/d/2025-02871/p-8.
[24] Protecting and Improving Medicare for Our Nation's Seniors, 84 Fed. Reg. 53573, 53574 (Oct. 8, 2019). Available at: https://www.federalregister.gov/d/2019-22073/p-16.

care.[25] Given their accessibility and expertise, pharmacists are in the prime position to help President Trump and HHS combat the current chronic disease epidemic.

While CMS has yet to take action to ensure pharmacists are reimbursed for their services under Medicare, pharmacists are initiating and prescribing a variety of medications, including tobacco cessation agents, hormonal contraceptives, PEP/PrEP medications, and treatments for strep, flu, and COVID-19, throughout the country, based on their state's authority. Pharmacists also play a crucial role in managing and preventing chronic diseases. Every day, pharmacists make interventions to ensure that patients are on the optimal medication regimen and offer counseling on lifestyle modifications to improve patients' physical and mental health. Many pharmacists also provide more specialized direct patient care services, including continuous glucose monitoring for patients with diabetes, nutritional counseling for patients with cardiovascular disease, patient assessments for patients with mental health disorders, and side effect management for patients with cancer. Pharmacists can also receive training to personalize medication regimens using pharmacogenomic testing, which enables pharmacists to select regimens tailored to a patient's unique metabolism of certain medications, thereby preventing gene-drug interactions and the adverse events that can result.

More state-funded and private health plans are beginning to recognize the full value and potential of payment for pharmacist-provided services, following the expansion of pharmacists' training and authority, through cost savings and improved patient outcomes. However, the federal government is falling behind the states and, unfortunately, bringing those who depend on Medicare with it. For a drastic shift to be seen in health care, more patients need to have easy access to health care providers who are capable not only of managing their current diseases but also of preventing future conditions. With the physician shortage worsening and the costs of treating chronic diseases continually rising, the utilization of pharmacists is a common-sense and necessary step towards a revolutionary breakthrough in the overall health care system. Ensuring that pharmacist-provided care services are covered under Medicare is the next logical step in effectuating HHS's goal of making Americans healthier. Additional opportunities to remove regulatory barriers for physicians utilizing pharmacists under "incident to relationships" are explained under #3, below.

APhA also reminds HHS that as it develops mechanisms to lower drug costs, it needs to separately consider the reimbursement of the product, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment to provide adequate reimbursement under a sustainable business model that improves and does not disrupt our nation's pharmacy distribution system. The current framework fails to provide coverage for the true cost of the medication and any payment for pharmacies to provide the

[25] *Reforming America's Healthcare System Through Choice and Competition*, U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor (Dec. 3, 2018). Available at: https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.

associated patient care services that come with dispensing a medication. Thus, pharmacies are closing at unprecedented rates, leaving both rural and urban Americans living in pharmacy deserts, without access to any form of preventive care or health care provider.[26] Investments in pharmacist-provided direct patient care services not only expand access to care but also ensure these critical hubs of patient care remain open and accessible to patients who need them the most.

Question 3: For more general deregulatory consideration under E.O. 14192, are there additional HHS regulations and/or guidance that: are confusing or unnecessarily complicated; require an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively; impose requirements on the wrong individual or group; carry excessive penalties; are conflicting (examples include but are not limited to conflicts between HHS and State regulations, public and private sectors); impede access to or delivery of care or services; impede efforts to innovate; are obsolete; and/or otherwise interfere with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans? Should they be modified or repealed? What would be the impact of this change, especially the costs and savings?

Centers for Disease Control and Prevention (CDC)

For over 25 years, APhA has been a liaison representative to the Advisory Committee on Immunization Practices (ACIP). APhA has proudly brought our members' expertise from across the country to the table and ensured that the voice of the nation's top and most trusted provider of vaccines is heard. Pharmacists consistently work with patients to balance their individual health conditions and risks with the choice of therapy, whether it be medications or immunizations. As such, pharmacists are best positioned to have these conversations with their patients. No pharmacists serve as voting members of ACIP, despite being the largest providers of adult vaccines. While APhA has supported the applications of pharmacists for such an appointment, none of our candidates have ever been selected. ACIP's recommendations help guide the use of vaccines to control diseases, these recommendations are only adopted as official CDC policy once approved by the CDC Director. Accordingly, APhA encourages CDC to remove any barriers or obstacles to pharmacists being appointed as voting members to the ACIP.

Centers for Medicare and Medicare Services (CMS)

Incident to Billing

Pharmacists are medication experts trained to optimize safe and effective medication regimens. However, the current incident to billing framework not only undervalues the role of

[26] Ruichen Xu, et al., *Mapping U.S. Pharmacy Closures January 2014 to March 2024*, University of Pittsburgh (May 14, 2024). Available at: https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e.

pharmacists within the health care team but also conflicts with the way states reimburse pharmacist-provided services, impedes access to care, and interferes with the private and public sectors' ability to address chronic health conditions. Accordingly, APhA recommends CMS remove the misguided restriction on physicians and nonphysician practitioners (NPPs) utilizing pharmacists under incident to models to bill at the lowest E/M code (99211), with an estimated time commitment of only 7 minutes that was imposed by the 2021 physician fee schedule final rule. This simple action would reduce the administrative burden on physicians and maximize the use of team-based care. CMS should permit physicians or nonphysician practitioners to bill for pharmacists' E/M services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-215) when the care provided supports the use of the higher code, as the majority of states do. Pharmacists are currently providing care and directly billing for services to complex patients in various state and commercial health plans at a level of complexity or time that aligns with E/M codes 99212-99215. Pharmacists' medication management services are more time-intensive and complex than described under E/M CPT code 99211. Despite strong evidence supporting positive outcomes from pharmacists' care,[27] this restriction is preventing their incorporation into team-based care models due to a lack of financial viability and confusion from billing coders that pharmacists' services include medical decision-making, which is not currently included in CPT code 99211. In multiple appropriations bills, Congress has clarified to CMS that "[t]he Committee understands this restriction has diminished providers' engagement with pharmacists in team-based care models across the country, and with provider shortages, this restriction may be furthering health inequities and care access. The Committee encourages CMS to identify mechanisms to attribute, report, and sustain pharmacists' patient care contributions to beneficiaries in the Medicare Part B program."[28]

The following brief case description highlights a common type of visit that pharmacists provide incident to physician services. These types of interventions are crucial for preventing and managing chronic diseases. Pharmacists often spend 15-60 minutes with patients during visits, depending on the patient's level of complexity and whether the visit is an initial encounter with the pharmacist or a follow-up. Eliminating the 7-minute restriction that limits team-based care models to code 99211 would reduce administrative tasks for physicians and free up other health care team members to provide more patient care services.

- Case example from an APhA member pharmacist in a state where pharmacist services are recognized for direct payment: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by a physician to the

[27] *Evidence Supporting Enhanced Medication Therapy Management*, Centers for Medicare & Medicaid Services Center for Medicare and Medicaid Innovation. Available at: https://www.cms.gov/priorities/innovation/files/x/mtm-evidencebase.pdf.

[28] *Report of the Committee on Appropriations House of Representatives Together with Minority Views to Accompany H.R. 8295*, Departments of Labor, Health and Human Services, and Education (July 5. 2022). Available at: https://www.congress.gov/117/crpt/hrpt403/CRPT-117hrpt403.pdf.

pharmacist for a follow-up visit. Patient is experiencing increased fatigue, nocturia, and weight loss. Patient is currently taking 6 medications. Pharmacist reviewed symptoms, evaluated the patient's medication regimen, and discontinued two medications and initiated two new medications in collaboration with the physician. The pharmacist provided education on diet and exercise and counseling on the new medications. The patient does not currently conduct self-blood glucose monitoring (SBGM), and the pharmacist also worked with the patient to initiate SBGM with a plan to consider continuous blood glucose monitoring to monitor progress in the future. A one-month follow-up visit was scheduled. The pharmacist's visit details were reviewed and approved by the supervising provider. Total patient visit time: 42 minutes.

Over $528 billion is wasted and 275,000 lives are lost each year in the United States due to non-optimized medication use.[29] Comparing this to the U.S. expenditure on prescription medications, $340 billion, for every $1.00 spent on drug therapy, we spend an additional $1.55 to address the problems associated with non-optimized drug therapy![30] Pharmacists can play a significant role in the solution. Accordingly, HHS, and in particular, CMS, should remove the restrictions on physicians utilizing pharmacists to provide incident to care services and create direct reimbursement pathways to reimburse pharmacist-provided health care services to drive down costs and improve health outcomes to meet your goal to "Make America Healthy Again."

Diabetes Self-Management Training

Within the Balanced Budget Act of 1997, Congress established diabetes self-management training (DSMT) as a Medicare benefit. Three years later, in 2000, HHS issued its final rule related to DSMT regulations entitled "Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements." This final rule established that "[p]harmacists, though not mandatory members of the team, can participate as optional team members, program coordinators, or team sponsors if they qualify as approved entities} and "have the option of becoming CDEs [Certified Diabetes Educator], which would enable them to be included as core team members."[31] 42 CFR 410.141(d) provides that Medicare Part B covers outpatient DSMT training for beneficiaries with diabetes, and 42 CFR 410.141(e) notes who may furnish these services. Pharmacists are now recognized as certified DSMT providers. DSMTs "furnished by certified DSMT … providers are billable visits in FQHCs

[29] Jonathan H. Watanabe, et al., *Cost of Prescription Drug-Related Morbidity and Mortality*, 52 Annals of Pharmacology 829 (2018). Available at: https://pubmed.ncbi.nlm.nih.gov/29577766/.

[30] *Prescription Drug Spending in the U.S. Health Care System*, American Academy of Actuaries (Mar. 2018). Available at: https://actuary.org/prescription-drug-spending-in-the-u-s-health-care-system/#:%7E:text=Health%20care%20spending%20in%20the,was%20spent%20on%20prescription%20drugs.

[31] Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements, 65 Fed. Reg. 83130, 83138 (Dec. 29, 2000). Available at: https://www.federalregister.gov/d/00-32703/p-128.

[federally qualified health centers] when they are provided in a one-on-one, face-to-face encounter and all program requirements are met."[32] However, CMS reimburses the National Provider Identifier (NPI) for a pharmacy or FQHCs or a registered pharmacy with a Provider Transaction Access Number (PTAN) directly for providing these services, rather than the DSMT provider, such as pharmacists, which significantly limits access to care. As a costly chronic condition, untreated diabetes has significant costs for Medicare beneficiaries. In 2017, complications from diabetes cost over $37 billion among Medicare beneficiaries 65 and older with type 2 diabetes.[33] As clinical integrated pharmacy networks are growing across the country, allowing pharmacists to provide clinically enhanced services in community-based care delivery systems, these networks could serve as a way to ensure continuity of care. If these networks could be recognized as "accredited entities" as accredited DSMT provider hubs, credentialed pharmacists could deliver diabetes care and education services across participating community pharmacy sites. This strategy, similar to the Medicare Diabetes Prevention Program (MDPP) hub model, would allow individual pharmacies that may lack the financial capacity to hire an additional full-time pharmacist to deliver these services independently to participate, ensuring that high-quality, evidence-based diabetes education remains accessible in the community setting. As such, APhA asks CMS to remove the requirement for pharmacists to need to bill through a Medicare supplier, such as a "brick and mortar" accredited pharmacy or an accredited FQHC, and instead utilize their National Provider Identifier (NPI) to bill directly for these vital health care services.

Food and Drug Administration (FDA)

Compounding MOU

In response to FDA's memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between States and the Food and Drug Administration," APhA submitted joint comments with other pharmacy organizations in 2020. The MOU published in 2020 has since been suspended. APhA reminds FDA that the MOU and extension conflicted with state laws, contained provisions that impeded access to and delivery of care, and were confusing. Examining these concerns one by one, APhA notes that certain states were unable to sign on to the MOU due to conflicts with their state laws, which caused patient access issues. For example, if certain conditions are met under section 503 of the Food, Drug and Cosmetic Act, drug products compounded by pharmacists may be exempt from key provisions. One of these provisions that these drug products could be exempted from "is that a compounder located in a state that has not entered into a standard MOU with FDA does not distribute compounded drugs out of the state in

[32] Medicare Benefit Policy Manual Chapter 13 – Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services, Centers for Medicare and Medicaid Services (Mar. 20, 2025). Available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c13.pdf.
[33] *Costs of Diabetes Complications for Medicare Beneficiaries*, CDC (May 14, 2025). Available at: https://www.cdc.gov/diabetes/data-research/research/older-adults.html.

which they are compounded in an amount that exceeds 5 percent of the compounder's total prescription orders dispensed or distributed."[34] This meant that pharmacies in states that were unable or unwilling to sign the MOU were statutorily prohibited from "distributing" more than five percent of their compounded products interstate. This placed an unnecessary restriction on pharmacies in these states, impeding access to and delivery of care. Imagine neighboring states, one of which had signed the MOU and the other had not, during a drug shortage. In such a scenario, compounding pharmacies in the state that had yet to sign onto the MOU would be unable to help alleviate patient access concerns associated with the drug shortage in a neighboring state if they had already distributed more than five percent of their total prescription orders out of state. Furthermore, because FDA attempted to redefine the term "distribution" to include the "dispensing" of compounded drugs, patients who relied on out-of-state pharmacies in states that do not sign the MOU could see their access to compounded medications significantly restricted. Defining "distribution" to include "dispensing" is also confusing, as the terms carry different meanings throughout statutory text and within the profession. Additionally, the inclusion of patient-specific dispensing within the definition of "distribution" is overly burdensome and does not align with the Federal Food, Drug, and Cosmetic Act, unlawfully granting FDA authority over the practice of pharmacy, which again has constitutional concerns and is not "the best reading of the statutory authority." While FDA has no current plans to enforce the five percent limit,[35] APhA encourages FDA not to seek future enforcement and to rescind the MOU and its subsequent proposals and work with compounding pharmacists on a solution that does not decrease patient access to prescribed medications.

ACNU

Earlier this year, APhA submitted comments to FDA's "Nonprescription Drug Product with an Additional Condition for Nonprescription Use" (ACNU) final rule urging FDA to consider delaying the implementation of this rule. This rule revises drug paradigms to allow greater access to certain medications under conditions of safe use.[36] APhA is concerned that this final rule is confusing and complicated, impedes access to and delivery of quality care, and creates patient safety concerns. Accordingly, APhA urges the FDA to withdraw the rule, as the concurrent marketing of prescription and non-prescription versions of the same drug products will lead to patient confusion and patient safety issues.

Having nonprescription drug products with an ACNU at the same point of purchase as those nonprescription drugs without it will lead to confusion among patients, as they may be unfamiliar with the process of meeting qualifying criteria. Additionally, pharmacies and other sellers would need to make significant modifications to their point-of-sale systems to implement

[34] *Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs*, Food and Drug Administration (Oct. 2022). Available at: https://www.fda.gov/drugs/human-drug-compounding/memorandum-understanding-addressing-certain-distributions-compounded-drugs.

[35] *Id.*

[36] Nonprescription Drug Product with an Additional Condition for Nonprescription Use, 89 Fed. Reg. 105288, 105288-89 (Dec. 26, 2024). Available at: https://www.federalregister.gov/d/2024-30261/p-46.

a "stop" feature, ensuring that the person selling the product confirms the patient has completed the ACNU self-assessment correctly. To avoid making this modification, pharmacies and sellers may move these products behind the counter to ensure that this additional step is satisfied. Once behind the counter, patients would have more limited access to reading the labeling and knowing that the product is available without a prescription. Patient confusion about the difference between the prescription and nonprescription versions of the same drug product, along with the need to ensure patients have completed the appropriate self-selection condition and are eligible to use it safely, will likely force pharmacies and other sellers to put mechanisms in place to ensure customers cannot acquire these medications without going through the proper protocols.

Pharmacists play an integral role in assisting patients to determine whether a particular nonprescription drug product with an ACNU is appropriate for each patient's health care needs. Patients may not be aware that they suffer from an underlying condition that may be worsened by that medication or are taking another drug or natural supplement that might result in an adverse drug reaction. The protocols within the self-assessments under the ANCU cannot replace the expertise of a pharmacist. As such, APhA strongly recommends FDA rescind this rule to ensure that patients consult with a health care provider, such as a pharmacist, before initiating a new medication under this framework.

<u>Oppose Drug Importation</u>

President Trump's desire to ensure that prescription medications are more affordable for Americans is commendable; however, these efforts should not be centered around the unsafe personal or commercial importation of prescription drugs from other countries. Regulations stemming from executive action, as well as federal legislation, often fail to recognize the additional risks associated with importation, including the impediment to health care providers delivering care. For example, patients seeking to obtain medications from pharmacies in Canada are required by law to establish a relationship with a Canadian-licensed physician. This can lead to suboptimal care, as these patient-provider relationships often are not documented in a patient's health record, resulting in fragmented care. Additionally, this can lead to incomplete medication lists and polypharmacy, increasing the risk of drug interactions and other adverse events. Furthermore, state importation programs would increase the flow of illicit, counterfeit, and misbranded medications into the United States, as fraudulent and illegitimate online pharmacies, disguised as legitimate pharmacies in other countries, may target susceptible patients seeking cheaper medications. As such, APhA encourages FDA to rescind regulations and Section 804 Importation Program (SIP) applications from states to import drugs from other countries that put patients at risk by allowing the use of drugs that do not meet U.S. gold-standard quality and safety standards.

Office of Inspector General (OIG)

HHS's Office of Inspector General (OIG) has confirmed that payments to PBMs under rebate agreements are not covered by an anti-kickback safe harbor for discounts if they "are not passed

through to any buyer."[37] In 2020, the first Trump Administration's OIG finalized its previous 2019 proposal to exclude certain rebates paid by drug manufacturers from the discount safe harbor to the federal anti-kickback statute (AKS).[38] The final rule was intended to implement President Trump's blueprint for lowering prescription drug prices and patient out-of-pocket costs, as well as President Trump's Executive Order 13939, "Lowering Prices for Patients by Eliminating Kickbacks to Middleman," but was delayed by the Biden Administration and the Inflation Reduction Act until 2027. APhA urges CMS to fix this to achieve President Trump's goals and use its full regulatory authority to implement these changes to the AKS and to also include PBMs' use of retroactive direct and indirect remuneration (DIR) fees in the definition of "discounts," that CMS found in 2021 had increased by an astonishing 91,500% over the past nine years.[39]

APhA appreciates the opportunity to provide HHS with recommendations for eliminating unnecessary, burdensome regulations and red tape that hinder pharmacists' ability to best serve their patients. APhA urges HHS to address the above issues, as pharmacists and pharmacies play a crucial role in preventing and treating chronic diseases. As the Secretary notes, "HHS cannot accomplish this feat alone." APhA is committed to working with HHS to achieve our shared goal to ensure that Americans live healthier lives by unlocking and maximizing the full value of pharmacist-provided patient care services. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

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[37] *General Questions Regarding Certain Fraud and Abuse Authorities*, HHS Office of Inspector General (May 31, 2024). Available: https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

[38] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 85 Fed. Reg. 76666 (Nov. 30, 2020). Available at: https://www.govinfo.gov/content/pkg/FR-2020-11-30/pdf/2020-25841.pdf.

[39] Justification of Estimates for Appropriations Committees, Centers for Medicare & Medicaid Services 242 (2022). Available at: https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf.