

## Oversight of the U.S. Drug Supply: H.R. 3204, the Drug Quality and Security Act

On November 27, 2013, President Obama signed the [Drug Quality and Security Act \(DQSA\)](#), amending the Federal Food Drug, and Cosmetic Act (FDCA) to address issues related to oversight of the practice of drug compounding, and incorporates a national prescription drug “track and trace” system inclusive of standards for prescription drug wholesale distributors and third-party logistics providers (3PLs).

It establishes a category of “outsourcing facilities” under which pharmacies conducting large-scale compounding of sterile drugs could voluntarily register and become subject to oversight by the Food and Drug Administration (FDA). It also imposes certain labeling requirements for compounded products. Traditional compounding pharmacies will remain under the oversight of state boards of pharmacies, and strives to improve communication between federal and state entities.

The measure also preempts state laws that establish requirements for tracing drugs through the distribution system that are inconsistent with or more stringent than, or in addition to, any track and trace standards of the enacted provisions.

The FDA has begun the implementation process with the release of several guidance documents related to compounding practices:

- [FDA Implementation of the Compounding Quality Act](#)
- [Compounding and the FDA Questions and Answers](#)
- [Interim Product Reporting for the Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#)
- [Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#)
- [Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#)
- [Final Guidance: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act \(PDF - 85KB\)](#), July 2014

### ***Drug Compounding***

Since [contaminated compounded drugs](#) caused infection in 750 individuals and the deaths of over 60 people in the fall of 2012, both chambers of Congress have worked to craft legislation that would strengthen the Food and Drug Administration’s ability to provide oversight of large scale drug compounders. Currently, the FDA’s ability to oversee drug compounding is unclear due to two inconsistent federal circuit court decisions and their limited authority to inspect pharmacies. Drug compounding, which has always been a part of the traditional practice of pharmacy, involves the mixing, combining, or altering of ingredients to create a customized medication for an individual patient. Traditional compounding pharmacies are not registered with the FDA as drug manufacturers, the agency doesn’t approve their prescriptions before marketing, and related adverse events need not be reported to the FDA. States have primary authority over the practice of both medicine and pharmacy, and state laws generally control recordkeeping, certifications, and licensing for compounding pharmacies. As the practice of compounding pharmaceuticals has evolved, large scale compounding pharmacies have emerged to widely distribute their products across state lines and in multiple states. In essence, they grew outside the traditional regulatory framework.

### ***Drug Supply Chain***

The complex drug supply chain from raw source materials to finished products for consumers presents multiple opportunities for the product to be contaminated, diverted, or otherwise adulterated. Federal efforts to secure the supply chain began in 1987, and were expected to be a logical method of ensuring the integrity of pharmaceuticals. Legal challenges forced a delay in implementation of federal law prompting some states to move ahead on their own requirements. California’s pedigree law has drawn the most attention nationwide; its comprehensive requirements include those for an electronic pedigree, product serialization, and track-and-trace capability from manufacturer to point of sale.

The bill’s sponsor, Representative Fred Upton (R-MI), said the legislation would clarify the FDA’s authority over the compounding of human drugs while requiring the agency to engage and coordinate with states to ensure the safety of compounded drugs. The legislation would also create a uniform national standard for drug supply chain security to protect Americans against counterfeit drugs while eliminating needless government red tape. It would help prevent increases in drug prices, avoid additional drug shortages and eliminate hundreds of millions of dollars worth of duplicative government regulations. The bill was approved in the U.S. House of Representatives Sept. 25, 2013.

## Summary of the H.R. 3204: Drug Quality and Security Act

### *Description*

Amends the Food, Drug, and Cosmetic Act to clarify the laws related to human drug compounding in response to the nationwide meningitis outbreak, and strengthens the prescription drug supply chain.

### *State Issues*

Beginning on the date of enactment, no state or political subdivision of one may establish or continue any requirements for tracing drugs through the distribution system which are inconsistent with, more stringent than, or in addition to, any track and trace standards in this legislation, or which are inconsistent with:

1. Any waiver, exception, or exemption issued by the secretary, or
2. Any enhanced distribution restriction.

### *Compounding Quality Act*

#### *Voluntary Registration*

- Creates a voluntary registration program for “*outsourcing facilities*.”
- Defines the term “*outsourcing facility*” as meaning a facility at one geographic location or address that: (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and complies with all of the requirements of this section. An outsourcing facility is not required to be a licensed pharmacy. An outsourcing facility may or may not obtain prescriptions from identified individual patients.
- Under the new framework outsourcing facilities voluntarily agree to subject themselves to certain requirements similar to those that currently govern traditional drug manufacturers.
- The language fails to differentiate the characteristics of an outsourcing facility and a compounding pharmacy.
- Creates an Advisory Committee on Compounding to consult with the secretary on the development of implementation of regulations.
- In fiscal year (FY) 2015, an assessment fee of \$15,000 and an additional \$15,000 (inflation adjusted) for inspections will be assessed on outsourcing facilities.
- Places certain limitations on registered outsourcing facilities by prohibiting them from compounding certain drugs such as drugs that have had their approval withdrawn for safety reasons or drugs included on a newly created list maintained by the FDA of drugs or categories of drugs that are reasonably likely to lead to adverse effects.

#### *Labeling*

- Drugs compounded by registered outsourcing facilities must be labeled in a manner that prominently identifies the drug as a compounded drug product.

#### *Reporting*

- Registered outsourcing facilities must submit biannual reports identifying the drugs compounded by the facility for the prior six-month period and information concerning each drug. Registered outsourcing facilities also must report adverse events to the FDA.

#### *Inspection*

- Registered outsourcing facilities will be subject to inspection by the FDA on a risk-based schedule that will consider factors such as the facility’s compliance and recall history or the inherent risk of the drugs compounded at the facility to determine inspection frequency. Registered outsourcing facilities will be subject to “reinspection” fees should the FDA inspect the facility more than once in a given year.

#### *Penalties*

- If a registered outsourcing facilities fails to pay its registration and reinspection fees, all of the drugs compounded by the facility will be considered misbranded until payment of the outstanding fees.

#### *State Boards of Pharmacy*

- State boards of pharmacy will retain primary oversight authority over traditional compounding activities.

#### *Enhanced Communications Between State Boards of Pharmacy and the Food and Drug Administration (FDA)*

- Directs the U.S. Department of Health and Human Services (HHS) to receive submissions from the State Boards of Pharmacy describing actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to the provisions in the Federal Food, Drug, and Cosmetic Act pertaining to compounding

pharmacies.

- Directs the secretary to immediately notify state boards of pharmacy when the secretary receives a submission or makes a determination that a pharmacy is acting contrary to the provisions of the Federal Food, Drug, and Cosmetic Act pertaining to compounding pharmacies.

#### *Government Accountability Office (GAO) Study*

- Directs the GAO to within 36 months of enactment of this measure to submit a report to congress on the adequacy of state and federal efforts to assure the safety of compounded drugs.

#### *Clarification of the Federal Food, Drug, and Cosmetic Act (FFDCA)*

- Modifies multiple provisions in the FFDCA relating to pharmacy compounding which led to a circuit court split and contributed to FDA's inability to take action.

### ***Drug Supply Chain Security Act***

- Directs HHS to issue draft guidance that establishes standards for the interoperable exchange of transaction information, history, and statements.
- Creates a new framework for drug security, and establishes a 10-year transition to a unit-level tracking system that would increase security.
- In establishing standards, HHS will consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain, and the standards established in relation to the provisions of law pertaining to pharmaceutical security under the Federal Food, Drug, and Cosmetic Act.

#### *Waivers, Exceptions, and Exemptions*

- Directs the secretary establish a process within two years of enactment by which:
  - A waiver of any requirements may be granted if it is determined that the requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration.
  - An exception may be granted related to the product identifier if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required.
  - The secretary may determine other products or transactions that will be exempt from the requirements.

#### *Manufacturer and Wholesale Distributor Requirements*

- Creates new manufacturer and wholesale distributor requirements pertaining to product tracing to be implemented Jan. 1, 2015.
- Establishes new transaction reporting and product identifier requirements specific to manufacturers and wholesale distributor.
- The term "manufacturer" with respect to a product means the person that holds an application approved under the Federal Food, Drug, and Cosmetic Act pertaining to new drugs, or a co-licensed partner or affiliate of the manufacturer.
- Requires manufacturers and wholesale distributor to have in place by Jan. 1, 2015 a system by which they can use if they determine a product in their possession or control is a suspect product.
- The manufacturer or wholesale distributor must quarantine suspect products, and promptly investigate to determine if the product is an illegitimate product.
- If the manufacturer or wholesale distributor makes a determination that a suspect product is not an illegitimate product, the manufacturer will promptly notify the Food and Drug Administration (FDA).
- If a product is deemed illegitimate the manufacturer or wholesale distributor must quarantine the product and remove the product from the pharmaceutical distribution supply chain, retain a sample of the product for further physical examination, and make specified notifications.
- Provides for a process for saleable returns on products intended for further distribution.
- Requires manufacturers and wholesale distributors to respond to requests for information from federal or state officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product no later than one business day and not to exceed 48 hours.
- Provides for similar requirements on dispensing entities defined as retail and hospital pharmacies, a group of chain pharmacy under common ownership and control that does not act as a wholesale distributor, and repackagers.

#### *Enhanced Drug Distribution Security*

- Imposes interoperable, electronic tracing of product at the package level requirements to be implemented 10 years after enactment which includes:
  - The exchange of transaction information and statements in accordance with standards established by the secretary,
  - Transaction information inclusive of a product identifier at the package level,

- A system and process for verification of product at the package level, including the standardized numerical identifier,
- A system and process to promptly respond with to a product request by the secretary in the event of a recall or for the purposes of an investigation of a suspect product, and
- A system and process in place to allow acceptance of a product and may accept a saleable returned products.
- Establishes requirements for information maintenance concerning agreements between dispensers and third parties.
- Establishes a process by which a small business (fewer than 25 full time employees) may receive a waiver of the requirements if they would result in an undue economic hardship and which will include a process for the biennial review and renewal of the waiver.
- Directs the secretary to, within 180 days of enactment, publish guidance to aid trading partners in the identification of a suspect product.

#### *Pilot Projects*

- Directs the secretary to establish pilot projects in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution chain.
- The pilot projects will be designed to utilize the product identifier for tracing of a product, improve technical capabilities, and identify system attributes that are necessary to implement security requirements.

#### *Provisions that Sunset*

- Provision relating to: (1) receipt of transaction history, and; (2) saleable returned products; will sunset within 10 years of enactment.

#### *National Standards for Prescription Drug Wholesale Distributors*

- Prohibits the distribution of a drug in any state unless the wholesale distributor is licensed by the state from which the drug is distributed, or if that state has not established a licensure requirement, is licensed by the secretary.
- If a drug is distributed interstate, the wholesale distributor must be licensed by the state into which the drug is distributed if the state requires the license for that purpose.
- Imposes new reporting requirements for wholesale distributors that begin Jan. 1, 2015 which the secretary will use in establishing a database of authorized wholesale distributors.
- The secretary is directed to coordinate with state officials who will have access to the information provided.
- Authorizes the secretary to establish and collect fees if a state does not establish a licensing program to cover the costs associated with establishing and administering a licensure program and conducting periodic inspections.
- Nothing in the act prohibits states from collecting fees from wholesale distributors in connection with state licensing.

#### *Standards for Licensing of Drug Wholesale Distributors*

- Directs the secretary to, within two years of enactment, establish by regulation standards for their licensing.
- For the purposes of ensuring uniformity with respect to standards set, the standards will apply to all state and federal licenses concerning wholesale distributors which will include standards for the following:
  - Storage and handling of prescription drugs, including facility requirements,
  - The establishment and maintenance of records of the distributions of the drugs,
  - The furnishing of a bond or other equivalent means of security, inclusive of a \$100,000 surety bond for nongovernmental entities or other equivalent means of security acceptable to the state,
  - Mandatory background checks and fingerprinting of facility managers or designated representatives,
  - The establishment and implementation of qualification for key personnel,
  - Mandatory physical inspection of the facility to be conducted by the licensing authority or the state, and
  - The prohibition of certain persons from receiving or maintaining licensure fro wholesale distribution.
- A federal or state licensing authority may conduct the inspection or may accept an inspection by the state in which the facility is located, or by third party accreditation or inspection service approved by HHS or the state.

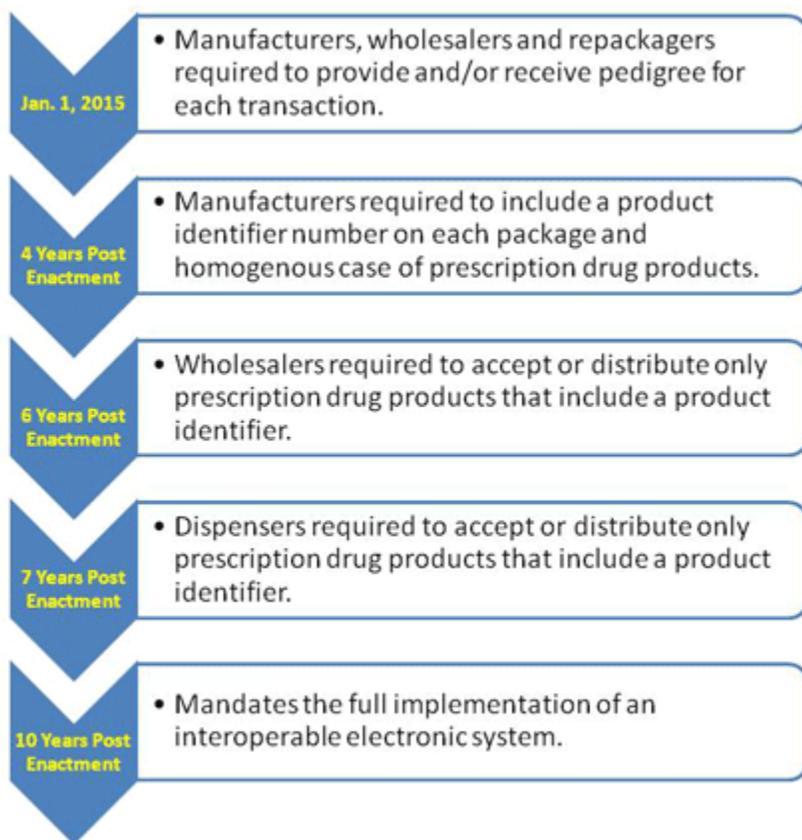
#### *Third-Party Logistics Providers*

- Requires the licensure of Third-Party Logistics Providers which is defined as an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.
- Requires third-party logistics providers to report annually to the secretary the state, by which the facility is licensed, and the name and address of the facility and all trade names under which they conduct business.
- If the state does not establish a licensing program, the secretary will license the entity.

### Uniform National Policy-Preemption of State Law

- Prohibits states or their political subdivisions from establishing or continuing in effect any requirements for tracing products through the distribution system after enactment of this act.
- Prohibits states or their political subdivisions from establishing or continuing in effect any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure, directly related to or covered by the standards and requirements as amended in this measure.
- Prohibits states from regulating third-party logistics providers as wholesale distributors.
- States may take administrative action including fines, to enforce requirements promulgated by the state.
- States may provide for the suspension or revocation of licenses issued by the state.

### Implementation Timeline



### Resources:

- [FDA and Pharmacy Compounding](#)—An educational video that brings awareness to consumers of what pharmacy compounding is and the role FDA plays. It highlights the risks and benefits associated with the practice and the medical necessity for it.
- [FDA Pharmacy Compounding Page](#)
- [FDA Guidance for Industry Standards for Securing the Drug Supply Chain](#)
- **FDA communications with states**
  - [Inter-governmental Working Meeting on Pharmacy Compounding March 20-21, 2014](#)
  - [“Dear Colleague” Letter to States \(PDF – 1.3 MB\)](#)

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