# TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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## REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

**1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

### Federal law

The movement of therapeutic products in the United States is governed by federal statutes and regulations administered by multiple agencies. The Food and Drug Administration (FDA) implements the Federal Food, Drug and Cosmetic Act (FDCA),[1] which establishes requirements for marketing authorisation of drugs and devices, establishment registration and product listing, import and export and labelling. The Public Health Service Act (PHSA)[2] provides parallel requirements for biologics. The Drug Supply Chain Security Act (DSCSA)[3] mandates interoperable, serialised traceability for prescription drugs from manufacturer to patient and establishes national standards for prescription drug wholesale distributors and third-party logistics providers (3PLs),[4] pre-empting inconsistent state pedigree laws and imposing authorised trading partner, licensure and interoperable product tracing obligations, while state boards retain licensing and inspection functions aligned with DSCSA standards.[5]

The Drug Enforcement Administration (DEA) administers the Controlled Substances Act (CSA),[6] regulating the manufacture, distribution, dispensing, import and export of controlled substances, which are drugs that are 'scheduled' in accordance with their potential for addiction. The CSA overlays additional registration, security, record-keeping and reporting requirements for scheduled drugs.[7]

### State law

Individual states maintain their own FDCA and CSA analogue statutes, but they cannot conflict with federal law. In practice, state drug and device regulatory frameworks track FDA approvals, states do not issue independent therapeutic product marketing authorisations, while state CSA analogues may provide reporting or oversight to state agencies. States also regulate areas outside of the federal scope, including the practice of medicine, requirements for medical provider

[1] 21 U.S.C. section 301 et seq.
[2] 21 U.S.C. section 201 et seq.
[3] 21 U.S.C. sections 360eee–360eee-4.
[4] 3PLs are entities that do not take title to products but assist in distribution.
[5] 21 U.S.C. section 360eee et seq. See the response to Question 3 for more information on the DSCSA and state licensing requirements.
[6] 21 U.S.C. section 801 et seq.
[7] 21 U.S.C. section 801 et seq. See the response to Question 5 for more information about requirements for controlled substances.

licensure and prescription and dispensing requirements, drug and device distribution and the practice of pharmacy.

States impose licensure requirements for drug and device manufacturers and distributors,[8] as well as retail and mail-order pharmacies operating within a state. In general, pharmacies must hold resident licensure (and, if dispensing into a state from elsewhere, non-resident licensure); designate a pharmacist-in-charge; and maintain compliant facilities and storage. Pharmacies are subject to routine and for-cause inspections, must retain prescription and distribution records for prescribed periods and must implement enhanced controls for controlled substances. Many states have prescription drug monitoring programmes (PDMPs) that require reporting of controlled substance dispensing and, in some cases, PDMP queries before dispensing.

**2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?**

The FDA classifies therapeutic products by type, namely drug, biologic or device, and, as applicable, by the conditions of use (prescription (Rx) versus over the counter (OTC)) or by device risk class. These classifications determine whether a premarket review is required, the nature of the supporting data and permissible distribution channels. Human cells, tissues and cellular or tissue-based products (HCTPs) can be regulated as one of the above categories requiring a premarket review, but may be subject to more limited requirements depending on their intended use and the extent of any manipulation or processing applied to them.[9]

States classify therapeutic products largely by reference to federal categories. The principal classes used by states are Rx-only drugs and devices, OTC drugs and devices and controlled substances.

**Drugs**

Under the FDCA, prescription drugs require FDA premarket approval via a new drug application (NDA) or an abbreviated new drug application (ANDA) (for generic drugs).[10] Some are subject to risk evaluation and mitigation strategies (REMS), which can impose restricted distribution, dispenser or prescriber certification and patient monitoring.[11] Biologics generally follow an analogous pathway, but require a biologics licence application (BLA).[12] Depending on the primary mode of action, certain biologic-based products may be regulated as devices.[13] The appropriate regulatory pathway for combination products is determined by the FDA based on an assessment of the product's primary mode of action.

OTC drugs may be marketed without prescriptions if they conform to the applicable conditions set out in 'monographs'.

**Medical devices**

The FDA classifies medical devices by the level of risk posed and the necessary controls.[14] Class I devices are generally low risk. Many are exempt from premarket notification and are subject to

[8] See the response to Question 3 regarding more information on state manufacturer and distributor licensing requirements.
[9] See FDA, Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use (July 2020) www.fda.gov/media/109176/download last accessed on 16 May 2026.
[10] 21 U.S.C. section 355(a), (b), (j).
[11] 21 U.S.C. section 355-1.
[12] 42 U.S.C. section 262(a).
[13] 21 U.S.C. section 353(g).
[14] 21 U.S.C. section 360c(a).

general controls, including registration, listing, some quality system requirements and adverse event reporting. Class II devices present moderate risk and typically require 510(k) clearance demonstrating substantial equivalence to a predicate or de novo authorisation for novel devices. They are also subject to medical device reporting and the Quality Management System Regulation (QMSR). Class III devices are high risk and require premarket approval (PMA), usually supported by clinical, bench and performance data, and are likewise subject to reporting and the QMSR.

Devices may be Rx or OTC. The FDA may impose additional conditions, such as user training and other restrictions, for certain 'restricted devices'.[15]

States generally regulate device distribution and related licensure according to the prescription (ie, 'by or on the order of' a licensed practitioner) status. Rx or restricted devices trigger tighter storage, security and policy standards under state laws.

Several states regulate the direct-to-patient supply of durable/home medical equipment (DME/HME) through the issuance of specific provider or outlet licences, including for out-of-state suppliers shipping to in-state patients. These permissions operate in addition to general medical device licensure.

**Prescription-only versus OTC drugs**

Prescription-only status restricts trade and distribution to licensed channels and recipients (eg, pharmacies, prescribers, hospitals and licensed outlets). Typically, wholesale supply must flow to entities authorised to receive Rx products, with the applicable record-keeping, storage and security requirements. OTC products may move through general retail, but distributors and pharmacies must still adhere to the relevant facility, labelling and quality controls for OTC products.

## LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

**3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?**

**Federal law**

Under the DSCSA, wholesale drug distributors must be deemed to be 'authorised trading partners' by the FDA, which requires maintaining an appropriate licence and reporting licensure and other information to the FDA annually.[16] States typically have their own distribution licence requirements, and compliance with state licensing regimes typically suffices for the FDA.

Any person or entity that holds controlled substances, including healthcare practitioners, pharmacies and distributors, must register with the DEA.[17] The registration application requirements vary based on the schedule in which the substance is controlled, which is determined by the potential for addiction posed by the substance. Registrations are conditioned upon compliance with certain requirements, including security controls and record-keeping requirements. States often have their own distribution licensing schemes and regulations governing controlled substances. States also often have their own registration and reporting requirements for handling controlled substances that may differ from the registration and reporting requirements under federal law. Regulated entities must comply with both sets of requirements.

[15] 21 U.S.C. section 360j(e).
[16] 21 U.S. Code section 360eee-2.
[17] 21 U.S.C. section 822(a).

Distributors of medical devices are not required to register with the FDA unless their other activities, such as re-labelling, re-packaging or manufacturing, require them to do so.[18]

**State laws**

US states generally impose licensure and operational requirements on pharmaceutical and medical device manufacturers, wholesalers, distributors and 3PLs operating within their borders. Core conditions routinely include facility and security standards, written policies and procedures, record-keeping, pre-licensure inspection or recognised accreditation, designated responsible personnel with background checks, proof of insurance and, in some states, surety bonds.

Separate licences may be required for wholesalers, distributors or 3PLs handling controlled substances. The regulations vary for prescription device wholesale distribution to healthcare providers. Several states do not licence device wholesalers for shipments to healthcare providers, but impose licensure when devices are shipped directly to patients, generally under pharmacy or DME rules. Of particular note are the following:

- Type of licence. Separate licence types may be required depending on the activity (eg, manufacturer, wholesaler, distributor). Some states have imposed additional licence requirements for opioid manufacturers (eg, Maine) or other controlled substances, as well as for durable home medical equipment (DME) suppliers that distribute directly to patients.
- Drug versus device. Every state has licensure requirements for the manufacture, sale or distribution of prescription drugs, and many states similarly regulate medical devices (eg, by inserting devices under pre-existing drug licensure types or creating new medical device categories).
- Regulators. Most frequently, state boards of pharmacy are responsible for such regulation, but there are exceptions (eg, the California Department of Public Health Food and Drug Branch, not the California Board of Pharmacy, regulates pharma and device companies).
- Resident vs non-resident. Typically, 'resident' state licences are required where the company's facility is located, and 'non-resident' state licences may be required where the company ships or sells products.
- Operational requirements. States generally require compliant facilities and written standard operating procedures; qualified personnel with a designated responsible individual; security controls and environmental monitoring; DSCSA-compliant tracing and distribution records; and product integrity/recall procedures. Licensure typically includes inspections, financial responsibility (eg, surety bonds), change notifications, renewals and cooperation with investigations.

**4. Are there any distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?**

As discussed in the response to Question 3, states impose distinct licensure and related obligations on businesses that dispense or supply therapeutic products directly to consumers. The sections below summarise the core, widely adopted requirements:

- Community (retail) pharmacies. Brick-and-mortar retail pharmacies must hold an in-state pharmacy licence for each location. Typical conditions include the designation of a pharmacist-in-charge (PIC); timely notice of ownership, management, location or PIC changes; and ongoing compliance with practice standards and inspections. When

[18] 21 U.S.C. section 360.

dispensing controlled substances, pharmacies generally require a state controlled-substance registration (in addition to DEA registration) and must comply with state PDMP rules (eg, pharmacist PDMP registration when dispensing Schedules II–IV).

- Mail-order and internet pharmacies (non-resident). Pharmacies that dispense from one state and ship into another generally must obtain a non-resident pharmacy licence or registration in each destination state. Common conditions include proof of home-state licensure and recent inspection, appointment of an in-state agent for service of process, maintenance of shipment records and compliance with the destination state's controlled substance and PDMP requirements. States apply these rules equally to internet pharmacies. There is typically no separate 'internet pharmacy' facility license.
- Durable medical equipment/home medical equipment (DME/HME). When supplying DME/HME directly to patients (sale or rental for home use), many states require a separate DME/HME supplier permit or treat suppliers under a pharmacy facility class. Typical conditions include the submission of an application and fee, insurance and policies/procedures, sometimes accreditation and non-resident licensure before shipping into the state operating a patient-facing unit.

**5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?**

**Federal regulation**

The FDA and the Federal Trade Commission (FTC) regulate the promotion and advertising of medical products on the internet and social media. These avenues of dissemination can meet the definitions for both labelling and advertising and, therefore, may be subject to regulatory oversight by either the FDA or FTC depending on the specific product and nature of the promotion. The FTC generally has primary responsibility for regulating advertising of OTC drugs and medical devices that is not considered 'labelling', while the FDA has primary responsibility for regulating labelling and prescription drug advertising. Regardless of the regulator involved, advertising and social media promotion must be truthful, not misleading and consistent with the product's FDA-authorised intended use. Both the FDA and FTC have issued guidance documents with non-binding recommendations regarding certain special considerations that may arise for promotion on internet or social media platforms.

In 2025, the Trump Administration signalled that it intended to increase enforcement actions related to direct-to-consumer advertising, including the advertising of products on social media.

**State regulation**

Across the US states, internet sales of therapeutic products to consumers is regulated primarily through existing pharmacy, drug/device and durable medical equipment (DME/HME) licensing frameworks. States treat online sales, including via social media and online marketplaces, as dispensing or distribution into the patient's state and, thus, require in-state or non-resident licensure and compliance with the applicable state labelling/counselling rules. Several states go further: Nevada requires specific 'internet pharmacy' certification and posts certified entities;[19] Washington bars advertising by unlicensed non-resident pharmacies;[20] Illinois expressly incorporates the federal Ryan Haight online-controlled-substance rules into state regulation;[21] and many states require a toll-free pharmacist line and the provision of counselling services for mail-order patients. For devices and DME/HME sold online direct to consumers, states commonly

[19] NRS section 639.23288.
[20] Wash. Rev. Code section 18.64.400.
[21] Ill. Admin. Code 68 section 1330.60.

require retailer or distributor permits (eg, California's home medical device retail (HMDR) programme, Florida's HME requirements).[22]

**IMPORT**

**6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?**

The FDA oversees the importation of FDA-regulated products.[23] Entries are screened electronically through the FDA's PREDICT system and products may be examined or sampled at the border. Imported products must comply with all of the applicable requirements, including any required premarket authorisation (eg, approved NDA or PMA, or cleared 510(k) for finished devices), labelling and current good manufacturing practices or quality control system requirements.

For drugs, the foreign manufacturer must register with the FDA and list each imported or marketed drug. The manufacturer's registration must identify all of the importers involved. Registration requirements also apply to manufacturers of active ingredients and other components. The FDA will verify compliance with the applicable labelling and current good manufacturing practice. Importers of controlled substances must also register with and obtain import permits from the DEA.[24]

For devices, the foreign manufacturer and the importer/initial distributor must register with the FDA and list all of the relevant devices. The FDA may conduct field examinations or analyse samples to assess compliance.

Shipments that appear non-compliant may be held, refused entry or destroyed.[25] The FDA may impose an import alert when a product merely appears violative, allowing detention of future shipments without the need for a physical examination.

Tariffs are generally set by the Harmonised Tariff Schedule and administered by Customs and Border Protection (CBP).

**7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?**

The FDA generally permits importation only of therapeutic products that comply with applicable US law. Historically, however, the agency has allowed the import of limited quantities of unapproved drugs for personal use under narrow circumstances, and pursuant to its enforcement discretion.[26] The contours of this policy differ for US citizens and visitors. For US citizens, the baseline rule is that unapproved drugs may not be imported for personal use, but FDA personnel may, according to their discretion, allow importation if the product is (1) not intended to treat a serious condition and poses no known significant health risk or (2) it is intended to treat a serious condition for which effective treatment may not be available domestically, provided the product

[22] CA HSC section 111656; Fla. Stat. section 400.93.
[23] 21 U.S.C. section 360.
[24] 21 CFR section 1312.
[25] 21 U.S.C. section 381.
[26] See FDA, 'Personal Importation' (August 2025) www.fda.gov/industry/import-basics/personal-importation last accessed on 16 May 2026.

does not present an unreasonable risk, the individual affirms in writing that it is for personal use and the quantity does not exceed a three-month supply. In the latter scenario, the individual should supply contact information for the treating US physician or evidence that the therapy is a continuation of treatment initiated abroad.

Temporary visitors may generally bring or ship up to a 90-day supply of medication for personal use and, if their stay exceeds 90 days, may often arrange for additional shipments. The FDA recommends that such shipments include documentation demonstrating personal use, such as a copy of the individual's visa or passport, a physician's letter and an English-language version of the prescription.

The CSA imposes additional restrictions on the personal importation of controlled substances. A US resident who wishes to import non-narcotic controlled substances for personal use, but lacks a valid prescription issued by a US-licensed and DEA-authorised prescriber, may import a maximum of 50 dosage units.[27]

**8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?**

Foreign establishments that seek to ship drugs or medical devices directly to consumers must comply with the FDA's registration and listing requirements, as this information will be reviewed during the import screening process. Foreign drug establishments must, in their FDA registrations, identify their US agent, each known US importer of the drugs manufactured, re-packed, re-labelled or salvaged at the establishment and each person who imports the drug or offers the drug for import to the US, including those who ship a drug from a foreign country to the US via international mail.[28] Unapproved prescription drugs generally cannot be shipped directly to consumers.

Medical devices can, in some circumstances, be shipped directly from a foreign establishment to the consumer or patient. In this circumstance, the consumer or patient is considered to be the 'importer' of the device.[29] In its annual FDA registration, the foreign establishment is required to identify any known importers, as well as the specific products the importer receives.[30]

Foreign suppliers must meet the applicable permit, licensure and other requirements for the states where recipient consumers reside, including the requirements discussed in the responses to Questions 3 and 4, above. Across jurisdictions, entities that ship, mail or deliver prescription products into a state generally trigger requirements for a 'non-resident' permit, licensure or registration of the dispensing entity, whether products are shipped business-to-business or directly to consumers. Internet or mail-order channels are commonly captured in pharmacy licensure and registration regulations, where the activity is regulated by destination, not by the medium through which the products are ordered.

Suppliers outside the US are typically treated the same as out-of-state US operators, although some states condition non-resident registration on good standing in the home jurisdiction, the maintenance of shipment records and cooperation with state information requests. Some states also require designation of an in-state agent for the service of process.

Business-to-business distribution to licensed providers typically implicates manufacturer/wholesaler or analogous registrations where the state's scheme covers the product category. By contrast, direct-to-patient shipments of prescription drugs and many prescription-only

[27] 21 U.S.C. section 956.
[28] 21 C.F.R. sections 207.1, 207.25.
[29] 21 C.F.R. section 807.3(x).
[30] 21 C.F.R. section 807.41.

devices frequently require a non-resident pharmacy licence and compliance with the receiving state's dispensing standards, which may include pharmacist oversight, counselling availability and labelling rules. States are more likely to impose registration requirements when products are dispensed directly to consumers.

States generally do not create standalone 'platform registrations', but they treat internet and mail order transactions as regulated dispensing or distribution if products are shipped into the state. Consequently, labelling, patient service and record-keeping obligations for mailed prescription drugs follow from the underlying non-resident pharmacy rules applied in the destination jurisdiction.

**9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?**

Importation of drugs manufactured for foreign markets without an approved NDA is generally prohibited, even if the product shares the same active ingredients and manufacturer as the US-approved version. Such products typically fail to meet FDCA requirements, particularly labelling requirements.

The FDA permits the importation of foreign-made, unapproved drugs in limited circumstances.[31] Devices imported into the United States must comply with US requirements before, during and after importation, regardless of any approvals elsewhere.

***EXPORT***

**10. Are there any quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

Products manufactured in the United States for domestic and foreign markets must generally meet FDA requirements. Upon request, the FDA issues export certificates that describe a product's US regulatory and marketing status.[32] While the FDA does not require these certificates for export, many foreign governments require them for import authorisation.

The FDA may decline to issue certificates if the manufacturer or product is not compliant with current good manufacturing practice regulations, if the establishment is not properly registered or the product not listed or if enforcement action has been initiated.

Separately, exporters of controlled substances must obtain exporter registration and export permits from the DEA.[33]

The US has no standing quantitative export quotas on therapeutic products. During the Covid-19 pandemic, Federal Emergency Management Agency imposed temporary, product-specific export controls under the Defense Production Act,[34] restricting exports of certain scarce medical resources. These controls expired in June 2021. No similar controls are currently in effect.

[31] 21 U.S.C. section 381; 384; 21 C.F.R. section 807.41.
[32] See FDA, FDA Export Certification (August 2021) www.fda.gov/media/151701/download last accessed on 16 May 2026.
[33] 21 U.S.C. section 958.
[34] 50 U.S.C. section 4501 et seq.

**11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing and, if so, what standards, labelling or record-keeping obligations apply?**

The FDCA permits the export of therapeutic products that are not legally marketable in the United States, but only through specific pathways. The requirements vary by product type, destination country and intended use.[35] Generally, exporters must notify the FDA of the product and its destination and maintain export records.

## LABELLING, TRACEABILITY AND PRODUCT INFORMATION

**12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

All therapeutic products must comply with the FDA's labelling requirements at the time of import. All required labelling text must appear in English, although products distributed solely in territories where the predominant language is not English may use the predominant language instead (eg, Spanish may be used instead of English for products distributed solely in Puerto Rico).[36]

Prescription drug manufacturers, re-packagers, wholesalers and dispensers must comply with the provisions of the DSCSA, which establishes requirements for product identifiers, traceability and authorised trading partners. The DSCSA imposes product verification and counterfeit detection obligations on stakeholders.[37]

Medical devices are subject to the unique device identification (UDI) system, which assigns a standardised identifier to the device label and package and requires submission of key device data to the Global Unique Device Identification Database (GUDID), which acts as a reference catalogue for all devices.[38]

## PRICING, REIMBURSEMENT AND MARKET ACCESS

**13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

The United States does not have a uniform fee schedule or drug pricing regime across payers. The cost of individual drugs and devices depends on whether the manufacturer is receiving reimbursement from a government programme (Medicare, Medicaid) or a private insurer.

Medicare Part B drugs, typically administered in professional settings, are generally reimbursed at the drug's average sales price (ASP) plus six per cent. The ASP reflects total US sales value divided by the total units sold, excluding Medicaid Drug Rebate Programme 'best price' transactions and other nominal sales.

[35] See FDA, Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996 (July 2007) www.fda.gov/media/138075/download last accessed on 16 May 2026.
[36] 21 C.F.R. sections 201.15, 801.15.
[37] See FDA, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs (December 2023) www.fda.gov/media/117950/download last accessed on 16 May 2026.
[38] For FDA's latest thinking, see FDA, Global Unique Device Identification Database (GUDID) (December 2024) www.fda.gov/media/86569/download last accessed on 16 May 2026.

Medicare Part D is an optional outpatient prescription drug benefit offered through private, Medicare-approved plans. Each plan must cover a broad range of drugs, including most drugs in certain protected classes (such as cancer, HIV/AIDS and depression therapies), but each maintains its own formulary. Recent Part D redesign features include a $2,000 annual out-of-pocket cap, a $35/month insulin cap and a Manufacturer Discount Programme for enrolees.

The Inflation Reduction Act of 2022 imposed system-wide changes to Medicare pricing, rebates and reimbursements. The federal government will set 'maximum fair prices' for selected Part B and Part D drugs and require inflation-based rebates when a drug's net price grows faster than inflation. Otherwise, Part D plans negotiate directly with manufacturers and pharmacies, leading to price variations across plans and insurers.

At a high level, Medicaid drug reimbursement reflects federal and state policies across the supply chain (manufacturer, wholesaler, pharmacy and PBM). Most states use maximum allowable cost (MAC) limits, and the federal government sets a federal upper limit (FUL) for generics, constraining state spending. For non-generics and drugs outside MAC/FUL, states typically cap payment at the actual acquisition cost plus a professional dispensing fee or the usual and customary charge, whichever is lower.

Outside of Medicare and Medicaid, private insurance drug prices are set through negotiations with manufacturers. States have enacted numerous drug pricing laws in recent years related to key reimbursement topics, including price reporting, cost-sharing caps, pharmacy benefit managers and drug payment limits. For example, in California, manufacturers must provide advance notice of price increases for certain drugs to the state and registered private purchasers.[39]

[39] Ca. Health and Saf. Code section 127675 et seq.

## ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

**14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

**Federal powers**

The FDA conducts inspections and investigations through its Office of Inspections and Investigations (OII) and its criminal law enforcement arm, the Office of Criminal Investigations (OCI).[40] The OII leads field inspections, import surveillance and emergency responses, while the OCI investigates criminal violations of the FDCA and related criminal statutes. The FDA lacks independent litigating power and relies on the Department of Justice (DOJ) to bring court actions like injunctions and seizures and to issue subpoenas or pursue criminal prosecution. The FDA's administrative tools include issuing regulatory letters (eg, 'warning letters' and 'untitled letters'), import alerts and civil money penalties.

Lawyers working in the Washington DC headquarters of the DOJ ('Main Justice') and local US lawyers residing in the 50 states bring FDCA injunction, seizure and criminal cases. The DOJ may also pursue parallel theories of liability, such as under the False Claims Act (FCA),[41] which, among other prohibitions, forbids causing the submission to the US government of a false claim for payment, like payment for materially non-compliant therapeutic products.

The FTC polices unfair or deceptive acts in commerce, including device and OTC drug advertising. The FTC is endowed with certain investigatory powers, including the power to issue civil investigative demands, warning letters, injunctive relief and civil monetary penalties.

**State powers**

Pursuant to their permit, licensure and registration frameworks, states routinely inspect and audit, with or without announcement, in-state and out-of-state facilities for compliance. In general, state regulators whose inspections and audits result in identified instances of non-compliance with trade and distribution rules issue warning letters and consent orders and require corrective action prior to the assessment of administrative penalties, including permit or licence denial, suspension or revocation or the imposition of civil monetary penalties.

States enter settlements with manufacturers and distributors following identified instances of non-compliance with the applicable regulations.

**15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?**

[40] 21 U.S.C. section 372.
[41] 31 U.S.C. section 3729.

**Pricing**

The second Trump Administration introduced executive order (EO) 14297, 'Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients', on 12 May 2025 that would implement 'most-favoured nation' pricing in the United States for prescription drugs.[42] The order, in part, includes a mandate to the Secretary of the Department of Health and Human Services (HHS) to 'establish a mechanism through which American patients can buy their drugs directly from manufacturers who sell to Americans at a "Most-Favored-Nation" price'. In the event drug manufacturers fail to offer most-favoured-nation pricing, the order subsequently directs the HHS Secretary to (1) propose rules that impose most-favoured-nation pricing and (2) take other aggressive measures to significantly reduce the cost of prescription drugs to the American consumer and end anti-competitive practices. Since 30 September 2025, the Trump Administration has announced deals with over a dozen major pharmaceutical manufacturers to bring prices in line with those paid in other developed nations, largely focusing on drugs treating chronic conditions. Patients will be able to purchase these discounted drugs directly through TrumpRx, which is scheduled to launch in early 2026.

Relatedly, EO 14273, 'Lowering Drug Prices by Once Again Putting Americans First', purports to ensure accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies and make insulin and injectable epinephrine more affordable for low-income individuals through a series of regulatory actions.[43] The HHS has been charged with generating guidance and recommendations to advance these objectives, although none have been finalised to date.

US tariffs on therapeutic products are currently in a state of flux. Announced tariffs have at times been delayed or avoided through deals with individual countries or with drug manufacturers themselves. Some countries have also placed reciprocal tariffs on US companies.

**Inspections and enforcement**

The FDA has indicated that it intends to increase its focus on unannounced inspections of foreign drug manufacturing facilities. While the Agency's inspection capacity has been somewhat diminished by support staff cuts, inspections that lead to regulatory violations could affect contract manufacturer relationships and reverberate throughout the supply chain.

The Trump Administration has further indicated that it plans to limit the use of criminal enforcement in regulatory matters. EO 14294, 'Fighting Overcriminalization in Federal Regulations', emphasises that criminal prosecution should be a last resort and calls for clear mens rea requirements.[44] This could impact the federal government's willingness to bring cases for strict liability misdemeanour violations of the FDCA.

The Trump Administration has also prioritised enforcement action against companies whose products may be used in gender-affirming care, such as gonadotropin-releasing hormone (GnRH) agonists and chest binders.[45]

[42] The White House, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients* www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/ last accessed on 16 May 2026.
[43] The White House, *Lowering Drug Prices by Once Again Putting Americans First* www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/ last accessed on 16 May 2026.
[44] Federal Register, *Fighting Overcriminalization in Federal Regulations* www.federalregister.gov/documents/2025/05/14/2025-08681/fighting-overcriminalization-in-federal-regulations last accessed on 16 May 2026.
[45] See EO 14187, Protecting Children from Chemical and Surgical Mutilation www.whitehouse.gov/presidential-actions/2025/01/protecting-children-from-chemical-and-surgical-mutilation/ last accessed on 16 May 2026

**Equipment/services from companies of concern**

In December 2025, President Trump signed the BIOSECURE Act into law, restricting the ability of entities that contract with federal agencies to use biotechnology equipment or services from a biotechnology company of concern. These biotechnology companies of concern are often closely linked with countries such as China, North Korea, Russia or Iran. The Act is predicted to disrupt supply chains as it forces companies to choose between maintaining ties with, for example, Chinese contract manufacturing organisations, or lucrative contracts with the federal government.