



## **Pharmaceutical Distribution Security Alliance (PDSA) FAQs on Preemptive Effect of the DSCSA**

The Drug Supply Chain Security Act (DSCSA) establishes a national system for the traceability of certain prescription pharmaceutical products through the distribution chain and provides for uniform national standards for licensure of pharmaceutical wholesale distributors and third-party logistics providers (3PLs). As explained by Representative Latta, the DSCSA was intended to “replac[e] the current patchwork of multiple State laws with a *uniform* national standard, [thereby] improving safety, eliminating duplicative regulations, and creating certainty for all members of the pharmaceutical supply chain.”<sup>1</sup>

National uniformity is established through the DSCSA by preempting certain state requirements related to product tracing, licensure of wholesale distributors, and licensure of 3PLs. The preemption provisions of the DSCSA are set out in Section 585 of the Food, Drug, and Cosmetic Act (FD&C Act).

The DSCSA requires a common understanding and approach from all stakeholders, including FDA, state regulators, and the regulated community. The questions and answers in this document are intended to promote such a common understanding among stakeholders by clarifying several issues that will help to facilitate a national uniform approach.

### **1. What is the purpose of the DSCSA preemption provision?**

**The DSCSA was intended to create a single, uniform set of requirements applicable across all states related to the tracing of pharmaceutical products and the licensure of wholesale distributors and 3PLs.**

The pharmaceutical distribution supply chain is a complex interstate network of manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers. A pharmaceutical product is typically moved among multiple entities and across multiple states prior to reaching the patient. The nature of the supply chain therefore made compliance with a patchwork of varying state requirements related to product tracing and distributor licensing extremely burdensome and prevented the stakeholders from realizing the full public health benefits of tracing and licensing schemes.

The DSCSA “creates a uniform national standard for drug supply chain security to protect Americans against counterfeit drugs while eliminating needless levels of bureaucracy.”<sup>2</sup> As noted above, the DSCSA is intended to establish a single, uniform national standard for both the tracing of pharmaceutical products through the supply chain and for the licensure of wholesale distributors and 3PLs.

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<sup>1</sup> H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5962 (statement of Rep. Latta) (2013) (emphasis added).

<sup>2</sup> H.R. 3204, 113th Cong., 159 Cong. Reg. 131, at 5961 (2013) (emphasis added).

## **2. What product tracing requirements are preempted by the DSCSA?**

**All state requirements related to product tracing, including state “pedigree” requirements, are preempted by the DSCSA.**

Section 585(a) of the FD&C Act, added by the DSCSA, preempts all state<sup>3</sup> “requirements for tracing products through the distribution system . . . which are inconsistent with, more stringent than, or in addition to, any requirements [established by the DSCSA].” The statute expressly defines such product tracing requirements as including any requirements related to:

- Statements of distribution history.
- Transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, and all information required for inclusion
- Verification, investigation, disposition, notification, or recordkeeping relating to such systems.
- Paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system.

Any state pedigree requirement or other requirement related to product tracing is necessarily “inconsistent with, more stringent than, or in addition to” the product tracing requirements in the DSCSA. Therefore, any such state requirement is preempted under the DSCSA.

## **3. What licensure requirements are preempted by the DSCSA?**

**The DSCSA preempts all state standards and requirements for licensing wholesale distributors and 3PLs that exceed or otherwise deviate from the federal standards and requirements.**

Section 585 of the FD&C Act, added by the DSCSA, establishes uniform licensure requirements for wholesale distributors and 3PLs by preempting state licensure requirements that do not utilize the federal standards to be developed by the Agency. Specifically, section 585(b) preempts all state “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 [the DSCSA].”

The language in section 585(b) has generated significant discussion within the regulated community with regard to whether a state may impose licensure standards or requirements that exceed the standards and requirements applicable under the DSCSA. Under a proper interpretation of section 585(b) states must not exceed or otherwise deviate from the federal standards that will be developed.

The clear and primary intent of the DSCSA was to establish uniformity among states. In fact, with regard to licensure, the statute itself expressly states its intent to establish uniformity. Section 583(b) provides that the licensing standards established by the DSCSA are “[f]or the purpose of

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<sup>3</sup> In this document, we use the term “state” as including any political subdivision of a state.

ensuring **uniformity** with respect to [the federal licensing] standards.”<sup>4</sup> That section goes on to explain that “the standards established [by the Agency] shall apply to all State and Federal licenses . . .” Uniformity<sup>5</sup> simply does not exist unless all states are required to utilize identical standards.

A conclusion that states may establish standards and requirements that exceed or differ from the federal standards and requirements is inconsistent with the statute and runs directly contrary to the legislative intent of the DSCSA. If states could establish higher standards, wholesale distributors and 3PLs could be left having to comply with 50 different sets of rules, which, as explained by Representative Matheson, “doesn’t make sense.”<sup>6</sup> A patchwork of licensing standards is precisely the regulatory burden the DSCSA was intended to eliminate.

Permitting states to establish standards that go beyond the standards established by the Agency pursuant to Sections 583 and 584 is also poor public policy. Many wholesale distributors and 3PLs operate, and are subject to licensure in, multiple states. Tracking and complying with different standards for different facilities is time consuming and adds unnecessary costs to the distribution chain. Furthermore, such variations are not necessary to protect patient health as the DSCSA was specifically designed to raise the standards for wholesale distributor and 3PL licensing.<sup>7</sup>

At first blush, one may be tempted to conclude that the difference in statutory language in Sections 585(a) and 585(b) suggests that the federal licensing standards are minimum standards only. That, however, is not an accurate representation of legislative intent. The difference in statutory language was intended to signal that traceability preemption under Section 585(a) is *broad* (*i.e.*, any requirement directly or indirectly related to product tracing including pedigree requirements) and complete (*i.e.*, any state requirement not identical to the federal standard), whereas licensure preemption under Section 585(b) is *narrow* (*i.e.*, strictly limited to licensing standards) and complete. This distinction is important.

The difference in statutory language in 585(a) and 585(b) was not intended to suggest that either is not complete preemption (*i.e.*, preemption of any state requirement not identical to the federal requirement), but rather to indicate a difference in breadth. With regard to product tracing, Congress sought to preempt any state requirement related, even indirectly, to product tracing. With regard to licensing standards, however, Congress sought to preempt only those state requirements that are *directly* related to<sup>8</sup> licensing standards. Specifically, Congress did not want to tread into other areas of regulation related only indirectly to licensing standards. For example, Congress wanted to ensure that Section 585(b) did not prevent states from continuing to collect fees for prescription drug monitoring programs, which are important tools for addressing prescription drug abuse and misuse. Similarly, Congress did not want Section 585(b) to prevent states from enforcing tangentially related, generally applicable regulatory requirements, such as environmental registration or permit requirements applicable to all types of businesses.

The preemptive effect of Section 585(b) applies to all state requirements that are “inconsistent with, less stringent than, directly related to, **or** covered by” the federal standards including requirements ancillary to traceability such as recordkeeping and reporting. Meaning and effect

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<sup>4</sup> FDCA § 583(b) (emphasis added).

<sup>5</sup> Black’s Law Dictionary defines “uniform” as “Characterized by a lack of variation; identical or consistent.”

<sup>6</sup> H.R. 3204, 113<sup>th</sup> Cong., 159 Cong. Reg. 131, at 5964 (statement of Rep. Matheson) (2013)

<sup>7</sup> See H.R. 3204, 113<sup>th</sup> Cong., 159 Cong. Reg. 131, at 5961 (statement of Rep. Pallone) (2013).

<sup>8</sup> FDCA § 585(b).

must be given to each and every one of the four standards included in Section 585(b). Take, for example, the wholesale distributor licensing standard regarding surety bonds. The statute provides that a non-governmental wholesale distributor must submit a surety bond of \$100,000. If a state were to require a surety bond of \$150,000, it is impossible to see how such a requirement would not be considered a standard which is “inconsistent with” the federal standard for surety bonds. Similarly, if a state were to require certification for a wholesale distributor’s designated representative, it is impossible to see how such a requirement is not “directly related to” or “covered by” the DSCSA, specifically sections 583 (b)(4)&(5).

The full text of section 585(b), the legislative intent underlying it, and the related practical implications make clear that all state standards and requirements for licensing wholesale distributors and 3PLs that exceed or otherwise deviate from the federal standards and requirements are preempted.

#### **4. How does DSCSA preemption affect VAWD and similar accreditation requirements?**

**The DSCSA prohibits states from requiring VAWD accreditation as a condition of wholesale distributor or 3PL licensure.**

The DSCSA (FD&C Act § 583(b)(6)) requires that a wholesale distributor be inspected within a reasonable time from submission of its initial application. The DSCSA does not require that a wholesale distributor be accredited by a third-party. Requiring accreditation by a third-party would be preempted by section 585(b)(1) because such requirement would impede national uniformity for wholesale distributor licensure by imposing burdens upon wholesale distributors that are covered by and directly related to the DSCSA standards and requirements.

A state may continue to use third-party inspectors that it has approved to conduct their inspections of wholesale distributors. Section 583(c) permits mandatory physical inspections of wholesale distributors by FDA, the State licensing authority, or a third-party accreditation or inspection service approved by FDA or the State licensing authority. However, any State inspector, including a third-party inspector inspecting on behalf of the State licensing authority, must inspect against the standards and requirements of the DSCSA and any State requirements that are not inconsistent with, less stringent than, directly related to, or covered by the DSCSA.

#### **5. Must states defer to the DSCSA’s definitions and terminology?**

**Yes, the preemptive effect of Section 585 extends to both the requirements of the DSCSA and the definitions set out in it.**

Section 585(a) of the FD&C Act preempts all state traceability requirements that are inconsistent with, more stringent than, or in addition to any requirement in Section 503(e) or Subchapter H. Subchapter H contains both the definitions set out in Section 581 and the traceability requirements set out in Section 582. Therefore, the preemptive effect of Section 585(a) extends to any state requirements related to product tracing, including the reporting of any licenses, as well as the definitions that underlay any such requirements.

The definitions in Section 581 are a critical part of the requirements in Section 582. For example, different requirements under Section 582 apply to manufacturers, repackagers, wholesale distributors, 3PLs, and dispensers. Each of those terms is specifically defined in Section 581. If a state were permitted to adopt different definitions of those terms, the state would effectively be able to alter the requirements under Section 582 and create significant confusion in the marketplace. Similarly, the scope of the requirements under Section 582 is largely determined by the definition of a “product” under Section 581(13)—a definition carefully crafted by Congress. Any state definition that were to narrow or expand the DSCSA definition of “product” would significantly alter the traceability requirements established by the DSCSA and clearly run contrary to the statute’s intent.

Similarly, the definition of “wholesale distribution” in Section 503(e)(4) and “third-party logistics provider” in Section 581(22) are critical to the licensure requirements in Sections 503, 583, and 584. In particular, the definition of “wholesale distribution” expressly excludes “the distribution of a drug by the manufacturer of such drug.”<sup>9</sup> Accordingly, a manufacturer is not a wholesale distributor when distributing its own products, and a state cannot require a manufacturer to be licensed as a wholesale distributor. Such state requirements for manufacturers are inconsistent with and directly related to the federal licensure requirement for wholesale distributors and therefore are preempted under Section 585(b)(1).

## **6. Does the DSCSA preempt state licensure requirements for manufacturers?**

### **The DSCSA preempts state licensure requirements for manufacturers that are related to the manufacturers’ distribution activities.**

As explained in Q&A #5, the preemption provisions of the DSCSA make the DSCSA’s definitions binding upon the states. The DSCSA definition of “wholesale distribution”—those activities for which the wholesale distributor must be licensed—expressly excludes “the distribution of a drug by the manufacturer of such drug.”<sup>10</sup> Accordingly, any state requirement that a manufacturer be licensed for distribution of its own products is inconsistent with the DSCSA and is therefore preempted under section 585(b). Such preemption includes the preemption of any state license not labeled as a wholesale distributor license (*e.g.*, a “manufacturer license” or “3PL license”) that has the effect of licensing a manufacturer for its distribution activities. The preemptive effect applies equally to both resident and non-resident licensure requirements.

## **7. When do the DSCSA preemption provisions take effect?**

### **Both preemption provisions took effect on November 27, 2013.**

Both the product tracing preemption provision in section 585(a) and the licensure preemption provision in 585(b) took effect on the date the DSCSA was enacted, which was November 27, 2013. Preempted state requirements were invalid as of that date.

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<sup>9</sup> FD&C Act § 503(e)(4)(H).

<sup>10</sup> FD&C Act § 503(e)(4)(h).

**8. What wholesale distributor licensing requirements apply prior to the effective date of the final federal standards for wholesale distributor licensing?**

**Until the effective date of the national licensing standards for wholesale distributors, existing state licensure requirements for wholesale distributors that are not inconsistent with the statutory text of the DSCSA remain in force.**

The licensure scheme established by the DSCSA leaves the licensing authority for wholesale distributors with the states, but states must use the national standards to be established by the FDA to carry out its licensure programs. The DSCSA sets out seven general types of standards to be used for purposes of wholesale distributor licensing but obligates FDA to establish more detailed standards by November 27, 2015. Those standards will go into effect two years after finalization.

Prior to the effective date of national licensing standards to be issued by FDA, existing state licensure requirements for wholesale distributors that are not inconsistent with the statutory text of the DSCSA remain in force. Any requirement that is inconsistent with the statutory text of the DSCSA is preempted. Such inconsistent requirements may include a requirement that wholesale distributor submit a \$150,000 surety bond. Similarly, a state definition of “wholesale distributor” that is inconsistent with the DSCSA definition of “wholesale distributor” (*e.g.*, a state definition that incorporates manufacturers or 3PLs) would also be preempted.

Once the FDA-established standards are in effect, all state licensure requirements that vary from those standards will be preempted, as explained in Q&A #3.

**9. What 3PL licensing requirements apply prior to the effective date of the final federal standards for 3PL licensing?**

**The DSCSA anticipates that states will not establish licensure requirements for 3PLs until the federal licensing standards for 3PLs are published by FDA.**

Similar to wholesale distributors, the DSCSA leaves licensure authority for 3PLs with the states but requires states to use the national standards, to be established by the FDA, to carry out their licensure programs. The DSCSA obligates FDA to establish national licensing standards for 3PLs by November 27, 2015. Those standards will go into effect one year after publication. Unlike wholesale distributors, only two states currently have a license for 3PLs.

The DSCSA anticipates that states will not establish licensure requirements for 3PLs until the federal licensing standards for 3PLs are published by FDA. The DSCSA was intended to eliminate the existing patchwork of licensing standards and establish a single, uniform set of licensing standards. The development of state licensing requirements for 3PLs prior to the FDA’s publication of federal licensing standards will only increase the patchwork of regulatory requirements 3PLs must navigate. Furthermore, given the preemptive effect of Section 585(b), any licensing requirements established prior to release of the federal standards will almost certainly have to be revised when those federal standards go into effect. This burdens state regulators and 3PLs alike.

The development of state licensure requirements prior to release of the federal standards also has the potential to create significant confusion. For example, assume a 3PL is licensed by a state prior

to release of the federal standards and the license does not expire until after the effective date of the federal standards. If the initial state licensing standards do not comply with the federal standards (which they almost certainly will not prior to development of the federal standards), there will be significant confusion surrounding the 3PL's licensure obligations as of the effective date of the federal standards.

The DSCSA statutory text itself also clearly contemplates that states will not establish 3PL licensure requirements until federal standards are developed and released. Specifically, unlike wholesale distributors, section 582(a)(7) provides that a 3PL is *deemed to be licensed* for purposes of the DSCSA until the relevant state properly establishes 3PL licensure requirements. Furthermore, until the federal standards are effective, Section 582(a)(7) grants the Agency adequate authority to protect the supply chain from unqualified and unscrupulous 3PLs by revoking their deemed licensed status. This clearly suggests that Congress expected states would refrain from establishing 3PL licensure requirements.

**10. If a state determines it can proceed with establishing a 3PL licensing requirement in advance of the national licensing standards, what standards would the state follow?**

**As explained in Q&A #9, the DSCSA anticipates that states will not establish licensure requirements for 3PLs until the federal licensing standards for 3PLs are published by FDA.**

The DSCSA deems all 3PLs licensed until the national standards go into effect, which clearly contemplates that states will not establish 3PL licensure requirements until that time. There are practical reasons for states to delay new licensing programs until the national standards are available as well. Most importantly, the statute provides only moderate direction as to what the licensing standards for 3PLs should be. As a result, any 3PL licensing requirements established by states in advance of the national standards will almost certainly have to be amended following finalization of the national standards (or will be preempted).

If a state concludes that it can establish a licensing requirement for 3PLs prior to finalization of the national standards, those requirements must not deviate from the express statutory standards and requirements in the DSCSA. For example, unlike the DSCSA standards for wholesale distributors, the DSCSA licensing standards for 3PLs do not permit states to require surety bonds from 3PLs. Rather than create confusion by establishing diverse and potentially inconsistent licensure requirements across states, the intent of the DSCSA is best advanced if states withhold establishing new licensing requirements for 3PLs and coordinate with the FDA to ensure (i) FDA is properly monitoring 3PL activities, and (ii) the states are well-positioned to tailor any future licensing programs to the national standards.

**11. Can states impose licensure requirements for nonresident 3PLs?**

**A state may only require a nonresident 3PL to be licensed if the nonresident 3PL does not hold a federal license.**

The 3PL licensure requirement under the DSCSA provides that a resident 3PL (*i.e.*, a 3PL that distributes from the relevant state) must be licensed (i) by the state from which the drug is

distributed by the 3PL, or (ii) if such state has not established a licensure requirement, by FDA. The DSCSA further provides that a nonresident 3PL (*i.e.*, an out-of-state 3PL distributing into the relevant state) must be licensed “by the state into which the drug is distributed by the third-party logistics provider if . . . the third-party logistics provider is not licensed by the [FDA] . . .”<sup>11</sup> Any additional licensure requirements for nonresident 3PLs clearly would be preempted by the DSCSA as inconsistent with, directly related to, or covered by the DSCSA requirements.

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<sup>11</sup> FD&C Act § 584(a)(2).