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**BY ELECTRONIC MAIL**
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Dear Dr. Jung:

The Healthcare Distribution Management Association (HDMA) thanks you and the Food and Drug Administration (FDA) for the collective efforts on implementation of Title II of Public Law No. 113-54, the Drug Supply Chain Security Act (DSCSA). On behalf of HDMA, this letter provides our views on FDA’s draft guidance: The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and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 [79 Fed. Reg. 60853 (Oct. 8, 2014)] (Draft Guidance).

HDMA is the national association representing primary healthcare distributors, the vital link between the nation’s pharmaceutical manufacturers and healthcare providers. Each business day, HDMA member companies ensure that 15 million prescription medicines and healthcare products are delivered safely and efficiently to more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. HDMA and its members work daily to provide value and
achieve cost savings, an estimated $42 billion each year to our nation’s healthcare system. For more information, visit www.HealthcareDistribution.org.

I. Introduction

HDMA has learned from State officials and members’ interactions with trading partners that there is considerable confusion regarding the DSCSA’s impact on State laws, regulations, and other requirements governing the pharmaceutical supply chain. Thus, although the Draft Guidance is not a requirement of the DSCSA, HDMA is pleased to see that FDA has chosen to clarify the ambiguities surrounding the law’s preemption of State requirements.

HDMA fully agrees with the Draft Guidance’s goal to “help industry and States understand the immediate effects of the law and … clarify section 585’s effect on State product tracing and standards and requirements for…” licensing.” Further, we believe the Questions and Answers (Q&A) format is a very appropriate vehicle for providing this information. HDMA also supports section III.A. (lines 85-124) of the Draft Guidance that addresses the scope of preemption of State product tracing requirements under §585(a). We believe this section of the Draft Guidance is legally accurate and is likely helpful to the States. We offer no further comment upon it, although HDMA does support the additional suggestions made by the Pharmaceutical Distribution Security Alliance (PDSA) regarding the need for examples and clarification that State definitions are also preempted.

HDMA has serious concerns regarding how the Draft Guidance addresses §585(b)(1). The Draft Guidance incorrectly interprets §585(b)(1) as merely establishing a minimum set of standards for wholesale distributor licensure that States may exceed. The preemptive impact of §585(b)(1) upon State wholesale licensure requirements is far broader than the Draft Guidance suggests. We believe the plain language of §585(b)(1), bolstered by numerous court interpretations of similar federal preemption clauses, precludes States from establishing or continuing any requirements that enlarge what the DSCSA requires. The DSCSA’s explicitly stated goals of national uniformity and the express preemption language in §585(b)(1), as interpreted by decades of court opinions, show that Congress intended a single set of federal wholesale distributor licensure standards and States may not impose burdens more onerous than what the DSCSA itself requires. HDMA urges significant revision to section III.B. of the Draft Guidance so that it both conforms to the legal authority that has long interpreted federal statutes containing similar language and is consistent with Congress’ intent to establish a national system of wholesale distributor licensure. We address this very important issue in an extensive legal discussion in part II below.

The effect of the DSCSA upon State licensure of third party logistic providers (3PLs) has been another source of confusion. HDMA agrees with the Draft Guidance Q&A that clarifies this

1 Draft Guidance at lines 32-34.
issue,\textsuperscript{2} but recommends slight wording revisions. We support FDA’s statements in the Q&A that States may license and regulate these entities as 3PLs until such time as the agency promulgates 3PL standards. We are concerned that otherwise there will be a “gap” in licensure that is potentially counter to public health and supply chain security. We conclude with a few additional recommendations for clarification of DSCSA definitions and terms. These issues are addressed collectively in Part III of this comment.

II. HDMA urges clarification of the preemptive scope of §585(b)(1) so that the Draft Guidance conforms with legal authority and is consistent with Congress’ intent to establish a single, uniform, national system of wholesale distributor licensure.

In Part II.A. below, we analyze the meaning of the terms Congress chose in §585(b)(1), place them in the necessary context, and explain the scope of the DSCSA’s preemption of State wholesale distributor licensure requirements. In Part II.B, we then recommend specific edits to the Draft Guidance so that it reflects the correct legal meaning of the terms used in §585(b)(1), accords with Congressional intent, and better guides States as to which of their wholesale distributor licensure requirements remain.

A. The Draft Guidance incorrectly interprets §585(b)(1). Section 585(b)(1) establishes both a minimum floor and a maximum set of standards for wholesale distributor licensure that States may not exceed.

1. The DSCSA

The Draft Guidance appropriately recites the express preemption provisions of §585(b)(1):

\textit{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.}

§585(b)(1) (emphasis supplied).

The Draft Guidance, however, simply repeats §585(b)(1) (at lines 135, 156, 172-73) without offering any explanation as to what these words mean and offers no aid to the States who are attempting to discern which of their requirements remain after passage of the DSCSA. Even where, as in the DSCSA, federal law expressly preempts State requirements, “the substance and scope of

\textsuperscript{2} Draft Guidance at lines 189-193.

To the extent the Draft Guidance does attempt to explain the meaning of §585(b)(1), it does so incorrectly.  The Draft Guidance summarizes the preemption provision by stating that State standards may not “fall below the minimum standards established by federal law.”  See e.g., Draft Guidance at lines 135, 148-49, 170.  HDMA vigorously disputes this interpretation as unfounded in law and contrary to Congress’ intent to better secure the pharmaceutical distribution supply chain by establishing a single, national, uniform program for wholesale distributor licensure.  All the terms in §585(b)(1) have been used in the preemption provisions of federal statutes for decades and have been repeatedly interpreted by U.S. Courts of Appeals and the U.S. Supreme Court.  These prior judicial interpretations of similar preemption clauses must guide the interpretation of §585(b)(1) as “repetition of the same language” from another preemption clause in another “statute indicates, as a general matter, [congressional] intent to incorporate its judicial interpretations as well.”  Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 85 (2006).  As this ample case law makes clear, §585(b)(1) sets both the minimum and the maximum reach – a floor and a ceiling – of State regulation of wholesale distributor licensure.  Although many aspects of State control of prescription drug manufacture, distribution, and dispensing remain, the DSCSA wholly preempts State wholesale distributor licensure requirements.

2.  The DSCSA is intended to bring national uniformity to wholesale distributor licensure

The DSCSA was enacted in part to establish uniform standards for wholesale distributor licensure.  Section 583 is entitled “National Standards for Prescription Drug Wholesale Distributors.”  Section 585 is entitled “National Uniform Policy.”  Section 585(b)(1) provides for the preemption of any State requirements “with respect to” wholesale distributor licensure that are “inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under §503(e).”  In turn, §503(e) mandates the establishment of federal requirements that States may then adopt; each such federally and State-issued license “shall meet the standards, terms, and conditions established by the Secretary under section 583.”  §503(e)(1)(B) (emphasis supplied).

Section 583 explicitly mandates national uniformity:

For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established … shall apply to all State and Federal [wholesale distributor] licenses and shall include standards for” (see §583(b)) (emphasis supplied) among other things:

- The storage and handling of prescription drugs, including facility requirements.
- The establishment and maintenance of records of the distributions of such drugs.
The furnishing of a bond or other equivalent means of security.

- Mandatory background checks and fingerprinting of facility managers or designated representatives.
- The establishment and implementation of qualifications for key personnel.
- The mandatory physical inspection of any facility following the facility’s initial licensure application.
- Prohibitions upon certain persons receiving or maintaining a wholesale distributor license.

See §583(b)(1)-(7).

Congress does not merely instruct FDA to promulgate regulations regarding wholesale distributor licensure. It specifically mandates that FDA establish a national “uniform” system for wholesale distributor licensure which States may then adopt. Simply put, wholesale distributor licensing cannot be “uniform” if every State is free to impose additional and more onerous licensure requirements.

Against this mandate for “ensuring uniformity” in wholesale distributor licensure standards (see §583(b)), we turn now to the meaning of “with respect to … licensure” and “inconsistent with, less stringent than, directly related to, or covered by,” to explain how the DSCSA does far more than simply establish a floor of minimum licensure standards States must meet.

3. The meaning of “with respect to … licensure”

The breadth of §585(b)(1)’s displacement of State licensure law is evident in the first clause – “no State .. may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure…” (emphasis supplied). “With respect to” means that the DSCSA preempts State laws that “concern” licensure and does not preempt laws that have only an indirect connection to licensure. See Dan’s City Used Cars, Inc. v. Pelkey, 133 S. Ct. 1769, 1778-79 (2013). See also §585(c) (DSCSA does not preempt State requirements unrelated to wholesale distributor licensure).

4. The meaning of “inconsistent with” and “less stringent than”

If §585(b)(1) had stopped at “inconsistent with” and “less stringent than,” the Draft Guidance might be accurate in characterizing the provision as doing no more than establishing a minimum floor for State licensure of wholesale distributors. These two phrases are not broadly preemptive. See Jones v. Rath Packing Co., 430 U.S. 519, 540 (1977) (explaining that federal statute that prohibits “inconsistent” or “less stringent than” State laws allows State requirements to go further than a federal statute, as long as compliance with both is possible and State law does not stand as an obstacle to the objectives of Congress). Congress, however, added two additional
phrases that significantly expand the preemptive reach of §585(b)(1). The Draft Guidance improperly ignores “directly related to” and “covered by.”

5. **The meaning of “directly related to”**

We are not aware of any statute which provides, as the DSCSA does, for federal preemption of State laws that are “directly related to” federal requirements. There is significant case law interpreting the phrase “related to” as being broadly preemptive in the context of the Employee Retirement Income Security Act of 1974 (ERISA). ERISA “supersed[e]s any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. § 1144. The Supreme Court has said that a State law “relates to” an ERISA employee benefit plan, and so is preempted, if it makes “reference to” or has a “connection with” employee benefit plans. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 (1983). This “relate to” preemption provision in ERISA “displace[s] all state laws that fall within its sphere, even including state laws that are consistent with ERISA’s substantive requirements.” *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 829 (1988).

The word “directly” modifies “related to” in the DSCSA and does not in ERISA. A court would, therefore, have to determine the meaning and qualifying impact of “directly” upon expansive “related to” preemption. To do so, courts would turn to ordinary definitions of the word “directly” found in dictionaries and legal treatises. *See CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664-65 (1993) (relying upon *Webster’s Third New International Dictionary* for definition of “covering”); *Shaw*, 463 U.S. at 97 n.16 (relying upon *Black’s Law Dictionary* for definition of “relate”). Black’s Law Dictionary defines “directly” as 1) in a straightforward manner, 2) in a straight line or course, or 3) immediately. *Black’s Law Dictionary* (9th ed. 2009). Webster’s Third New International Dictionary defines “directly” as “in a direct manner; in immediate physical contact; in the manner of direct variation.” *Webster’s Third New International Dictionary* (1993).

Based upon these common, dictionary definitions, the word “directly” would modify to some extent the broad “related to” preemption in §585(b)(1). Any State requirements with a “straightforward” or “immediate” connection to the DSCSA’s wholesale distributor licensure standards would be squarely preempted under § 585(b)(1).

6. **The meaning of “covered by”**

A phrase similar to “covered by” appears in several federal statutes and has been interpreted by courts, including the U.S. Supreme Court, to be broadly preemptive, although not as broad as “related to” preemption. In *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658 (1993), the Court interpreted the preemption language in the Federal Railroad Safety Act (FRSA) which, at the time the case was decided, permitted the States to “adopt or continue in force any law, rule, regulation, order, or standard relating to railroad safety until such time as the Secretary has adopted a rule, regulation, order, or standard covering the subject matter of such State requirement.” 45 U.S.C.
§434, amended by 49 U.S.C. §20106(a)(2) (emphasis supplied).³ At issue in Easterwood was whether FRSA regulations regarding maximum train speeds preempted a State law personal injury negligence claim. Even though the train at issue in the case was traveling below and complying with the federal maximum of 60 miles per hour, the petitioner attempted to hold CSX to a higher standard by arguing that the railroad breached its common-law duty to operate its train at a moderate and safe rate of speed.

The Supreme Court disagreed with the petitioner and determined that the “covering” language in FRSA preempted any State law action and CSX could not be held to a higher, State-imposed standard. Federal requirements covered and preempted State requirements if they “comprised,” included,” or “embraced” the State requirements, or if the State requirement was “substantially subsumed by” the federal requirement. Easterwood, 507 U.S. at 664-65. Accord Shanklin, 529 U.S. at 352. The “covering” language acted as a “ceiling” that preempted any State requirement more stringent than that imposed by federal requirements. The federal limits “must be read as not only establishing a ceiling, but also precluding additional state regulation of the sort which respondent seeks to impose on petitioner.” Easterwood, 507 U.S. at 674 (emphasis supplied).

The Second Circuit, relying upon Easterwood and Shanklin, undertook a detailed analysis of “covering the subject matter” preemption language found in the FAA’s implementing regulations to the Federal Aviation Act’s drug testing requirements. Drake v. Lab. Corp. of Am. Holdings, 488 F.3d 48 (2d Cir. 2006). A State requirement is preempted if there is a “substantial intersection” between the State and Federal requirements. Id. at 60. If State law “regulates conduct that is addressed by a specific provision of the FAA regulations, it is preempted.” Id. at 63. Further, because of the FAA’s interest in “consistency and uniformity” in drug testing, a State “cannot enlarge or enhance” its requirements “to impose burdens more onerous than those of the federal requirements on matters addressed by the federal regulations.” Id. at 65 (citing Am. Airlines, Inc. v. Wolens, 513 U.S. 219, 233 (1995) (internal quotations omitted)).⁴

7. In §585(b)(1), Congress wrote what it intended

In the DSCSA, Congress did not write on a blank slate. The legislative history of the DSCSA confirms that Congress intended the law to operate as both floor and ceiling and to achieve


⁴ The FRSA and FAA preemption clauses, unlike the DSCSA, include the concept of covering the “subject matter.” See Drake, 488 F.3d at 60. This distinction, however, is not relevant to interpreting the DCSA’s “covered by” preemption. In Easterwood, the Supreme Court expressly imposed a “ceiling” that precluded the State from imposing a standard more onerous than the federal limit. Easterwood, 507 U.S. at 674. In Drake, the FAA’s interest in uniformity and the express “covering” preemption meant the State could not impose more onerous burdens if those burdens were already addressed in the federal requirements. Drake, 488 F.3d at 65.

In the DSCSA, Congress repeated preemption language from other statutes that has long since been interpreted by the Supreme Court and other courts. These interpretations guided Congress in the drafting of the DSCSA and they must guide FDA now. See Merrill Lynch, Pierce, Fenner & Smith Inc., 547 U.S. at 85 (repetition of language from one statute in another indicates congressional intent to incorporate judicial interpretations of that language).

**B. The scope of §585(b)(1) – States may not establish or continue any requirements that enlarge what the DSCSA requires.**

Based upon the foregoing, it is clear that §585(b)(1) does far more than merely establish a minimum floor for State regulation of wholesale distributors as the Draft Guidance supposes. Section 585(b)(1) will preempt any State requirement if:

- The State requirement is comprised, included, embraced, or substantially subsumed in, specifically addressed by, or intersects in a substantial way with, the federal requirement (Easterwood, 507 U.S. at 664-65; Drake, 488 F.3d at 60-63); or
- The State requirement is so substantial, it impedes the national uniformity and consistency in wholesale distributor licensure Congress mandated in the DSCSA (Drake, 488 F.3d at 63); or
- The State requirement enlarges or enhances requirements to impose burdens more onerous than what the federal requirement imposes (Easterwood, 507 U.S. at 674; Drake, 488 F.3d at 65).

Therefore, for example, §585(b)(1) preempts State requirements with respect to:

- Warehouse controls and security as these are “directly related” to the DSCSA-mandated storage and facility requirements (§583(b)(1));
Length of time distribution records must be maintained because these are “directly related” to the DSCSA-mandated maintenance of records of distributions (§583(b)(2));

Scope, duration, and conduct of an inspection because these are “directly related” to the DSCSA-mandated establishment of mandatory physical inspections (§583(b)(6));

Continued requirement of third-party accreditation, such as the Verified-Accredited Wholesale Distributors (VAWD) accreditation mandated in the States of Indiana and North Dakota, as this requirement imposes a burden more onerous upon a wholesale distributor than the DSCSA-mandated establishment of mandatory physical inspections (§583(b)(6));

Licensure inspections conducted to other than DSCSA-mandated requirements and criteria (§583(b)(6)); and

More stringent requirements for facility managers’ qualifications than what would be imposed under (§583(b)(2),(4), and (5)).

These types of State requirements create a patchwork of inconsistent and variable standards that disrupt the national uniformity of the DSCSA and impose burdens upon wholesale distributors in addition to those of the DSCSA that §585(b)(1) does not permit.

We do not advocate the preemption of all State requirements with respect to wholesale distributors. There are several savings clauses in the DSCSA that preserve the ability of States to impose some requirements not concerned with licensure. See §§§585(b)(4)(D), (c). However, the Supreme Court has stated that it will not “give broad effect to the saving clauses where doing so would upset the careful regulatory scheme established by federal law.” Geier v. Am. Honda Motor Co., 529 U.S. 861, 870 (2000) (internal quotations and citations omitted). The DSCSA’s mandate to establish uniform federal licensure standards, the express preemption in §585(b), and the savings clauses, may all be read together to prevent States from imposing their own licensure standards while leaving them free to regulate areas outside of wholesale distributor licensure. For example, States may continue to regulate the scheduling of controlled substances, environmental quality, assessment and collection of licensing fees, and prescription drug monitoring programs.

C. In light of the foregoing, HDMA suggests revisions so that the Draft Guidance is in accordance with applicable legal authority and is consistent with Congress’ intent to establish a single, uniform, national system of wholesale distributor licensure.

HDMA suggests the following changes to section III.B. of the Draft Guidance. Deletions are indicated with double strikeouts and additions are in bold. (Note that the original text from the Draft Guidance includes footnotes. Their presence is indicated in the block quotations below, although the text of the footnotes themselves is not repeated.)
At lines 131-136 (the response to Question III.B.1)

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 standards 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. This provision also means that States may not impose standards, requirements, or regulations with respect to wholesale distributor licensure that

- Are comprised, included, embraced, or substantially subsumed in, specifically addressed by, or intersect in a substantial way with, the standards established by Federal law; or
- Impede the national uniformity and consistency in wholesale distributor licensure Congress mandated in the DSCSA; or
- Enlarge or enhance requirements in order to impose burdens more onerous than what the Federal law imposes.

At lines 141-149

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. States will need to evaluate and amend their standards, requirements or regulations that impede national uniformity for wholesale distributor licensure by imposing burdens upon wholesale distributors that are more onerous than what Federal law imposes. See III.B.1. above.

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 or are more onerous than the minimum standards established by federal law.

At lines 168-173

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 falls below the minimum standards established by those Federal regulations or that impede the national uniformity for wholesale
distributor licensure by imposing burdens upon wholesale distributors that are more onerous than what Federal law imposes. See III.B.1. above. 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.

As there is particular confusion among the States regarding the impact of §585(b)(1) upon State-mandated VAWD accreditation, we suggest the following additional Q&As:

**Can States continue to require third-party accreditation as a condition of licensure of a wholesale distributor?**

No. The DSCSA requires that a wholesale distributor be inspected within a reasonable time from submission of its initial application §583(b)(6). 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 §585(b)(1) because the requirement impedes national uniformity for wholesale distributor licensure by imposing burdens upon wholesale distributors that are more onerous than what Federal law imposes.

**Can a State continue to use third-party inspectors that it has approved to conduct their inspections of wholesale distributors?**

Yes. 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 standards or requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA).

To the extent that section III.C. of the Draft Guidance, regarding 3PL standards and licensing, is inconsistent with the above, it will also need to be changed as §585(b)(1) applies to and preempts both wholesale distributor and 3PL licensure requirements.
III. HDMA has other suggested editorial changes to the Draft Guidance.

**Lines 186-193**

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. **However, any new or existing State 3PL requirements and standards will be preempted by §585(b)(1) if they are inconsistent with, less stringent than, directly related to, or covered by the standards or requirements applicable under §503(e) of the FD&C Act (as amended by the DSCSA).**

As noted at the outset, we are concerned that the lack of 3PL licensure creates a “gap” that is potentially counter to public health and supply chain security. Though 3PLs are “deemed” licensed, FDA has not yet promulgated its own standards, and most States do not have requirements specific to 3PLs. This gap creates an additional problem in that trading partners must be “authorized” and in the absence of any licensure standards, it is difficult to know how a 3PL “deemed” to be licensed can demonstrate it is “authorized.” We urge FDA to issue guidance to address this issue as soon as possible.

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HDMA thanks you for this opportunity to provide initial suggestions on wholesale distributor licensure. If you have any questions, please contact me at 703-885-0240 or at aducca@hdmanet.org.

Sincerely,

Anita T. Ducca
Vice President, Regulatory Affairs