

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



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

November 18, 2013

*Note: This summary only describes provisions of the Drug Quality and Security Act that provide minor changes to the existing section 503A of the Food, Drug & Cosmetic Act (FD&C) intended to address constitutional questions raised since that Section was enacted in 1997. In general, hospital and health systems will be subject to Section 503A. The bill also describes a new category of “outsourcing facilities” and creates a new section, 503B, of the Food, Drug & Cosmetic Act (FD&C). Please see the summary of the compounding requirements specified under Section 503B of the FD&C for more information.*

Oversight of pharmacy compounding defined under Section 127 of the Food and Drug Administration Modernization Act of 1997, (P.L. 105-115), has not been strictly enforced by the Food and Drug Administration (FDA) and varies by geographic region due to conflicting legal interpretations of the provision restricting the advertising and promotion of drugs. This conflict is resolved by H.R. 3204, which was approved by the House of Representatives on September 28, 2013, and on November 18, 2013 by the Senate.

H.R. 3204 removes the requirement that a pharmacy, licensed pharmacist, or licensed physician cannot advertise or promote the compounding of any drug, class of drug, or type of drug. It also removes the requirement that a prescription be “unsolicited” from a compounding pharmacy. A licensed pharmacist, physician, or other licensed prescriber who compounds a drug based on a prescription is not required to meet current Good Manufacturing Practices (cGMP), does not have to meet manufacturer standards for adequate directions for use on a label, and does not have to file a new drug application.

## What Drugs Can Be Compounded?

A drug can be compounded by a licensed pharmacist or physician if the following requirements are met:

- The product is compounded from bulk drug substances that:
    - Comply with U.S. Pharmacopoeia standards, or a National Formulary monograph if one exists, and the U.S. Pharmacopoeia pharmacy compounding chapters (USP Chapter <797> and USP Chapter <795>); are components of drugs approved by the FDA, if a monograph does not exist; or appear on a list of drug substances that may be used in compounding.
    - Are manufactured by a drug producer registered with the FDA.
    - Have a valid certificate of analysis for each bulk drug.
  - The product is compounded from ingredients that are not in bulk that comply with U.S. Pharmacopoeia standards, or a National Formulary monograph, if one exists, and the U.S. Pharmacopoeia pharmacy compounding chapters.
  - The drug is not on a list of drugs that were withdrawn or removed from market because the drug was not safe and effective.
- The pharmacist or physician does not compound regularly or in inordinate amounts any drugs that are essentially copies of a commercially available drug product.
  - It is not demonstrably difficult to compound such that doing so would reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and
  - It is compounded in a state that entered into a memorandum of understanding with the FDA addressing the interstate distribution of inordinate amounts of compounded drugs and provides for state investigation of complaints of the drug distributed outside of the state; or
  - It is compounded in a state that has not entered into such a memorandum of understanding with the FDA and the compounded drug distributed out of the state where it was compounded does not exceed 5% of the total prescription orders dispensed or distributed by the pharmacy or physician.

## What Isn't Compounding?

Compounding does not include mixing, reconstituting, or other acts necessary in following the directions on a manufacturer's label.