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What are the Key Implementation Challenges in the Supply Chain Security Provisions of the Drug Quality and Security Act?

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TABLE OF CONTENTS

I. Introduction 1

Policy Recommendations 1

II. Background 1

III. Overview Of Proposed Federal Traceability System 3

A. Scope of the DQSA 3

B. Traceability 4

C. Wholesale Distributor and Third-Party Logistics Provider Standards 7

D. Preemption 7

E. Penalties 7

F. FDA Implementation Plan 8

IV. Implementation Challenges 11

A. Interoperability 11

B. Licensing 11

C. Preemption 14

D. Other Topics 15

V. Conclusion 16

About the Authors 20

About the Food and Drug Policy Forum 21

About FDLI 21

What are the Key Implementation Challenges in the Supply Chain Security Provisions of the Drug Quality and Security Act?

I. INTRODUCTION

On November 27, 2013, President Obama signed into law the Drug Quality and Security Act (DQSA, or the Act), Pub. L. 113-54. The DQSA enhances the security of the pharmaceutical supply chain by establishing a national system for tracing and serializing pharmaceutical products and for establishing national licensing standards for wholesale distributors and third-party logistics providers.[1] The DQSA is an enormous step forward in reducing potential threats to supply chain security and patient safety associated with pharmaceutical distribution.

While the Act establishes a comprehensive and detailed federal framework for further securing the pharmaceutical supply chain beyond the current state framework of regulation, many of the details associated with implementation of the systems and processes established by the Act are left to the Food and Drug Administration (FDA, or the Agency) and industry. In this article, we provide a comprehensive overview of the DQSA and explore three areas of implementation that we believe will present the most important issues for resolution by FDA and industry.

POLICY RECOMMENDATIONS

- Establishing interoperability requirements and standards, whether developed by the Agency or by stakeholders, between the various supply chain stakeholders.
- Clarification by the FDA of licensing obligations, especially prior to the effective date of applicable federal standards.
- Clarifying the scope of preemption of state law, whether through Agency action or through litigation, particularly with regard to licensure.

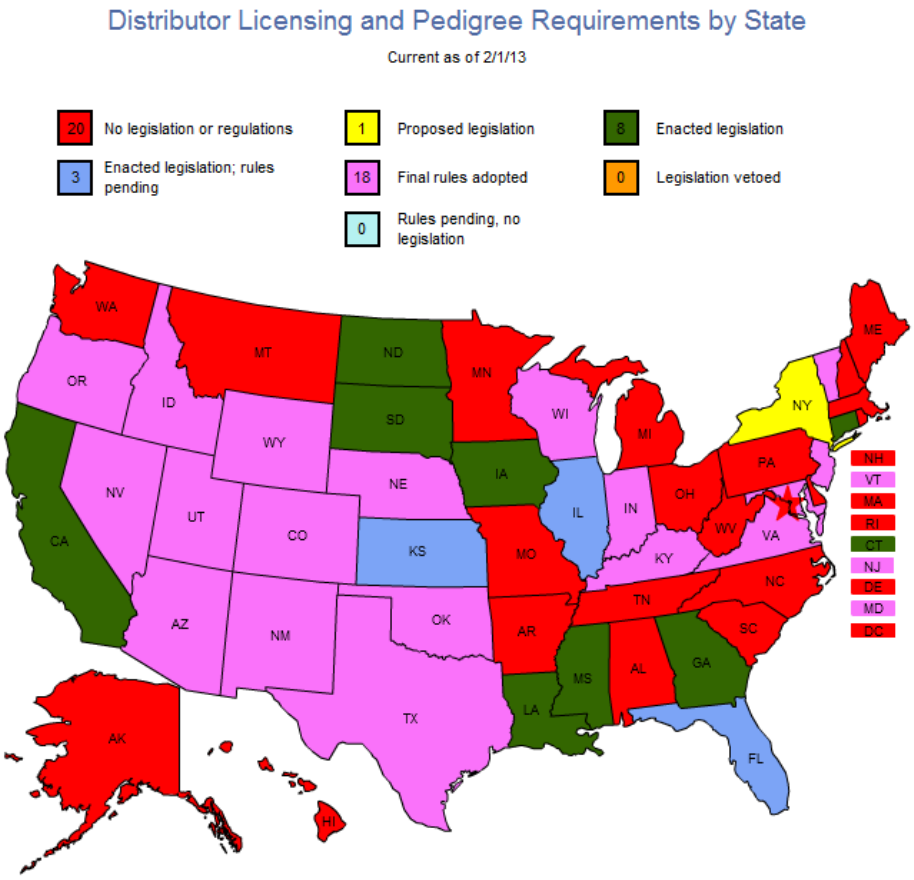
II. BACKGROUND

For at least the past decade, federal and state regulators have been concerned about potential threats to supply chain security and patient safety, which may arise from gaps in the pharmaceutical supply chain. The threats have been reassuringly few in number and limited in severity, the risk to patients, to stakeholder brands, and even national security. Nevertheless, more focused attention from regulatory and legislative bodies was justified with each new threat to supply chain integrity.

The threats came in the form of some documented history, at the distributor and pharmacy level, of counterfeited product; as well as some history of product stolen from manufacturer warehouses or trucks.[2] There was also some evidence of a gray market, especially around drug-shortage products.[3] In addition, there was an understanding that occasional recalls of pharmaceutical products were not as efficient as they could be, and they might also benefit from tracing and serializing product.

The response generated at the state level was varied, and of mixed effectiveness:

- Some states had only limited serialization,[4] traceability,[5] or licensing protections in place.
- Conflicts among state requirements presented confusion, complexity, burden, and, at the same time, limited benefit.
- Even robust requirements, such as those envisioned under the California pedigree system, were not proving practical when regulators attempted implementation.



Healthcare Distribution Management Association, Distributor Licensing and Pedigree Requirements by State, available at http://www.hdma.net/gov_affairs/.state/state_legis-static.asp (last visited Dec. 20, 2013).

In any event, a 50-state system with wide variation in requirements risked leaving patient safety exposed to weak links in some states, conflicting rules among the states, or unnecessary burdens on stakeholders. With the advent of high-profile counterfeiting cases in 2011 and 2012,[6] the need for a single, uniform, national system of regulation of the drug supply chain was apparent to regulators and a number of stakeholders.

III. OVERVIEW OF PROPOSED FEDERAL TRACEABILITY SYSTEM

The DQSA creates uniform systems and establishes uniform federal standards to improve the security of the drug supply chain and reduce the impact of the burdensome patchwork of state laws related to pedigree requirements for drug distribution. The Act establishes a national system for tracing pharmaceutical products through the supply chain and sets national licensing standards for wholesale distributors and third-party logistics providers.

A. Scope of the DQSA

The DQSA is intended to reach all sectors of the drug supply chain, including manufacturers, wholesale distributors, third-party logistics providers,[7] repackagers, and dispensers.[8] Different requirements apply to each of these sectors and a company's sector classification is determined on a transaction-by-transaction basis. For example, a company may be regulated as a manufacturer for one transaction (*i.e.*, a single transfer of a product between two supply chain participants) but as a wholesale distributor for another, different transaction. Although a single company may act and be regulated in multiple capacities, the company is not obligated to duplicate requirements.[9]

The obligations and conditions of the DQSA only apply to "products," which are defined as prescription drugs in finished dosage form intended for human use.[10] A number of exemptions exist, however, including:[11]

- Blood and blood components intended for transfusion.
- Radioactive drugs and radioactive biologics.
- Intravenous products.
- Medical gas.
- Compounded drugs.
- Dispensing drugs pursuant to a prescription.
- Medical convenience kits and combination products not approved as drugs or biologics.
- Sterile water and products intended for irrigation.

The traceability[12] obligations discussed below generally apply with regard to each product "transaction," meaning each individual transfer of ownership from one supply chain participant to another (*e.g.*, the transfer of ownership from manufacturer to a wholesale distributor).[13] The DQSA therefore adopts an *ownership* model for traceability. Information is not required to be passed when transferring only *possession* of a product or when a product is transferred within a company.[14]

B. Traceability

The DQSA establishes a national traceability system by ensuring that supply chain participants pass and capture, in an efficient manner, the information needed to trace prescription drugs back through the supply chain. Recognizing the technological and operational challenges associated with moving from a patchwork of state pedigree requirements to a national traceability system, the DQSA adopts a phased approach. The DQSA enhances information sharing, as follows:

- **Enactment.** The DQSA immediately locks in the existing federal pedigree requirements under the Prescription Drug Marketing Act (PDMA) to avoid gaps in supply chain security until the new DQSA information-sharing requirements go into effect.[15]

- **January 1, 2015.** The PDMA federal pedigree requirements are replaced by the DQSA on January 1, 2015, and supply chain participants must begin to participate in four primary activities. First, all supply chain participants must work only with authorized (*i.e.*, duly registered or licensed) trading partners. Second, companies must pass, capture, and maintain certain information with respect to each product transaction.[16] Third, companies must implement processes and procedures to respond to requests for information from federal and state officials. Fourth, companies must have systems and processes to investigate, verify (generally using lot number information associated with the product), and respond to suspect and illegitimate products.[17]

- **November 27, 2017.** Manufacturers must begin to serialize (*i.e.,* place unique product identifiers on)[18] prescription drug products no later than four years after enactment by affixing to each package and homogenous case of product a "product identifier" that will carry key data about the product. In subsequent years, other sectors must also comply with enhanced verification requirements and ensure the ability to verify the information contained on a package's unique product identifier.

- **November 27, 2023.** In parallel with the information-sharing and lot-level activities that commence on January 1, 2015, the DQSA requires development of a self-effectuating "Phase II" in which product identifiers will be utilized to electronically pass the information necessary to trace activity at the package level.[19]

The Secretary is required to establish a process for granting waivers and exceptions (*e.g.*, economic hardship exemptions for certain supply chain participants, and exemptions for packages that are too small to accommodate a product identifier) to the traceability and product identifier requirements discussed above. Additionally, products already in the supply chain will generally be grandfathered for purposes of the traceability and product identifier requirements.

1. January 1, 2015 Requirements

The traceability requirements that commence January 1, 2015 are based on the passing and maintaining of three types of information.

- The **transaction information**, which includes the name of the product, its strength and dosage form, its National Drug Code, the container size, the number of containers, the lot number, the transaction date, the shipment date, and the name and address of the businesses from which and to which ownership is transferred.[20]

- A **transaction history**, which is a paper or electronic statement that includes the transaction information for each prior transaction back to the manufacturer.[21]

- A **transaction statement**, which is a paper or electronic statement by the business transferring ownership of the product attesting that it has complied with the DQSA.[22]

Nuances apply within each sector, but the traceability obligations effective January 1, 2015 generally require businesses to (i) provide the transaction information, transaction history, and transaction statement to the subsequent owner for each transaction, and (ii) capture and maintain for six years the transaction information, transaction history, and transaction statement for each transaction, whether as the buyer or as the seller.[23] This obligation begins on January 1, 2015 for manufacturers, wholesaler distributors, and repackagers; dispensers, however, have until July 1, 2015 to begin providing, capturing, and maintaining this information.

An important exception to the information passing requirements is that primary wholesale distributors[24] are not required to pass lot numbers, initial transaction dates, and initial shipment dates to subsequent owners prior to Phase II.[25] Consequently, secondary wholesale distributors are only required to pass the information they receive. Initially, the required information may be passed in paper or electronic format. However, manufacturers are required to pass this information in electronic format beginning no later than four years after enactment of the DQSA.[26]

In addition to simply passing and maintaining information, companies must also be able to use that information to confirm the validity of product that it handles. Beginning January 1, 2015, trading partners must maintain systems and processes for quarantining and investigating products that are suspect or illegitimate.[27] As part of that investigation, companies must be able to verify the

transaction history and transaction information of a product.[28] In essence, although a company is not required to verify all transaction history and transaction information upon the receipt of each product, companies must be able to retroactively verify the information they have, upon request. If a product is determined to be illegitimate, the partner must notify the Secretary and its trading partners, take steps to disposition the product, and, if requested by an appropriate government official, retain a sample of the product.

Companies must also provide transaction information, transaction history, and transaction statement to the FDA and other appropriate federal and state officials upon request as part of a recall or investigation of a suspect or illegitimate product.[29] Manufacturers, wholesale distributors, and repackagers must respond to such requests within one business day, but not more than 48 hours.[30] Dispensers must respond to requests within two business days.

The DQSA also seeks to secure the supply chain by ensuring that participants are properly vetted and licensed. To that end, manufacturers, wholesale distributors, dispensers, and repackagers must only utilize "authorized trading partners" beginning January 1, 2015, meaning all trading partners must be validly registered or licensed.[31]

2. November 27, 2017 Requirements

The DQSA seeks to further enhance the security of the supply chain within four years of enactment through the serialization of drug products. Serialization is accomplished by affixing to packages and cases a "product identifier," which is a standardized graphic (*i.e.*, a two-dimensional dot matrix[32]) that carries, among other data, the product's standardized numerical identifier (SNI),[33] lot number, and expiration date in both human- and machine-readable format.

No later than November 27, 2017 (*i.e.*, four years after enactment), manufacturers must begin affixing a "product identifier" to each individual package and homogenous case of product. Repackagers must affix product identifiers within five years of enactment.[34] Wholesale distributors and dispensers must only accept products that contain the required product identifier beginning six and seven years after enactment, respectively.[35]

Enhanced verification requirements also go into effect, incrementally, beginning November 27, 2017. Contemporaneous with the obligation to affix and/or receive product identifiers, manufacturers, repackagers, wholesale distributors, and dispensers must have systems and processes in place to verify the SNI of suspect products upon request by a trading partner.[36]

3. Phase II

The traceability requirements above generally require products to be traceable at the lot level. A second phase of requirements will go into effect 10 years after enactment to allow the interoperable, electronic tracing of products at the package level.[37] A second hallmark of Phase II is the transition away from the requirement under Phase I that each transfer of a product include the full transaction

histories of the product back to the manufacturer. Instead, under Phase II, a "one up and one back" model will be in effect. Under this approach each supply chain participant must essentially capture the transaction information associated with its own receipt and distribution of a product, which comprehensively, will allow the product to be traced back to the manufacturer. A series of assessments, public meetings, and at least one pilot program will be conducted over the interim period to develop the precise requirements for, and ensure the technological feasibility of, Phase II.

C. Wholesale Distributor and Third-Party Logistics Provider Standards

The second major portion of the DQSA establishes uniform national licensing standards for wholesale distributors and third-party logistics providers. The DQSA sets out seven broad categories of licensing standards for wholesale distributors and for third-party logistics providers.[38] The Secretary is then tasked with issuing regulations to further define those standards. States will continue to license wholesale distributors and third-party logistics providers, but they will be required to do so utilizing the federal standards when they are established. In the absence of a state licensing program that satisfies the federal requirements, a federal licensing program will be established to license wholesale distributors and third-party logistics providers in those states. The licensure requirements and related questions and implementation challenges are discussed in more detail in section IV.B., below.

D. Preemption

The final major piece of the DQSA preempts certain state laws. The DQSA immediately preempts all state laws, regulations, and requirements for tracing products through the supply chain, including any recordkeeping and pedigree requirements, such as the California pedigree law.[39] All such laws are preempted, regardless of whether they are more burdensome, less burdensome, or inconsistent with the federal traceability requirements. The preemption provision applies to state requirements for tracing "products." Therefore, the preemption provision does not extend to items that are not products under the DQSA, such as animal drugs, medical devices, over-the-counter drugs,[40] active pharmaceutical ingredients, and clinical trial drugs, and states retain the authority to impose tracing or pedigree requirements on such items.

The DQSA also preempts state laws, regulations, and requirements regarding wholesale distributor and third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards established by the DQSA.[41] In other words, states cannot alter the standards established by the DQSA, but they may continue to regulate wholesale distributors and third-party logistics providers in areas that are not covered by and not directly related to the licensing standards in the DQSA. The preemption provisions and related questions and challenges are discussed in more detail in section IV.C., below.

E. Penalties

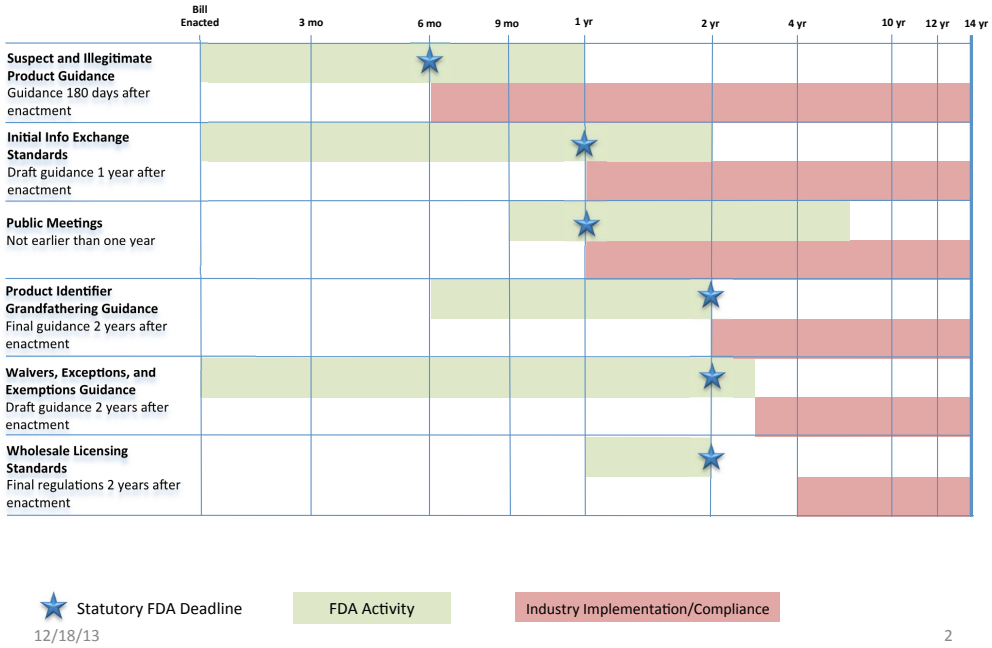
The final portion of the DQSA establishes stiffer penalties for companies and individuals who fail to comply with the new supply chain requirements. A failure to comply with the traceability provisions

or the licensure requirements under the DQSA is a prohibited act under the FDCA.[42] Additionally, the failure to affix a product identifier as required by the DQSA now constitutes misbranding, which is also punishable as a prohibited act.[43]

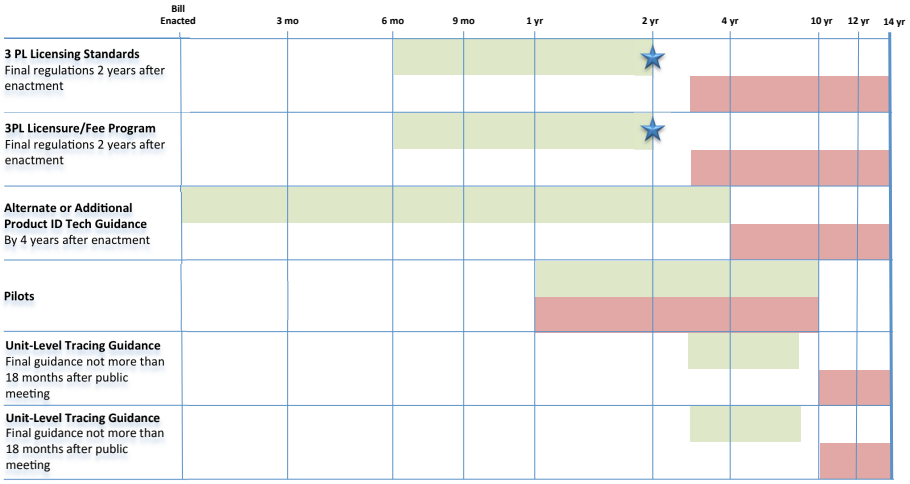
F. FDA Implementation Plan

The DQSA sets forth a number of requirements and deadlines that expressly direct some aspects of the FDA's implementation of the statute.

FDA Implementation of DQSA

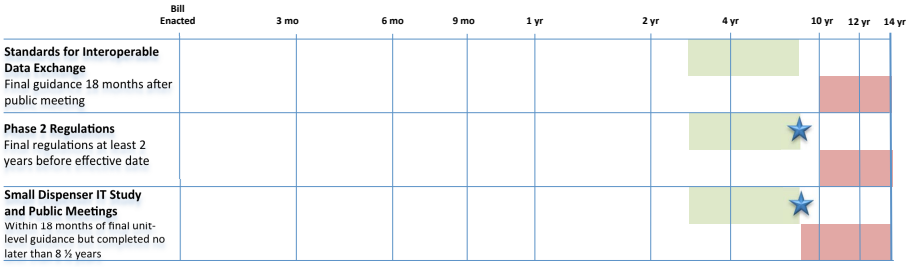


DQSA Implementation



Statutory FDA Deadline | FDA Activity | Industry Implementation/Compliance

DQSA Implementation



Statutory FDA Deadline | FDA Activity | Industry Implementation/Compliance

However, by any reckoning, FDA has a daunting task ahead of it to propose and finalize the various standards documents, guidances, regulations, and public meetings on time. Similarly, regulated industry faces a considerable challenge in assisting FDA with its implementation tasks, whether through advance communication, responses to FDA documents, or compliance with agency and statutory requirements.

FDA indicated in a recent call with stakeholders that it understands the significance of the task, the need to give guidance to stakeholders as quickly as possible, and the need to collaborate with stakeholders to the extent appropriate.

We expect FDA initially to take stock internally of the assignments and resources required; to develop an FDA team supplemented by full Department of Health and Human Services (HHS) policy, legislative, budget, and other resources; to develop and publish an implementation plan early in 2014 that will set forth for the public the various tasks and timelines on which it will work; and to begin work, attempting to meet statutory deadlines in every event possible.

Several considerations, beyond the technical complexity of the subject matter, will impact the FDA's implementation, including the documents produced, the timing of those documents, and the extent to which it can engage supply chain stakeholders. Those considerations include:

- **Agency resources.** Dr. Ilisa Bernstein will lead the implementation team, and others (some with long experience in this area) will join her. However, in this time of constrained resources, Dr. Bernstein's access to many, qualified additional team members may be constrained.

- **Related regulatory matters.** FDA may do a broader review of related regulatory matters, including labeling requirements and their current pedigree standards, to ensure that new DQSA requirements align appropriately.

- **Department review.** Health and Human Services, and potentially the Office of Management and Budget at the White House, will review and perhaps even help develop the guidances, regulations, and standards prior to their public release. Increased involvement by HHS and OMB will likely slow the release of documents, though a case could be made that an early Department role might facilitate and speed document clearance.

- **Engagement with stakeholders.** Similarly, to the extent that the Agency engages with stakeholders with experience in supply chain, document development might be perceived as slowing. But it may also help accelerate the process where the Agency can reliably prioritize matters and propose documents that are particularly well-informed by real-world experience.

IV. IMPLEMENTATION CHALLENGES

We believe that three of the most substantial implementation challenges for the Agency and industry are:

- Establishing interoperability requirements and standards, whether developed by the Agency or by stakeholders, between the various supply chain stakeholders.
- Clarification by the FDA of licensing obligations, especially prior to the effective date of applicable federal standards.
- Clarifying the scope of preemption of state law, whether through Agency action or through litigation, particularly with regard to licensure.

A. Interoperability

The Act establishes systems and processes for the supply chain as a whole. As a result, cooperation and communication among sectors will be critical. Establishing appropriate interoperability standards to develop this cohesion will be particularly challenging for the Agency, given the variety and complexity of supply chain stakeholders, and the costs, benefits, and risks of requiring standards uniformity. Some areas that the Agency may want to address, or that stakeholders may also try to work on include:

- Standards for communication of information or data between authorized trading partners.
- Interaction with partners in conjunction with investigations of suspect or illegitimate product and the retention or disposition of product.
- Processes and standards for notification of partners regarding suspect or illegitimate product.
- Development of one or more pilots under Phase I that seek to integrate partners in the supply chain.

B. Licensing

In addition to establishing a national, interoperable traceability system, the DQSA also seeks to secure the drug supply chain by establishing uniform standards for licensure of wholesale distributors and third-party logistics providers. The Act sets out general topics to be addressed in federal standards, such as facility inspections, document maintenance, bond requirements, and classes of individuals prohibited from managing facilities, but the FDA is left to establish specific standards through regulation. States that choose to license wholesale distributors and third-party logistics providers

must utilize these federal standards. If a state does not operate such a licensing program, a federal license will be available to wholesale distributors and third-party logistics providers in those states.

The Act requires the FDA to issue the necessary regulations no later than November 27, 2015.[44] However, the regulations establishing wholesale distributor licensing standards will not be effective until two years after the final regulations are published;[45] the regulations establishing third-party logistics provider licensing standards will not be effective until one year after the final regulations are published.[46] The delayed effective dates are intended to provide states adequate time to implement the federal standards.

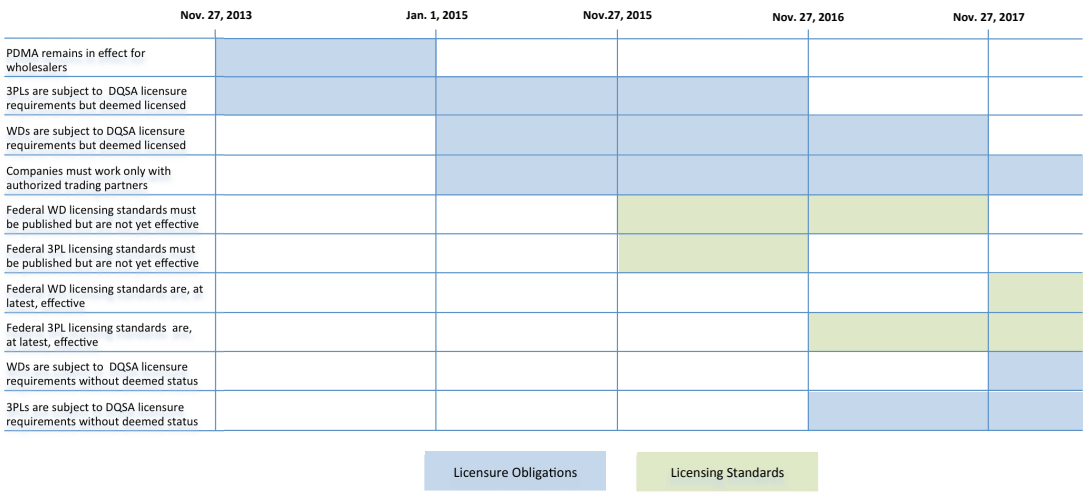
Although final licensing standards are unlikely to be effective until late 2016 and late 2017 for third-party logistics providers and wholesale distributors, respectively, the obligation that wholesale distributors and third-party logistics providers be licensed, and for other supply chain sectors to work only with licensed trading partners, are effective much earlier. Beginning January 1, 2015[47] a wholesale distributor must be licensed by each state from which it distributes drugs and each state into which it distributes drugs, if those states have licensure programs. If the state from which a wholesale distributor distributes drugs does not have a licensure program, the distributor must obtain a federal license.[48]

As of November 27, 2013, a third-party logistics provider must be licensed by each state from which it distributes drugs. However, if a state from which the third-party logistics provider distributes drugs does not have a licensure program, the third-party logistics provider must obtain a federal license. If a third-party logistics provider does not have such a federal license, it must also be licensed by each state into which it distributes drugs.[49]

Until the effective date of the wholesale distributor licensure standards (which must be on or before November 27, 2017), a wholesale distributor is deemed to be licensed for purposes of the DQSA if it holds "a valid license under State law."[50] Similarly, until the effective date of the third-party logistics provider licensure standards (which must be on or before November 27, 2016), a third-party logistics provider is deemed to be licensed for purposes of the DQSA unless the Secretary makes an affirmative determination that the third-party logistics provider "does not utilize good handling and distribution practices and publishes notice" of that determination.[51]

This licensure structure sets up a number of distinct time periods.

Timing of DQSA Licensure Obligations and Standards Development for Wholesale Distributors (WDs) and Third-Party Logistics Providers (3PLs)



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Stated more simply, the DQSA's licensure obligations precede development and effectiveness of the federal licensing standards that the DQSA requires to be used for licensure. This alignment of dates, along with the particular preemption provisions discussed below, raises a number of questions with significant operational implications.

- At what time are existing or new and modified state licensure programs first subject to potential preemption—immediately, upon issuance of federal standards, or upon the effective date of federal standards?
- Can states require third-party logistics providers to be licensed as wholesale distributors pursuant to PDMA until January 1, 2015?
- Can a state that does not currently have a licensure program adopt one prior to the effective date of the federal standards, and if so, are there restrictions on the standards that may be adopted?

- Can a state that currently has a licensure program change the requirements or standards of that program prior to issuance of the federal standard, and if so, are there restrictions on the standards that may be adopted?

- Can new state licensure programs and changes to existing licensure programs be effective prior to the effective date of the federal standards?

- If a state's licensing standards are not consistent with the federal licensing standards, at what time is the state's licensing program preempted?

- Can the Secretary revoke a wholesale distributor's "deemed authorized" status in the same way he or she can for a third-party logistics provider?

- Given the lack of clarity around these issues, how does a company know whether its trading partners are properly licensed, as required by the DQSA?

Prompt answers to these questions will be critical to industry as existing state licenses begin to expire and companies will need to understand their renewal obligations. Speed will also be of the essence as companies begin to negotiate distribution and purchase agreements and seek assurances that their trading partners are properly licensed.

C. Preemption

The cornerstone of the DQSA is its preemption provisions. Much of the operational difficulty associated with existing state pedigree laws arose from the inconsistency of those state systems. To ensure predictability in the traceability system established by the DQSA, the DQSA immediately preempted all state pedigree and traceability laws and all other state laws and rules that are "inconsistent with, more stringent than, or in addition to" the DQSA traceability provisions.[52] These include any state requirements regarding statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, and verification, investigation, disposition, notification, or recordkeeping relating to such systems.[53]

The DQSA also sought to ensure predictability in the licensure of wholesale distributors and third-party logistics providers by preempting state licensure programs that are not consistent with the federal standards established by the FDA pursuant to the DQSA. One of the final issues that faced the negotiators of the DQSA was whether states must adopt the precise standards established by the FDA or whether states should be permitted to adopt licensing standards that are *more* stringent than those established by the FDA. An eleventh-hour agreement sought to ensure that states did not alter or add to the licensing standards established by the FDA while also maintaining states' ability to regulate wholesaler and third-party logistics provider conduct unrelated to licensure, such as prescription drug monitoring programs.

Unfortunately, this bargain resulted in statutory language for which there is no significant judicial precedent. Specifically, the DQSA preempts all state "standards, requirements, or regulations" that are "inconsistent with, less stringent than, directly related

to, or covered by" the wholesale distributor and third-party logistics provider licensing standards and obligations established by the DQSA.[54]

The novelty of the "related to, or covered by" preemption formulation leaves three primary questions open to discussion.

- Can states add to or raise the standards established by the FDA? For example, if the FDA standards require distribution records to be maintained for three years, could a state require distribution records to be maintained for five years?[55] Alternatively, if the FDA does not set square footage requirements for distribution facilities, even while addressing other facility requirements, could a state do so?[56]

- Can states establish non-licensure requirements for which violations affect licensure granted pursuant to standards under the DQSA? For example, can violation of generally applicable state environmental laws be punishable through suspension of a wholesale distributor or third-party logistics provider's license? Similarly, can states require wholesale distributors and third-party logistics providers to obtain a general license to do business in their states?[57]

- What licensure requirements can states impose other than wholesale distributor and third-party logistics provider licensure? For example, it is relatively clear that states can no longer require manufacturers to be licensed as wholesale distributors (unless they separately engage in wholesale distribution), but can states require manufacturers to be licensed as manufacturers?[58]

Answers to these questions may be provided first by FDA, or by the courts in the course of litigation.

D. Other Topics

Other topics for further guidance may include:

- Integrating current standards and requirements, such as the current SNI standards or FDA barcode requirements, and determining what to integrate and what to develop anew.

- Definitions of specific statutory terms (*e.g.*, "minimal quantities"[59] and "entered the pharmaceutical distribution supply chain"[60]).

- How to address potential conflict between the ability to use alphanumeric identifiers in the statute, versus international standards that are "mostly" numeric.

- How downstream trading partners will know whether a product is non-compliant or was grandfathered or subject to an exception.

- The application of the traceability provisions to novel, atypical, and hybrid distribution models.

V. CONCLUSION

In enacting the Drug Quality and Security Act, the U.S. Congress demonstrated its ability to enact on a bipartisan basis a sophisticated, unusually technical, and highly detailed public policy response to potential threats to public health and supply chain security. The technical sophistication of the legislation is evident from a quick glance at the legislation and the review we provide here.

As supply chain stakeholders now move to fulfill their responsibilities under the law, and as the FDA proceeds to implement its obligations, it is clear that the Agency and stakeholders will need to collaborate closely regarding implementation priorities, policy implications, and operational considerations. Doing so will help ensure an effective single, national, uniform supply chain that protects patient safety and ensures the security of the country's pharmaceutical supply chain.

ENDNOTES

1. This article discusses Title II of the DQSA only. Title I of the DQSA establishes national standards for compounding pharmaceuticals and is outside the scope of this article.

2. *See, e.g.,* Katherine Eban, *Drug Theft Goes Big,* Fortune, Mar. 31, 2011, *available at* http://features.blogs.fortune.cnn.com/2011/03/31/drug-theft-goes-big/ (last visited Dec. 18, 2013).

3. *Short-Supply Prescription Drugs: Shining a Light on the Gray Market*, 112th Cong. (July 25, 2012) (statement of Hon. John D. Rockefeller IV), *available at* http://www.gpo.gov/fdsys/pkg/CHRG-112shrg79524/pdf/CHRG-112shrg79524.pdf (last visited Dec. 18, 2013).

4. "Serialization" refers to the placement of a unique identifier on each package.

5. "Traceability" refers to a system that has the capacity for determining where a product has been in a supply chain (*i.e.*, the ability to trace the product back through the supply chain). Similar, but distinguishable, systems are frequently referenced. A "track and trace" system is typically one that more firmly requires data collection to monitor product as it moves through the supply chain. A "pedigree" system uses *nested* data packages that travel with the product through the supply chain. These data packages are initiated at the manufacturer and are added to and passed through to each step of the supply chain, all the way to the prescriber or provider, and potentially to the patient.

6. *Counterfeit Doses of Avastin Distributed in the U.S., N.Y.* Times, Feb. 14, 2012, *available at* http://www.nytimes.com/2012/02/15/business/counterfeit-doses-of-avastin-distributed-in-the-us.html?_r=0 (last visited Dec. 18, 2013).

7. The DQSA establishes a licensure scheme for third-party logistics providers that take possession, but not ownership, of products; however, third-party logistics providers are not subject to the traceability provisions of the DQSA.

8. The Act does not extend to actual dispensing and similar direct interactions with patients. Additionally, the Act generally does not cover individual health care practitioners, although it does extend to hospital pharmacies and similar health care entities that dispense or administer prescription drugs.

9. Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. § 301, *et seq.*), § 582(a)(1), *as amended* by the Drug Quality and Security Act, Pub. L. 113-54 (hereinafter "FDCA"), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf (last visited Dec. 18, 2013).

10. FDCA § 581(13). This does not include, for example, animal drugs, medical devices, active pharmaceutical ingredients, or clinical trial drugs.

11. FDCA § 581(13), (24).

12. As explained in FN5, traceability is the ability to determine where a product has been. We also refer to the set of requirements contained in § 582 of the DQSA and discussed in Section III.B. of this article, which comprehensively establishes a traceability system, as the "traceability obligations," "traceability requirements" or "traceability provisions" of the DQSA.

13. FDCA § 581(24). The DQSA only applies to products intended for distribution in interstate commerce

14. This includes transfers to an affiliated company, which is a company that controls, is controlled by, or is under common control with the company transferring the product. DQSA § 581(1).

15. Drug Quality and Security Act, Pub. L. 113-54 § 204(c).

16. Dispensers are not required to pass, capture, and maintain information until July 1, 2015.

17. A "suspect product" is defined as "a product for which there is reason to believe that such product—(A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans." FDCA § 581(21). If there is "credible evidence" that a product does, in fact, fall within one of those categories, it is considered an "illegitimate product." FDCA § 581(8).

18. The precise requirements for serialization are discussed in more detail in Section III.B.2.

19. Initially, the transaction information passed by trading partners, and the associated ability to trace product, will be based on the manufacturer's production lot. Through serialization and Phase II systems

and processes, products will be traceable by individual package, which is the smallest unit that a manufacturer intends to be sold to a dispenser.

20. FDCA § 581(26).

21. FDCA § 581(25).

22. FDCA § 581(27).

23. FDCA §§ 582(b)(1)(A), (c)(1)(A), (d)(1)(A), (e)(1)(A).

24. A primary wholesale distributor is a wholesale distributor that purchases a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer. All other wholesale distributors are considered secondary wholesale distributors.

25. FDCA §§ 582(c)(1)(A)(ii).

26. FDCA §§ 582(b)(1)(C).

27. FDCA §§ 582(b)(4)(A), (c)(4)(A), (d)(4)(A), (e)(4)(A).

28. *Id.*

29. FDCA §§ 582(b)(1)(B), (c)(1)(C), (d)(1)(D), (e)(1)(C).

30. For example, a manufacturer would have until Monday to respond to a request for information received on Saturday.

31. FDCA §§ 581(2), 582(b)(3), (c)(3), (d)(3), (e)(3).

32. The product identifier affixed to a homogenous case may use a two-dimensional dot matrix or a linear bar code. FDCA §§ 582(a)(9)(A)(ii).

33. A product SNI is "a set of numbers or characters . . . composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters." FDCA § 581(20).

34. FDCA §§ 582(b)(2)(A).

35. FDCA §§ 582(c)(2), (d)(2).

36. FDCA §§ 582(b)(4)(A), (c)(4)(A), (d)(4)(A), (e)(4)(A).

37. FDCA § 582(g).

38. FDCA §§ 583(b), 584(d)(2).

39. FDCA § 585(a).

40. The DQSA relies on the FDA's classification of a drug as a prescription or over-the-counter drug, not a given state's classification.

41. FDCA § 585(b).

42. FDCA §§ 301(t), 502(cc). The penalty for a prohibited act is imprisonment for not more than one year and/or a fine of not more than $1,000. A subsequent violation or an intentional violation is punishable by imprisonment of not more than three years and/or a fine of not more than $10,000. Equitable remedies, such as restitution, disgorgement of profits, and product seizure are also available. Each transaction is separately subject to these penalties.

43. 21 U.S.C. § 331(a)–(c).

44. FDCA §§ 583(a), 584(d)(1).

45. FDCA § 583(e)(3).

46. FDCA § 584(d)(3)(C).

47. Until January 1, 2015, PDMA requires wholesale distributors to be licensed in each state in which they engage in wholesale distribution. 21 C.F.R. § 205.4.

48. FDCA § 503(e)(1)(A).

49. FDCA § 584(a).

50. FDCA § 582(a)(6).

51. FDCA § 582(a)(7).

52. FDCA § 585(a).

53. *Id.*

54. FDCA § 585(b).

55. We believe it is clear that such action by a state would be directly related to and covered by the federal standards and, therefore, would be impermissible.

56. We believe this type of additional requirement is directly related to the federal standards and, therefore, would be impermissible. Furthermore, we believe additional requirements of this type would be inconsistent with the comprehensive federal licensure scheme established by the DQSA.

57. We believe that it is likely permissible for states to require wholesale distributors and third-party logistics providers to comply with *generally applicable* registration requirements such as this. Accordingly, we do not believe that states can suspend, revoke or take similar action against a company's wholesale distributor license or third-party logistics provider license for violation of generally applicable state requirements—action against the company's general registration to do business provides states a sufficient remedy.

58. The DQSA clearly provides that the transfer of product by a manufacturer is not wholesale distribution. FDCA § 503(e)(4)(H). Therefore, we believe it is clear that any state requirement that a manufacturer be licensed as a wholesale distributor would be inconsistent with the DQSA licensure provisions and, therefore, would be preempted. For the same reason, we believe any requirement that a manufacturer be licensed as a manufacturer would also be preempted if the manufacturer license were so similar to a wholesale distributor license as to operate as a *de facto* wholesale distributor license. There may, however, be manufacturer licenses that are clearly distinct from a wholesale distributor license, and it is unlikely that such a licensure requirement would be preempted by the DQSA. This, of course, leaves open the difficult question of how a true manufacturer license is distinguished from a *de facto* wholesale distributor license.

59. The traceability requirements do not apply to "the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use." FDCA § 581(24)(B)(vii).

60. Products that "entered the pharmaceutical distribution supply chain prior to January 1, 2015" are grandfathered for purposes of certain traceability requirements. FDCA § 582(a)(5)(B).

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** Ventimiglia and Marshall are both advisors to the Pharmaceutical Distribution Security Alliance, a multi-sector industry alliance involved in passage and implementation of the DQSA.

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