
The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document contact CDER Office of Compliance at 301-796-3100 or drugtrackandtrace@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)**

**October 2014
Procedural**

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Center for Drug Evaluation and Research

Food and Drug Administration

10903 New Hampshire Ave., Silver Spring, MD 20993

Phone: 301-796-3400; Fax: 301-847-8714

druginfo@fda.hhs.gov

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Center for Biologics Evaluation and Research

Food and Drug Administration

10903 New Hampshire Ave., Silver Spring, MD 20993

Phone: 800-835-4709 or 240-402-7800

ocod@fda.hhs.gov

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**The Effect of Section 585 of the FD&C Act on Drug Product
Tracing and Wholesale Drug Distributor and Third-Party Logistics
Provider Licensing Standards and Requirements:
Questions and Answers
Guidance for Industry¹**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The Food and Drug Administration (FDA) is issuing these questions and answers to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)² added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013. Title II, which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third party logistics providers; the Agency is currently drafting these regulations. Section 585 sets forth a uniform national policy preempting States³ from establishing or continuing in effect certain standards and requirements.

FDA is issuing this guidance to (1) help industry and States understand the immediate effects of the law and (2) clarify section 585's effect on State product tracing and standards and requirements for wholesale distributor and third-party logistics provider (3PL) licensing.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should

¹ This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² For brevity, in this guidance, references to section 585 of the FD&C Act are cited as section 585.

³ Section 585 uses the phrase "State and political subdivision of a State." For purposes of this document, the word *States* will mean States and political subdivisions of States.

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be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. The DSCSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The DSCSA adds sections 581 through 585 as Subchapter H of the FD&C Act. These sections establish definitions (section 581), requirements for supply chain participants (section 582), standards for and licensing of wholesale drug distributors (section 583) and third-party logistics providers (section 584), and a Uniform National Policy (section 585).

Section 585, as added by section 205 of the DQSA, states:

(a) **PRODUCT TRACING AND OTHER REQUIREMENTS.**—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—

- (1) any waiver, exception, or exemption pursuant to section 581 or 582; or
- (2) any restrictions specified in section 582.

(b) **Wholesale Distributor and Third-Party Logistics Provider Standards—**

(1) **IN GENERAL.**—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

(2) **State Regulation of Third-Party Logistics Providers.**—No State shall regulate third-party logistics providers as wholesale distributors.

III. QUESTIONS AND ANSWERS

A. *Product Tracing*

1. How does section 585(a) affect State tracing requirements?

Beginning on November 27, 2013, the date of enactment of the DSCSA, States were preempted from establishing or continuing in effect any requirements for tracing prescription drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act (21 U.S.C. 353(e) (as amended by the DSCSA)) or Subchapter H (added by the DSCSA) or regulations issued thereunder.

Section 585 enumerates the types of requirements that States are preempted from establishing or continuing in effect in any manner that is inconsistent with, more stringent than, or in addition to Federal law, including: statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, verification, investigation, disposition, notification, or recordkeeping relating to the distribution systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

In addition, no State may establish, continue in effect, or apply any requirement that is inconsistent with any waiver, exception, or exemption granted by FDA pursuant to sections 581 or 582 of the FD&C Act or any restrictions specified in section 582.

2. What product tracing requirements apply before January 1, 2015?

Prior to January 1, 2015, the Federal pedigree requirements of section 503(e)(1) of the FD&C Act, remain in effect. Therefore, until January 1, 2015, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to the requirements of section 503(e)(1) of the FD&C Act.

3. What product tracing requirements apply on or after January 1, 2015?

Beginning January 1, 2015, the Federal tracing requirements of section 582 of the FD&C Act established under the DSCSA, go into effect. After that date, States may not regulate tracing in any way that is inconsistent with, more stringent than, or in addition to those requirements.

4. Which State requirements are preempted?

Any requirements for tracing drugs through the pharmaceutical distribution supply chain that are inconsistent with, more stringent than, or in addition to any requirements applicable under section 503(e) of the FD&C Act, as amended by the DSCSA, or under subchapter H (or regulations issued thereunder) are preempted.

B. Wholesale Drug Distributor Standards and Licensing

1. How does section 585(b) affect State wholesale drug distributor standards and licensing?

Beginning on November 27, 2013, States were preempted from establishing or continuing any standards, requirements, or regulations with respect to wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards⁴ or requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA). Thus, States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law.

2. Will States need to change their wholesale drug distributor licensing laws before the new Federal wholesale drug distributor regulations take effect?

Each State will have to analyze its own laws to determine the impact of section 585; however, FDA understands that, in general, the current Federal standards, requirements, and regulations have been the basis for most current State laws. Therefore it is likely those State laws would not fall below the minimum standards established by federal law and would not need to be changed.

The new wholesale drug distributor regulations issued under section 583 will take effect two years after they are finalized by FDA. By that time, States should have reanalyzed their licensing laws in order to determine if those laws fall below the minimum standards established by federal law.

3. Can States continue to license wholesale drug distributors before the new Federal regulations for wholesale drug distributor standards and licensing go into effect?

Yes. States can continue to license wholesale drug distributors before the regulations issued according to section 583 (as added by 204 of the DSCSA) become effective, as long as the State regulations are not inconsistent with, less stringent than, directly related to, or covered by Federal law. The DSCSA contemplates that states will continue to license wholesale drug distributors before the new regulations go into effect. For example, section 503(e)(1)(A) (as amended) requires a wholesale drug distributor to be licensed by the State from which the drug is distributed or else by the Secretary of Health and Human Services if the distributing wholesale drug distributor's State chooses not to have a licensing program. In addition, the distributor must be licensed by the State into which the drug is distributed (if required by that State).

4. What wholesale drug distributor standards and licensing requirements apply after the new Federal regulations go into effect?

When the new Federal licensure regulations of the FD&C Act become effective (see section 583(a), (e)), States will be preempted from continuing or establishing licensure in any way that

⁴ Please refer to section 583(b) of the FD&C Act for additional information on content requirements for wholesale drug distributor licensing standards.

falls below the minimum standards established by those Federal regulations.⁵ When the final regulations are published, States will know whether they need to change any standards, requirements, or regulations that they may have established that are inconsistent with, less stringent than, directly related to, or covered by those Federal regulations.

C. Third-Party Logistics (3PL) Provider Standards and Licensing

1. How does section 585(b) affect 3PL standards and licensing?

Beginning on November 27, 2013, States are preempted from establishing or continuing any standards, requirements, or regulations with respect to 3PLs that are inconsistent with, less stringent than, directly related to, or covered by the standards⁶ or requirements applicable under section 584 of the FD&C Act. Thus, States may not impose standards, requirements, or regulations with respect to 3PLs that fall below the minimum standards established by Federal law.

2. Can States license 3PLs before the new Federal regulations for 3PL standards and licensing go into effect?

Yes. States can license 3PLs before the new Federal regulations issued according to section 584 become effective. The DSCSA contemplates that States can license 3PLs before the new Federal regulations become effective. For example, section 584(b) of the FD&C Act requires 3PLs to report “the State by which the facility is licensed” beginning 1 year after the date of enactment of the DSCSA.

3. What 3PL standards and licensing requirements apply after Federal regulations go into effect?

Once the new Federal licensing regulations for 3PLs become effective (see section 584(d)), States will be preempted from continuing or establishing licensure in any way that falls below the minimum standards established by those regulations.⁷ When the final regulations are published, States will know whether they need to change any standards, requirements, or regulations that they may have established that are inconsistent with, less stringent than, directly related to, or covered by those Federal regulations.

⁵ The licensing regulations for wholesale drug distributors are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 583(a)); the final regulation will take effect “2 years after the date that such final regulation is published” (section 583(e)(3)).

⁶ Please refer to section 584(d)(2)(C) – (H) of the FD&C Act for additional information on content requirements for third-party logistics provider licensing standards.

⁷ The licensing regulations for 3PLs are to be issued not later than 2 years after the date of enactment of the Drug Supply Chain Security Act (section 584(d)(1)); the final regulation will take effect “1 year after the date that such final regulation is issued” (section 584(d)(3)(C)).

4. Can States license 3PLs using their licensing program for wholesale drug distributors?

Section 585(b)(2) does not permit states to license 3PLs as wholesale drug distributors. States would need to establish separate licensing programs for wholesale drug distributors and 3PLs.