# The Drug Quality and Security Act (H.R. 3204) Section 503B of The Food, Drug & Cosmetic Act

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*as passed by the House of Representatives on September 28, 2013 and the Senate on November 18, 2013*

*November 18, 2013*

*Note: There are two titles in the Drug Quality and Security Act: Title I relates to drug compounding and Title II relates to drug supply chain security, commonly known as track and trace. The bill creates a new section, 503B, of the Food, Drug & Cosmetic Act (FD&C), which describes "outsourcing facilities," and renumbers the existing section 503B as 503C. This summary only includes the provisions dealing with "outsourcing facilities." Please see the summary of the compounding requirements specified under Section 503A of the FD&C for more information.*

H.R. 3204 allows outsource drug compounding facilities ("outsourcing facilities") to voluntarily register with the Food and Drug Administration (FDA) and submit to inspections on a risk-based schedule set by the Secretary of Health and Human Services (HHS). Further, if any provision of this bill is declared unconstitutional or declared invalid, the remainder of this bill would not be affected.

Under this bill, compounding performed by health-system pharmacies is not changed. Only "outsourcing facilities" that choose to be registered with and inspected by the FDA would be affected.

## Outsourcing Facilities

An "outsourcing facility" is defined as a facility at one geographic location that

- Compounds sterile drugs;
- Has registered as an "outsourcing facility" with the FDA; and
- Complies with the requirements established in the bill.

An "outsourcing facility" is not required to be a licensed pharmacy and may or may not obtain patient-specific prescriptions.

An "outsourcing facility" that chooses to annually register with the FDA would submit a list of compounded drugs made by the facility every six months. The following information would be identified for each compounded drug: the active ingredient, its source, and its strength per unit; the National Drug Code (NDC) number of the source drug or bulk active ingredient; the dosage form and route of administration; the number of individual units produced; and the NDC number of the final product. These facilities also must submit adverse event reports to the FDA.

## Risk-based Inspections

Outsourcing facilities will be inspected based on the following known safety risk factors:

- Compliance history;
- Record, history, and nature of recalls linked to the facility;
- Inherent risk of the compounded drugs;
- Inspection frequency and history of the facility;
- Whether the facility has registered that it intends to compound a drug that appears on the list in effect under section 506E (FDA's drug shortage list); and
- Any other criteria determined by the Secretary.

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## Fees

An outsourcing facility would pay an annual establishment fee beginning in fiscal year 2015 to offset inspection costs. A facility requiring a reinspection within the same fiscal year will pay a reinspection fee each time inspectors are required to revisit the facility.

## State Boards of Pharmacy Enhanced Communication

In consultation with the National Association of the Boards of Pharmacy, the HHS Secretary would be required to receive information from state boards of pharmacy about compounding pharmacies and outsourcing facilities. This information could include descriptions of actions they have taken against these entities, such as imposing sanctions or penalties, suspending or revoking a pharmacy license or registration, or the recall of a compounded drug. A state board of pharmacy also could submit to HHS any concerns that a compounding pharmacy could be acting contrary to section 503A.

The Secretary would be required to notify all state boards of pharmacy when information is received from a state board regarding actions taken against a compounding pharmacy or when the Secretary determines a pharmacy is acting contrary to Section 503A.

## Advisory Committee on Compounding

The Secretary must convene and consult an Advisory Committee on Compounding before issuing regulations that identify the drugs that are demonstrably difficult to compound and are reasonably likely to lead to adverse effects.

## Report/Study

The HHS Secretary would be required to submit an annual report on outsourcing facility fees and the inspections they support to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce.

Three years after the bill is enacted, the Government Accountability Office would be required to submit a report to Congress on pharmacy compounding and the adequacy of state and federal efforts to assure the safety of compounded drugs. This report would include:

- A review of pharmacy compounding by state and by compounding settings;
- A review of state pharmacy compounding laws and policies;
- An assessment of the available tools for determining the safety and quality of compounded drugs;
- An analysis of the effectiveness of communication about compounding between states and between states and the FDA; and
- An evaluation of the FDA's implementation of sections 503A and 503B of the FD& C.