

PHARMACY BENEFITS COMPLIANCE ALERT!

New CBP International Mail Rule Adds Customs Entry Requirements for FDA-Regulated Shipments



September 28, 2026

U.S. Customs and Border Protection (CBP) has adopted a new rule that overhauls how goods arriving in the United States by international mail are processed and cleared. Under the new interim final regulation (the “Rule”),¹ most low-value international mail shipments must now move through a formal customs entry process instead of entering duty-free under the long-standing “de minimis” exemption. Most significantly for the prescription drug supply chain, the Rule requires a formal customs entry for any mail shipment that is subject to the requirements of another federal agency, including the U.S. Food and Drug Administration (FDA). CBP has set October 22, 2026 as the compliance date for enforcing this requirement. The change is expected to add cost, delay and legal risk to cross-border shipments of medications, including prescription drugs mailed directly to U.S. consumers by Canadian and other international pharmacies, and it warrants attention from employers, plan sponsors and others connected to the pharmacy benefit and drug-sourcing supply chain.

ACTION REQUIRED

Identify any
prescription drug
sourcing outside the
U.S.

Assess the impact of
new entry requirements
effective October 22,
2026.

Confirm compliance
with FDA importation
laws and CBP rules.

Always document your review and fiduciary due diligence.

¹ The rule is called “Indefinite Suspension of the De Minimis Exemption for Mail Shipments and New Postal Informal Entry Process.” 91 Fed. Reg. 37801 (June 24, 2026).

BACKGROUND

CBP has historically allowed most shipments valued at \$800 or less to enter the United States free of duty and with minimal paperwork under the “de minimis” exemption. Large volumes of international mail, including medications ordered online from foreign pharmacies, moved into the country this way. The Rule ends that treatment for international mail. Published on June 24, 2026, and effective July 24, 2026, the Rule suspends the \$800 de minimis exemption for international mail and replaces it with a structured entry process under the customs regulations governing mail importations. A separate, permanent elimination of the de minimis exemption is scheduled to take effect July 1, 2027 under recently enacted federal legislation, so the new mail entry process is best understood as the beginning of a lasting structural change rather than a temporary measure.

Because the Rule is an interim final rule, it took effect immediately but remains open for public comment. Certain of its most consequential requirements, including the formal-entry requirement for shipments regulated by other federal agencies, are subject to a delayed compliance date of October 22, 2026.

WHAT DOES THE NEW RULE REQUIRE

For eligible low-value mail shipments (generally \$2,500 or less), the Rule establishes a new postal informal entry process. A party authorized to make entry must transmit detailed shipment data to CBP each month, including a description of the goods, country of origin, 10-digit tariff classification, declared value, and duties owed, and pay the applicable duties through CBP’s designated payment system. Importantly, only owners, purchasers, or licensed U.S. customs brokers may file these entries; foreign postal operators and unlicensed third parties may no longer clear these shipments. Filers must also have a customs bond on file with CBP before filing.

Certain categories of merchandise are excluded from the streamlined postal process and must instead move through a full formal entry or CBP’s electronic entry option for low-value shipments (known as Entry Type 13, which began operating September 22, 2026). Those excluded categories include goods regulated by other federal agencies (referred to as “partner government agencies”), goods over \$2,500, quota goods, goods subject to antidumping or countervailing duties, alcohol and tobacco, and certain tariff-preference claims.

HOW DOES THE RULE AFFECT FDA-REGULATED AND OTHER AGENCY-REGULATED SHIPMENTS

This is the heart of the change for the prescription drug supply chain. The Rule provides that formal entry is required for any mail shipment subject to the requirements of another government agency. Prescription drugs and many other health-related products fall squarely within the FDA's regulatory authority, so mailed shipments containing them are no longer eligible for the simplified postal process. Instead, they must clear through a formal entry or Entry Type 13.

Formal entry is a more demanding, transparent process. It requires a qualified filer, a customs bond, precise product and manufacturer information, tariff classification, valuation, and the submission of FDA-specific admissibility data through CBP's electronic systems. CBP enforces FDA's requirements at the border, and FDA screens these entries for compliance. Shipments that appear to violate FDA law can be detained, refused admission, and, in the case of unapproved drugs, destroyed, with potential referral for seizure, injunction, or criminal prosecution. In short, the Rule pulls mailed medication shipments out of a low-visibility channel and into a formal process where FDA and CBP have full data and clear authority to act. CBP is enforcing this requirement for agency-regulated mail beginning October 22, 2026.

WHAT DOES THIS MEAN FOR CANADIAN AND OTHER INTERNATIONAL PHARMACIES

Foreign pharmacies that ship prescription drugs directly to U.S. consumers by mail have long operated in a legal gray zone in practice, even though the underlying conduct is generally unlawful. Under federal law, prescription drugs manufactured for and dispensed in foreign markets are typically treated as unapproved new drugs and as misbranded, even when they are chemically identical to an FDA-approved product, because FDA approval is specific to each manufacturer, product, and label.

Congress created a narrow potential pathway for importing certain drugs from Canada and a limited personal-use waiver, but those provisions have never been made operational: they depend on a federal certification and rulemaking steps that have not occurred. The FDA's own guidance states that, in most circumstances, it is illegal for individuals to import drugs for personal use. Although the FDA has historically exercised enforcement discretion for certain limited personal-use imports, that policy has never created a legal right to import prescription drugs. The new CBP procedures in the new Rule provide regulators with greater visibility into

incoming medication shipments and may reduce the practical effectiveness of that enforcement discretion. Notably, the Rule does not materially expand FDA's authority over imported drugs - it simply changes the customs-entry process in a manner that makes FDA review and enforcement significantly easier.

What the Rule changes is enforcement visibility and friction. By forcing these shipments into a formal entry process, complete with data submission, a licensed filer, a bond, and FDA screening, the Rule makes it substantially harder for foreign pharmacies to move prescription drugs into the United States through the mail without detection. Expect increased detentions, refusals, shipment delays, added costs and destruction of noncompliant packages. Business models built on the prior low-visibility mail channel face significant disruption.

WHY DOES THIS MATTER FOR EMPLOYERS AND PLAN SPONSORS

Rising drug costs have prompted some employers, plan sponsors, PBMs and third-party vendors to explore international drug-sourcing strategies, including Canadian mail-order arrangements and “personal importation” programs, to reduce spending on expensive specialty and brand-name medications. The Rule directly affects these strategies in several ways:

- **Program viability and cost.** Arrangements that rely on mailing foreign-sourced prescription drugs to plan members will face new entry requirements, added costs, delays, and a higher risk of detention or refusal at the border beginning October 22, 2026.
- **Legal and reputational risk.** Facilitating the importation of unapproved or misbranded drugs can expose a plan, its vendors, and potentially the sponsor to FDA enforcement and related liability. Heightened, coordinated federal enforcement, including a cross-agency trade-fraud initiative launched in 2025, and centralized FDA import screening, increase the likelihood that noncompliant arrangements will be identified.
- **Fiduciary considerations.** For ERISA-governed plans, cost-management decisions are judged on the prudence of the process, not the outcome. Plan sponsors that adopt or continue a cross-border drug-sourcing program should be able to show that they evaluated its legal compliance, safety and disruption risk. Prescription drug pricing decisions are already drawing fiduciary-breach litigation, making documented, careful review especially important.

- **Employee impact.** Even where a plan does not sponsor an importation program, employees who personally order medications from foreign pharmacies may experience delays, added charges, or non-delivery once the Rule is enforced. Clear communication can help manage expectations

WHEN DO THE NEW REQUIREMENTS TAKE EFFECT

The Rule became effective July 24, 2026, but CBP delayed enforcement of the formal-entry requirement for agency-regulated (including FDA-regulated) mail until October 22, 2026. CBP's electronic entry option for low-value excluded shipments began operating September 22, 2026. The broader elimination of the de minimis exemption becomes permanent on July 1, 2027. Stakeholders should use the window before October 22, 2026 to review their supply chains and confirm how each affected product line will be entered.

WHAT EMPLOYERS SHOULD DO NEXT

Employers and plan sponsors connected to the prescription drug supply chain should consider taking the following steps now:

- Inventory whether your health plan, PBM, or any vendor sources or facilitates prescription drugs from outside the United States, including any Canadian mail-order or personal-importation option.
- Ask your PBM and vendors how the new CBP entry requirements will affect the cost, timing, and reliability of any cross-border drug shipments after October 22, 2026, and request their compliance plan.
- Confirm that any international drug-sourcing arrangement complies with both FDA importation law and the new customs entry requirements, and obtain contractual assurances and indemnification where appropriate.
- Evaluate the legal, safety, and continuity risks of relying on foreign-sourced medications, and consider domestic alternatives for at-risk therapies.

- If your plan is subject to ERISA, document your review and decision-making as part of a prudent fiduciary process, and confirm that adequate fiduciary liability insurance is in place. More specifically, plan fiduciaries should consider obtaining and reviewing PBM sourcing information, evaluating vendor compensation and contractual risk allocation, and maintaining documentation of the review process.
- Communicate proactively with employees who may be personally importing medications so they can anticipate potential delays or disruptions.

The Rule reflects a broader federal trend toward tighter control of low-value imports and stricter enforcement of drug importation laws. Employers and plan sponsors that source medications across borders, or whose members do, should treat the October 22, 2026 compliance date as a planning deadline and review their arrangements accordingly.

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