COLORADO
Department of Health Care Policy & Financing
303 E. 17th Ave. Suite 1100
Denver, CO 80203

Date July 14, 2025

BY ELECTRONIC FILING (via www.regulations.gov)
Jennifer Burnszynski and Laina Bush
Office of the Assistant Secretary for Planning and Evaluation
200 Independence Avenue, SW, Room 424-E
Washington D.C., 20201

Re: Request for Information: Docket No. AHRQ-2025-0001

Dear Ms. Burnszynski and Ms. Bush,

On behalf of the Colorado Department of Health Care Policy & Financing (HCPF), we appreciate the opportunity to provide comments in response to the Health and Human Services (HHS)'s Agency for Healthcare Research and Quality (AHRQ) Request for Information: Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again (AHRQ-2025-0001). We appreciate AHRQ's efforts to identify federal rules that may be outdated, unduly burdensome, or in need of amendment. HCPF has the privilege of being the single state agency that administers the state's Medicaid program as well as pursuing policy solutions to save Coloradans Money on Health Care which includes Colorado's Drug Importation Program. We respectfully provide comments on deregulatory opportunities in both of those spaces.

Medicaid

HCPF respectfully requests that HHS rescind or extend deadlines by no less than an additional two years out (2027) for states to implement the following federal rules (Managed Care, Access, Interoperability, and Eligibility Rules), and not impose federal financial participation (FFP) reductions or withholding or other penalties on states:

1. The Managed Care Rule, Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality; Correction 42 CFR Parts 430, 438, and 457
2. The Access Rule, Medicaid Program; Ensuring Access to Medicaid Services 42 CFR Parts 431, 438, 441, and 447
3. The Interoperability Rule, Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive

Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program 42 CFR Parts 422, 431, 435, 438, 440, and 457, and 45 CFR Part 156. HCPF submitted a request per CMS requirements for an extension on March 31, 2025.

   a. HCPF respectfully requests this rescission or additional two-year implementation extension (2027) include the aspects of the rule related to the Provider Directory API requirement per 85 FR 25510 and SHO #24-003, as well, by exercising enforcement discretion concerning this deadline. HCPF requests reductions to FFP from 75 percent to 50 percent for expenditures for the operations of non-compliant functionality or system components not be imposed during this extension time period related to the Provider Directory API requirements.

4. Eligibility Rules, including:
   a. Streamlining Medicaid; Medicare Savings Program Eligibility Determination and Enrollment 42 CFR Parts 406 and 435
   b. Medicaid Program; Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes 42 CFR Parts 431, 435, 436, 447, 457, and 600

Final Rule on Importation of Prescription Drugs, codified at 21 CFR Parts 1 and 251.

HCPF appreciates the continued communication and partnership with FDA regarding the status of Colorado's pending Section 804 Importation Program (SIP) Proposal and appreciates the Final Rule's foundational framework for the importation of prescription drugs from Canada. HCPF is committed to successfully importing prescription drugs from Canada in a safe, cost-effective, and administratively workable manner.

However, we are concerned about requirements in the rule that rely extensively on manufacturer cooperation, restrict supply chain flexibility, and impose unnecessary program shipping costs, the ability for importation programs to be arbitrarily paused or ended, and FDA's current guidance regarding imported drug relabeling processes. Please find below HCPF's comments about how the rule can be made less burdensome and still support importing prescription drugs from Canada in a safe, cost-effective, and administratively workable manner.

1. **Manufacturer Cooperation:**
   a. The Final Rule is silent on the practical necessity for direct negotiation with manufacturers, even though Canadian wholesalers typically operate under contracts barring export to the United States. Because the rule does not anticipate this scenario, states are left with no clear regulatory path for incorporating negotiations into their SIPs. We have raised this issue with FDA since 2023[1] and continue to urge our federal partners to issue supplementary guidance or amend the rule to clarify how a SIP might proceed in compliance with labeling, attestation, and other requirements when direct manufacturer negotiations are required to secure product supply. As reflected in public

[1] Colorado SIP Application Appendix H, FDA Correspondence (Pages 16-34)

petitions and in direct outreach to companies,[2] manufacturers have repeatedly indicated a reluctance to participate. This dynamic has the potential to undermine our ability to implement a Section 804 importation program. Colorado has already devoted significant time and resources trying to navigate this legal gray area, which has already impeded progress toward implementation and discouraged potential partners. **Allowing the FDA to impose reasonable manufacturer incentives or other means to encourage participation would further safeguard the viability of state-led SIPs, thereby generating much needed savings for Coloradans.** Without such measures, manufacturer intransigence is likely to create a significant barrier to the success of any state importation effort.

b. We also call attention to provisions at 21 CFR 251.16 that place substantial responsibilities on drug manufacturers, including the need to provide timely attestations and disclosures to U.S. Importers or other SIP participants. In practice, we have found that manufacturers will likely resist these requirements, which will lead to delays or complete nonparticipation. **We therefore urge the FDA to restore or incorporate language similar to what was proposed in 21 CFR 251.16(i) of the Notice of Proposed Rulemaking (NPRM),[3] under which the FDA could provide the necessary information to the Importer if a manufacturer fails to do so.** We believe that adopting such authority in the event of manufacturer noncompliance would mitigate this risk and help avoid the frequent stalemates that arise when manufacturers simply decline to cooperate with a SIP. Reducing direct reliance on manufacturers for operational data or confirmations and supporting FDA's responsibility in these actions would foster more predictable, streamlined compliance and reduce the risk that a manufacturer can unilaterally derail an entire importation program in direct opposition to Congress' and FDA's clear intentions.

2. **Lack of supply chain flexibility:** The language at 21 CFR 251.3(b) restricts an initially authorized SIP to a single designated Foreign Seller.[4] Consequently, a state must rely on a singular Canadian Foreign Seller as the program becomes established.[5] This creates undue burden and unnecessary risk to the Foreign Seller, and the SIP Sponsor, by allowing drug manufacturers to punish that single Foreign Seller by curtailing or refusing product sales. This limitation hinders robust competition and jeopardizes Colorado's ability to import prescription drugs under the program in a manner that reliably delivers cost savings to Coloradans. **We respectfully recommend that the Final Rule be revised to permit supply chain flexibility** so Colorado can protect our contracted partners, including Colorado's Foreign Seller, i.e., flexibility permitting multiple Foreign Sellers or unique contracting relationships to procure imported drugs to support importation programs. This simple change will not overly burden the FDA's oversight because all

[2] Colorado SIP Application Appendix H, FDA Correspondence (Pages 28-29)

[3] NPRM - Importation of Prescription Drugs 12.18.19

[4] Colorado's pending SIP with FDA has one singular foreign seller as per regulatory requirements.

[5] Drug Importation Final Rule (page 23-24)

Foreign Sellers and their compliance programs will be laid bare for the agency's review. It also will limit manufacturers' (and even large distributors') abilities to punish participants. Like any free market, more suppliers increase competition and thus reduce costs.

3. **Overly complex supply chain steps for testing, labeling, relabeling, and distributing prescription drugs:** Currently, imported drugs must undergo multiple, often redundant, transitions within the supply chain after importation for sampling and testing, relabeling, and the admissibility decision before they can be made available for distribution. Though well intentioned, this approach is unnecessarily cumbersome, adds significant costs, and reduces savings. There are multiple ways the process could be simplified. For example, FDA could allow sampling for statutory testing[6] to take place in Canada. This one step would speed up the testing process and avoid duplicative shipping while minimizing administrative burdens and related costs. In addition, after testing is approved and drugs are relabeled, a small sample of relabeled drugs could be submitted to FDA's local port for a final admissibility decision. Alternatively, FDA could inspect relabeled drugs for admissibility at the relabeler's facility. Shipping complete pallets of drugs multiple times throughout the US[7] is burdensome and expensive, cutting into the potential savings for Coloradans to enjoy.

4. **Automatic Termination of Authorized SIPS after 2 years:** 21 CFR 251.6(a), mandates automatic termination of an authorized SIP after two years unless proactively extended by FDA. This approach is a direct disincentive. States already are taking financial risks in investing to establish a SIP and proposing it to FDA. But in this provision, the Rule's own terms forecast that the savings that might be achieved will be short lived and therefore, unnecessarily, stunted. There should be little doubt that the first years of a SIP would include the lowest importation volume and therefore be the least efficient. We also note there are no clearly stated criteria for continuing a SIP after the two-year mark, creating substantial uncertainty for states and private-sector participants. Section 804 already equips FDA with sufficient authority to suspend or terminate a SIP that compromises public health or violates regulatory standards. An automatic two-year cutoff is therefore unnecessary. It further undermines sponsor and partner confidence, particularly when implementing new and complicated programs that require substantial start-up investments. **Allowing SIPs to continue, unless specifically found noncompliant, alleviates unnecessary risk and enables long-term planning, learnings and improvements from prior years' experiences, the addition of new Foreign Sellers and supply chains to increase competition and reduce costs, and greater efficiency in the outyears.** HCPF would gladly work with FDA to provide for keeping SIPs current with regular reporting.

5. **Preventing the termination of all importation**: HCPF would like to request FDA

[6] HCPF is aware that statutory testing must take place in the United States as defined by 21 USC 384, Importation of Prescription Drugs (a)(4) and (e).

[7] In Colorado's case, imported medications would travel from the C.B.P. Port of Entry in Detroit, MI, to the importer/relabeler in Boise, ID, back to C.B.P. Port of Entry in Detroit, MI, for the admissibility decision by FDA, and then back to Boise, ID, for distribution as referenced on page 2.

specify the areas of a SIP where noncompliance would lead to a SIP sponsor ceasing all importations under 21 CFR 251.18. As drafted, the provision grants FDA authority to halt a SIP Sponsor's importations if "any aspect of the SIP does not meet applicable requirements of the FDCA, FDA regulations, or the authorized SIP." This provision is extraordinarily broad. It could mean that a single instance of drug degradation or a minor labeling oversight, either of which could happen in any ordinary imported drug supply chain operated by the manufacturer itself, would nonetheless require halting every import under the entire program, regardless of its scope. **We urge FDA to adopt a more tailored approach, whereby complete cessation of all import activities would be reserved for the most serious of situations** – e.g., circumstances where counterfeits are found by FDA which were missed by the SIP sponsor and SIP market participants. Further, the agency should limit this recourse to the affected drug(s) - and not to the entire SIP. Finally, FDA could replace cessation with a prompt notification requirement to FDA. These proposed revisions ensure protection of public health in real time without unnecessarily completely halting a SIP that is otherwise fully compliant.

6. **Concerns Regarding FDA's Labeling Processes for Imported Medications:** HCPF has corresponded with FDA regarding labeling processes for imported medications. FDA labeling guidance thus far has been noncommittal and places additional uncertainty and added costs for Importation programs.
    a. **Support to Continue Dispensing of Labeled Imported Medications:** In December 2023, Colorado submitted a formal request to FDA seeking clarification on whether imported medications that have been relabeled and approved for importation may continue to be dispensed following subsequent changes to FDA-approved labeling. The FDA's response did not provide the specific guidance requested and referenced potential recall scenarios without adequate explanation or context.[8] HCPF is requesting FDA to permit the distribution and subsequent dispensing of imported medications, even if the FDA approves new labeling for the U.S.-based product, after relabeling of the imported medication has been completed. Currently FDA doesn't require companies to recall medications already in distribution just because of FDA approved labeling changes. HCPF is requesting imported medications to receive the same treatment.
    b. **30-Day Approval Timelines of Submitted Labels:** On January 16, 2025, HCPF submitted a separate request for an expedited approval process for labeling of imported medications. We acknowledge FDA's timely response.[9] However, the guidance provided lacks the specificity and clarity necessary for Colorado to develop comprehensive implementation protocols for our state importation program. The current uncertainty regarding approval timelines—potentially extending several months—presents significant operational and financial challenges for state importation programs. Extended approval periods result in substantial holding costs for medications that cannot be distributed during the review process and create risks of medication expiration prior to market availability. These factors fundamentally

[8] Appendix H pages 33-34

[9] Enclosure

undermine the economic viability and public health objectives of state importation initiatives. **HCPF is renewing our request to have FDA approve submitted labels within 30 days of submission prior to the drug being purchased by the Program to avoid unnecessary holding costs incurred by the Program.**

We believe these necessary clarifications will enable more effective implementation of importation programs while maintaining the safety and regulatory standards that protect public health.

Thank you for the opportunity to submit these comments. We believe our request to extend certain Medicaid deadlines by no less than two years (2027) and the proposed changes for importation programs would significantly reduce regulatory burdens and enhance the feasibility of Colorado's Section 804 Importation Program without compromising the safety or authenticity of imported prescription drugs. We look forward to continued engagement with federal partners to refine the Importation Final Rule, improve the labeling approval process, reduce unnecessary barriers to importation, and provide significant savings to consumers while preserving public health.

Sincerely,

Kim Bimestefer
Executive Director
Department of Health Care Policy & Financing

cc:
Office of Drug Security, Integrity and Response, Office of Compliance, & Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Karen Meister, Senior Policy Advisor, U.S. Food and Drug Administration

STATE OF COLORADO

Swartzendruber - HCPF, Kelly <kelly.swartzendruber@state.co.us>

RE: [EXTERNAL] Re: Colorado SIP - Request for Information Letter

SIPDrugImportsandRFP <SIPDrugImportsandRFP@fda.hhs.gov> Mon, Feb 24, 2025 at 9:20 AM
To: "Swartzendruber - HCPF, Kelly" <kelly.swartzendruber@state.co.us>, SIPDrugImportsandRFP <SIPDrugImportsandRFP@fda.hhs.gov>
Cc: "Verbois, Leigh" <Leigh.Verbois@fda.hhs.gov>, "Reveley - HCPF, Lauren" <lauren.reveley@state.co.us>, "Campbell, Christopher C" <Christopher.Campbell@fda.hhs.gov>, "Peterson, Michael" <Michael.Peterson@fda.hhs.gov>, Vincent Giglierano - HCPF <vincent.giglierano@state.co.us>

Kelly,

The following Questions and answer respond to the email you sent on January 13th in advance of a requested meeting:

Q: Could FDA confirm that the "Additional Comments" section of the RFI does not introduce any new requirements that must be satisfied before granting SIP approval?

A: Yes, we can confirm that the "Additional Notes" section does not require anything new at this time, for purposes of the SIP proposal. Rather, it highlights information FDA believes you should consider in order to be able to successfully import eligible drugs under your SIP proposal.

Q: Could FDA confirm that if additional detail is needed beyond Colorado's upcoming submission in response to the RFI we received on 12/20/2024, can FDA ask for clarification via email or a meeting versus sending Colorado another RFI?

A: Although minor clarifications may be possible via email, FDA has sent RFIs for any substantive information that is incomplete or inadequate to meet the requirements of 21 CFR part 251.

Q: To address comments raised in question number 4 of the RFI, we plan to submit a detailed SOP outlining temperature logging, environmental monitoring, cleaning protocols, and the relabeling environment requirements. Could FDA confirm whether this SOP will adequately meet the RFI comments regarding storage, handling, and distribution practices for sterile/ refrigerated drugs? If this approach is not sufficient, please clarify which additional data, procedural details and format FDA would require for approval.

A: This approach may be sufficient, but a determination cannot be made until FDA evaluates the contents of the detailed SOP.

Q: We have several programmatic/operational questions that do not require a response before submitting our updated SIP in response to the RFI, but would help us continue to move forward with the program while our updated submission is under review. Are we able to submit these questions without impacting our SIP review or the review timeline?

A: Generally, programmatic or operational questions will probably not delay review of your SIP proposal. However, any resulting amendments to the SIP proposal, particularly amendments that do not correlate to an RFI letter from the FDA, may require thorough re-review and will likely impact FDA's ability to respond to a submission expeditiously. Because of this, FDA continues to recommend that the state amend the SIP only after receiving feedback from FDA.

This responds to the email you sent on January 16th asking FDA additional questions.

Q: Does FDA require the drug manufacturer to review or approve ICSRs before submission to FDA, or may RMPDS submit ICSRs directly to FDA (e.g., via E2b), then forward a copy to the manufacturer afterward?

A: No, manufacturer review is not required prior to submitting ICSRs to FDA. 21 CFR 251.18(d) requires the importer to submit ICSRs to FDA and the drug manufacturer. However, there is no requirement for the drug manufacturer to review or approve the ICSRs prior to the importer submitting them to FDA.

Q: How does the FDA prefer to receive non-expedited reports that require submission within 90 calendar days of first awareness?

A: 21 CFR 251.18 (d)(6) requires ICSRs (expedited or non-expedited) to be submitted in an electronic format that FDA can process, review, and archive. FDA currently provides two methods for the electronic submission of ICSRs, E2b via the Electronic Submission Gateway (ESG) or via the Safety Reporting Portal (SRP). Importers should submit ICSRs via the same process (E2b or SRP) whether expedited or non-expedited.

Q: Once the SIP is approved, how should we proceed if we add or change a relabeler, lab, or other supply chain partner? Is an update in the Pre-Import Request(s) sufficient? If not, what is required for the change?

A: Changing a relabeler or laboratory identified in a SIP proposal constitutes a change to the SIP, see 21 CFR 251.3(d)(10) & (e)(7). An update to the Pre-Import Request is not sufficient. A SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA's authorization, see 21 CFR 251.8(e). We suggest sending a supplemental proposal to modify the SIP to our mailbox. Of note, if FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request once the amended SIP is authorized, see 21 CFR 251.8(d).

It is unclear what entity you were referring to as a “supply chain partner” and we therefore cannot fully answer this question.

Q: Per FDA & HCPF March & April Correspondence in 2024, FDA indicated they did not want HCPF to send in periodic updates to keep the SIP current (examples given were the pending ISO 17025 Certification or Foreign Seller inspection documents from Health Canada). Another example would include State Board of Pharmacy inspection documents. Can FDA clarify how they would like to receive these documents to keep the SIP current, regardless of whether the SIP is under review or has been approved?

A: When Colorado corresponded with FDA in March and April of 2024 the SIP proposal had not been authorized. At the time, FDA was conducting a review of the SIP proposal and responded by advising with the most efficient way to provide additional information under that specific circumstance. It will take longer to complete the review of a SIP proposal if it is revised while FDA is reviewing it. As such, FDA generally does not recommend making any revisions to the SIP proposal while it is under review.

Once a SIP proposal has been authorized, if the SIP Sponsor determines, based on information from an inspection or otherwise, that any participant in or element of the authorized SIP’s supply chain does not meet all applicable requirements, importation must be stopped and FDA must be notified, per 21 CFR 251.18(a). In addition, a SIP Sponsor must not make any changes or permit any changes to be made to a SIP without first securing FDA's authorization. The regulation at 21 CFR 251.8 specifies the obligations a sponsor has regarding any such changes.

Q: FDA indicated we could receive final approval of our labeling after a SIP is authorized but that the Foreign Seller would be required to purchase the drug first. It would be unreasonable to ask our Foreign Seller to purchase a drug and wait for an unknown amount of time while FDA reviews the imported drug's label unless FDA can confirm the turnaround on the label approval is fast (i.e. ~30 days). What is FDA’s review timeline for label approvals?

- ***Colorado would request the labeling be submitted and accepted after the SIP is approved but before the drug is purchased by the Foreign Seller and Pre-Import request is submitted (this assumes no labeling changes by the original manufacturer) to ensure the drug is not sitting, unable to be sold, for months, prior to the importation process beginning.***
- ***Example Ideal Timeline:***
- ***State SIP approved 12/1/25***
- ***Labeling submitted for FDA review 2/1/26***
- ***FDA approves labeling 3/1/26***
- ***Drug Purchased 3/2/26***
- ***Pre-Import request filed 3/3/26***
- ***Pre-Import request approved 4/2/26***
- ***Importation next steps***
- ***Even with this timeline, the drug will be sitting in a Canadian warehouse, unable to be sold (or moved) for at least 30 days.***

A: Under 21 CFR 251.13(b)(4), a drug’s labeling must be the same as the FDA-approved labeling under the applicable NDA or ANDA, with only certain specified exceptions, “[a]t the time the drug is sold or dispensed…” In light of this requirement, FDA intends to evaluate a drug’s labeling as close in time to importation as is practicable, i.e. **after** the drug is sold to the Foreign Seller and before a Pre-Import Request is granted and the drug is relabeled.

FDA cannot provide a timeline for labeling review and approval because each will vary in scope and complexity. Nonetheless, FDA is committed to promptly reviewing labeling and will strive to minimize time that purchased product sits in a warehouse.

Q: Given the hesitancy of some drug manufacturers to engage with the program, we want to ensure we can accommodate eligible drugs from manufacturers that are willing to participate. If the Colorado SIP is approved with the existing drug list but we find a manufacturer willing to participate not on the initial drug list, how do we add a drug to the program if it’s not part of the original approved SIP if we know it is eligible and cost effective? What documentation would FDA need to see to have the drug approved for importation so a Pre-Import request could be filed?

A: As we understand your question, you are asking what steps you will need to take to source an eligible prescription drug from a manufacturer that is not originally identified in an authorized SIP proposal.

Among other things, a SIP proposal must identify the applicant that holds the approved NDA or ANDA for each eligible prescription drug's FDA-approved counterpart, see 21 CFR 251.3(d)(4). The proposal must also identify the manufacturer(s) of the eligible prescription drug's finished dosage form and the manufacturer(s) of its active ingredient or ingredients, if known or reasonably known, see 21 CFR 251.3(d)(5) & (6). Although information about an eligible prescription drug's manufacturer does not need to be included in a SIP Proposal if it is not known or reasonably known, information about an eligible prescription drug's manufacturer does need to be included in the Pre-Import Request. A Pre-Import Request must include, among other things, the manufacturer of the active pharmaceutical ingredient and its unique facility identifier, the manufacturer of the eligible prescription drug with the business address and unique facility identifier, copies of the invoice of the sale from the manufacturer to the Foreign Seller, and the attestation and information statement from the manufacturer, see 21 CFR 251.5(c).

With regard to an authorized SIP, adding an eligible prescription drug for importation would require a supplemental SIP proposal under 21 CFR 251.8. Such drugs are not eligible for importation under section 804 unless the relevant supplemental SIP proposal is authorized by FDA, see 21 CFR 251.8. Additionally, an eligible prescription drug may not be imported or offered for import unless the Importer has filed a Pre-Import Request for that drug and FDA has granted the Pre-Import Request, see 21 CFR 251.5(a).

Thank you,

Office of Drug Security, Integrity and Response

Office of Compliance

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

SIPDrugImportsandRFP@fda.hhs.gov

From: Swartzendruber - HCPF, Kelly <kelly.swartzendruber@state.co.us>
Sent: Thursday, January 16, 2025 10:25 PM
To: SIPDrugImportsandRFP <SIPDrugImportsandRFP@fda.hhs.gov>
Cc: Verbois, Leigh <Leigh.Verbois@fda.hhs.gov>; Reveley - HCPF, Lauren <lauren.reveley@state.co.us>; Campbell, Christopher C <Christopher.Campbell@fda.hhs.gov>; Peterson, Michael <Michael.Peterson@fda.hhs.gov>; Vincent Giglierano - HCPF <vincent.giglierano@state.co.us>
Subject: Re: [EXTERNAL] Re: Colorado SIP - Request for Information Letter

Good evening,

Thank you for the opportunity to send additional questions for discussion. We look forward to our meeting on January 28.

1.
2.
3. Adverse Event Reporting
4.
    a.
    b.
    c. Does FDA require the drug manufacturer to review or approve ICSRs before submission to FDA, or may RMPDS