



September 11, 2026

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1848-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements (CMS-1848-P), 91 Fed. Reg. 43842 (July 16, 2026)

To Whom It May Concern:

The Alliance for Safe Online Pharmacies (ASOP Global) respectfully submits the following comments in response to the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2027 Physician Fee Schedule (PFS) proposed rule.

ASOP Global is a nonprofit, multi-stakeholder coalition dedicated to protecting patients from the dangers posed by illegal online drug sellers. ASOP Global convenes pharmaceutical manufacturers, telehealth companies, practitioners, payers, payment processors, academic researchers, and patient advocates in a shared mission to combat the growing threat of unsafe medicines sold illegally online.

Executive Summary

Americans have moved rapidly to obtaining prescription medicines online, and the safety conversation that once accompanied a visit to the pharmacy counter has not moved with them. ASOP Global asks CMS to recognize medication sourcing safety as a legitimate patient-safety concern within the Quality Payment Program, and to encourage practitioner organizations, pharmacy regulators, and patient advocates to support interventions aimed at reducing patients' risk of buying prescription drugs from unlicensed sources. Two findings support that request.

First, practitioners are already the most influential voice in where patients buy. Among Americans who purchase prescription medicines online, 49% report that a practitioner recommended a specific online source — more than pharmacists (31%), health insurers (27%), or family and friends (27%).¹ Second,

¹ASOP Global Foundation, 2025 U.S. Consumer Behavior Survey (Abacus Data; fielded online August 22–26, 2025; n=1,501), 2025, <https://asopfoundation.pharmacy/wp-content/uploads/2025/11/ASOP-Foundation-2025-Consumer-Behavior->

practitioners have not been equipped for that role. Approximately 2% of practitioners have received any training on identifying counterfeit medicines or counseling patients about them, and 89% report not knowing what actions they can take to protect patients.²

Section VI sets out several approaches CMS might take, ranging from acknowledgment in preamble discussion to a distinct Improvement Activity. We are not proposing a documentation mandate, and we are not proposing that practitioners themselves verify pharmacies or assume responsibility for where a patient ultimately purchases; Section VII sets out in full the limits we would place on any approach CMS adopts. We look forward to working with CMS towards our shared goals of healthcare quality improvement and patient safety.

I. A Change in How Patients Obtain Medicines

Americans increasingly obtain prescription medicines outside the traditional brick-and-mortar pharmacy, driven by advances in technology, rising medication costs, drug shortages, and a fragmented delivery system. Telehealth platforms, mail-order fulfillment, and direct-to-consumer arrangements have expanded access in ways that are often beneficial to patients and, when operated lawfully, entirely appropriate.

This shift in medication sourcing habits has an unintended consequence. Where a medicine is ordered online and shipped to the patient's door, the patient may never stand at a pharmacy counter — and the pharmacist counseling interactions that have anchored medication safety for generations may never occur. No one designed this outcome. The delivery model moved, and the safety conversation did keep pace.

The result is not that patients have become careless. Pharmacist counseling is a step that Congress mandated by law and that the health care system performed on the patient's behalf. Where a medicine is bought online, that step is now, in effect, the patient's own: to seek out information about the medicines they are prescribed and about where to buy them safely. Few patients have been given the tools to make that informed decision.

II. Patients Are Trying to Verify — and Cannot

38% of U.S. adults report having purchased prescription medicines online for home delivery, and among those purchasers 55% now obtain all or most of their prescriptions that way. 73% began doing so within the past three years.³ This is a recent and rapidly consolidating change in behavior, not a marginal one.

[Survey.pdf](#). The 2025 survey instrument used the term “health care provider.” This comment uses “practitioner” as a broad term to include both physician and non-physician health providers

² Koffi AK, Michalik HJ, Merchant L, Pal E, Kubiak L, Rusatira JC, Ahmed S: Awareness and Current Practice of Healthcare Providers Regarding Counterfeit, Substandard, and Falsified Medicines: Results from an Online Survey in the United States and South Africa. In.; 2023. <https://fakemedicinenomore.org/2024-besafe-symposium/>

³Supra note 1.

ASOP Global Foundation's 2025 national survey of 1,501 U.S. adults found that among Americans who purchase prescription medicines online, 91% report that they verify that the seller is a licensed pharmacy — always (56%) or sometimes (35%). But when asked how they verify, only 39% name an official verification source: the National Association of Boards of Pharmacy (NABP), a state board of pharmacy, LegitScript, or PCAB. A related finding suggests why the gap persists. 46% of online purchasers report submitting their prescriptions by email, scan, or fax — a practice inconsistent with NABP standards, and one that a patient reading a professional-looking website has no way to recognize as irregular.⁴

Patients are not declining to verify. They believe they are verifying appropriately but are not verifying primary-source confirmation of licensure. The distance between those two figures is where preventable harm occurs.

That distance has persisted for nearly a decade. An earlier ASOP Global survey, conducted in 2017, found that fewer than 5% of consumers were aware that verification tools existed at all — including NABP's .Pharmacy program and LegitScript's URL checker.⁵ Awareness has not improved at the pace of the behavior: online purchasing has grown exponentially over the same period, while the share of purchasers consulting an authoritative verification source remains under 40%. This gap has not closed on its own in the last decade, and there is little reason to expect that it will.

That gap is exacerbated by reasonable but mistaken assumptions about how the online marketplace is regulated. 65% of U.S. adults believe that websites selling prescription medicines are reviewed or approved by the Food and Drug Administration or state regulators, and 51% believe that verified sellers appear on the first page of search results. Among online purchasers themselves, those figures rise to 75% and 64%.⁶ These are not unreasonable beliefs. They describe how patients expect a regulated market to work; it simply does not describe the internet.

III. Practitioners Are Already in This Conversation

The most striking finding in ASOP Global Foundation's 2025 survey concerns practitioners. Among Americans who purchase prescription medicines online, 49% report that a practitioner recommended they use a specific online source — more than pharmacists (31%), health insurers (27%), or family and friends (27%). Among online GLP-1 purchasers the figure rises to 67%.⁷ Practitioners are the single most influential voice in where patients obtain medicines online.

⁴Supra note 1.

⁵ASOP Global, Online Pharmacy Consumer Behavior and Perception Survey, 2017, <https://buysaferx.pharmacy/public-awareness-campaigns/drug-importation/factsheets/online-pharmacy-consumer-behavior-and-perception-survey/>. Methodology: poll of 500 registered voters in Indiana conducted over five days in May 2017 by Baselice & Associates, Inc. (33% online panel, 37% landline, 30% mobile); ASOP Global reports that the sample's gender and age distribution approximate national averages. Offered here as historical context rather than as a current national estimate.

⁶Supra note 1.

⁷Supra note 1.

We want to be careful about what this does and does not mean. It does not mean practitioners are intentionally directing patients to unsafe sellers. In the great majority of cases a practitioner is pointing a patient toward a legitimate mail-order benefit or home-delivery pharmacy, often to solve a real problem of cost or access. What it does mean is that the referral into online purchasing frequently originates in the clinical encounter — and that a recommendation to use an online pharmacy is not the same thing as guidance on how to confirm that a particular seller is safe and licensed. Patients listen to the first half of that conversation and then search widely online — therein lies the risk we need to address.

Patients also return to practitioners when something goes wrong. 48% of online purchasers say they would report a problem to their practitioner — ahead of pharmacists, the seller, or the FDA.⁸ Practitioners are the first call before the purchase and the first call after the harm. The one point at which they are currently absent is the moment in between, when the information would still be protective.

IV. Practitioners Have Not Been Equipped for Educating on Safe Sourcing

If practitioners are not completing that conversation, the evidence suggests the reason is not indifference. Research by the BESAFE initiative at the Johns Hopkins Bloomberg School of Public Health found that approximately 2% of practitioners have received any training on identifying counterfeit medicines or counseling patients about them, and that 89% report not knowing what actions they can take to help protect patients.⁹

That is not a finding about practitioner commitment. It is a finding about a subject that has never been part of professional training, never been supported by practice tools, and never been anyone's defined responsibility. Practitioners have been placed at the center of a patient safety decision without being given anything to work with.

We think this is the most important fact in the record, because it reframes the question. The issue is not whether practitioners should be doing something they are declining to do. It is whether the system should equip them for a conversation they have already initiated with patients.

V. Precedent: What OBRA '90 Assumed

Congress addressed a version of this question thirty-six years ago. The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) required states, as a condition of federal Medicaid participation, to establish standards under which pharmacists offer to counsel patients presenting a prescription.¹⁰ The mechanism is instructive: Congress did not mandate a mode of practice. It conditioned participation in a federal program on the availability of a safety conversation.

⁸Supra note 1.

⁹Supra note 2.

¹⁰Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508; 42 U.S.C. § 1396r-8(g)(2)(A)(ii); 42 C.F.R. § 456.705. See also Centers for Medicare & Medicaid Services, Drug Diversion Toolkit: Patient Counseling — A Pharmacist's Responsibility to Ensure Compliance (2014), <https://www.cms.gov/files/document/patientcounselingbooklet111414pdf>.

The content of that conversation is equally instructive. The statute enumerates what the pharmacist must offer to discuss: the description of the medication; dosage form, route, and duration of therapy; precautions and interactions; storage; refills; and what to do if a dose is missed.¹¹ Every enumerated item concerns how to use a medicine the patient already holds. None concerns where the medicine came from.

That omission was not an oversight. In 1990, the source of a prescription medicine was not a variable. A patient presenting a prescription was standing in a state-licensed pharmacy, and the integrity of the source was guaranteed by the structure of the transaction. Congress had no reason to legislate a conversation about a risk that the architecture had already eliminated.

That assumption no longer holds for every patient. The counseling framework has not failed — the premise underneath it has changed. What is missing today is not a better version of the pharmacist's conversation, but a conversation about a category of risk that did not exist when the framework was built.

VI. Approaches for CMS's Consideration

ASOP Global does not come to CMS with a fixed view of the right instrument. We recognize that CMS is best positioned to judge which program vehicle fits this issue, and that practitioner organizations are best positioned to judge what is workable in practice. We therefore offer a range of approaches CMS might consider, from the most modest to the most fully developed:

- **Signal interest.** CMS could acknowledge medication sourcing safety as an emerging patient-safety concern in preamble discussion, or seek comment through a future request for information, without adopting any requirement.
- **Recognize the activity within existing structures.** CMS could clarify that counseling on safe medication sourcing may count toward existing Improvement Activities relating to patient safety, health literacy, or medication management — recognizing MIPS eligible practitioners who already do this without creating anything new.
- **Establish a distinct activity.** CMS could add a new Improvement Activity, potentially within the Advancing Health and Wellness subcategory, recognizing MIPS eligible practitioners who offer patients guidance on obtaining medicines from licensed sources.
- **Convene rather than regulate.** CMS could bring practitioner organizations, pharmacy regulators, and patient advocates together to determine whether a clinical intervention is warranted at all, and what form would be least burdensome if so.

¹¹42 U.S.C. § 1396r-8(g)(2)(A)(ii)(I) (enumerating the name and description of the medication; dosage form, dosage, route of administration, and duration of drug therapy; special directions and precautions; common severe side effects, interactions, and contraindications; techniques for self-monitoring; proper storage; refill information; and action to be taken in the event of a missed dose).

We would support any of these. We would also welcome an approach CMS or other commenters identify that we have not anticipated.

VII. On Practitioner Burden

We want to be direct about a concern we expect other commenters to raise, and which we share.

Practitioners face substantial and growing documentation obligations, and the history of well-intentioned additions to the clinical encounter is not encouraging. We are not proposing a documentation mandate. We are not proposing that practitioners verify pharmacies, evaluate sellers, or assume responsibility for where a patient ultimately purchases. We would oppose any approach that placed a meaningful new administrative load on the clinical encounter, and we do not believe such an approach is necessary to address this gap.

If CMS pursues this question, we would urge that any resulting activity be attestation-based rather than documentation-intensive, be satisfiable by any part of the care team (including technology-assisted counseling) and be designed with direct input from the practitioner organizations that would carry it out. We would also urge CMS to treat the offer of guidance — not the patient’s acceptance, and not any downstream outcome — as the operative act, consistent with the OBRA ’90 model.

One further observation. Because a conversation about where to buy medicines online is already occurring in roughly half of these clinical encounters — the practitioner recommends an online source, and the exchange ends there — the question is not whether to add an interaction but whether the interaction already taking place should end where it currently ends. Framed that way, the incremental burden is measured in seconds and a link — and the greater burden may fall on practitioners who currently field the call after something has gone wrong.

If CMS pursues this question, we would urge that any resulting activity be attestation-based rather than documentation-intensive, be satisfiable by any part of the care team (including technology-assisted counseling) and be designed with direct input from the practitioner organizations that would carry it out. We would also urge CMS to treat the offer of guidance — not the patient’s acceptance, and not any downstream outcome — as the operative act, consistent with the OBRA ’90 model.

Should CMS find the question worth pursuing, existing public health models suggest the intervention need not be elaborate. The “5 A’s” framework used in tobacco cessation¹² and the screening and brief intervention model used for unhealthy alcohol use¹³ both demonstrate that a short, structured exchange at the point of care can identify risk and deliver targeted guidance without significant disruption.

¹²Agency for Healthcare Research and Quality, Five Major Steps to Intervention (The “5 A’s”), 2012, <https://www.ahrq.gov/prevention/guidelines/tobacco/5steps.html>

¹³U.S. Preventive Services Task Force, Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement, 2018, <https://pubmed.ncbi.nlm.nih.gov/30422199/>.

Applied here, the first two steps of the “5 A’s” carry nearly all of the protective value:

- **Ask.** “Where are you getting your prescription medicines?” For most patients the answer is a local pharmacy or a mail-order benefit, and the conversation ends there. The question is brief, non-judgmental, and universally applicable.
- **Advise.** Where a patient is purchasing or considering purchasing online, the practitioner or care team member points to an authoritative verification resource — the National Association of Boards of Pharmacy’s safe.pharmacy, LegitScript, or the patient’s own state board of pharmacy, each of which maintains a public licensure lookup. The guidance is specific and actionable, and it requires no expertise in pharmacy licensure.

The remaining steps — exploring why a patient is seeking an alternative source, sharing a verification tool, and revisiting the subject at follow-up — represent opportunities for deeper engagement where clinical judgment warrants, not a threshold any practitioner must meet. We note that “Verify Before You Buy” is already familiar language in federal public awareness efforts, which may ease implementation and reduce the need for new patient-facing materials.¹⁴

IX. Illustration

A Medicare beneficiary with type 2 diabetes is prescribed a GLP-1 receptor agonist. At her pharmacy, she learns her out-of-pocket cost. She may fill the initial prescription there, but many patients in her position will eventually search online for a lower price. She finds a site that presents professionally, offers a price she can afford, displays what appears to be an accreditation seal, and asks her to complete a brief questionnaire in place of a prescription.

She looks at the site, reads its assurances, and concludes it is legitimate. In doing so she is entirely typical: 91% of online purchasers believe they verify licensure, yet only 39% consult a source that could actually confirm it.¹⁵

At no point in her care was she asked where she intended to obtain the medicine, and at no point was she told that a public tool existed to check. The question would have taken seconds. It was simply never anyone’s to ask.

The aggregate consequences are not small. Analysis by the IQVIA Institute for Human Data Science estimated that illegal online pharmacies dispensed approximately 416 million prescriptions in the United States between 2017 and 2022, that roughly 12.6% of U.S. adverse drug events may be linked to medicines obtained from such sellers, and that the associated additional annual U.S. health care cost

¹⁴“Verify Before You Buy” has been used in public awareness efforts by U.S. government partners including the National Intellectual Property Rights Coordination Center and the U.S. Department of Homeland Security, and in ASOP Global Foundation public education campaigns.

¹⁵Supra note 1.

approaches \$67 billion.¹⁶ Those estimates capture harms that can be observed and attributed. They do not capture the effect of medicines that simply do not work: a substandard product containing too little active ingredient produces a treatment failure that is rarely traced back to its source, and it has not yet been possible to estimate that burden. Whatever the precision of any single estimate, the order of magnitude suggests that a conversation costing seconds is worth examining seriously.

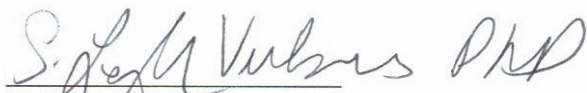
X. Conclusion

We opened by saying we came to raise a question rather than press an answer. On one point, however, we do not think the question is genuinely open. In roughly half of cases a practitioner is already telling the patient where to buy. The prescriber is the last licensed professional a patient sees before deciding, and frequently the first one they call afterward. If a conversation about safe sourcing is going to happen anywhere in the care pathway, it will happen in the clinical encounter — or it will not happen at all.

We therefore ask CMS to take this issue up in the CY 2027 cycle — to recognize medication sourcing safety as a legitimate patient-safety concern within the Quality Payment Program and to invite practitioner organizations, pharmacy regulators, and patient advocates into a structured conversation about what should follow. That first step asks nothing of any practitioner, and yet everything that might eventually protect patients depends on it.

ASOP Global stands ready to serve as a resource to CMS on this topic, and we would welcome the opportunity to provide additional research, data, or technical assistance. We appreciate the opportunity to comment on the CY 2027 PFS proposed rule.

Respectfully submitted,

A handwritten signature in dark ink, reading "S. Leigh Verbois PhD". The signature is fluid and cursive, with the first name "S. Leigh" and the last name "Verbois" clearly legible, followed by "PhD".

S. Leigh Verbois, PhD

on behalf of the ASOP Global Board of Directors

¹⁶IQVIA Institute for Human Data Science, Assessing the Impact of Illegal Online Pharmacies in the U.S., 2023, <https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/assessing-the-impact-of-illegal-online-pharmacies-in-the-us>