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DEPARTMENT OF CONSUMER AFFAIRS

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MEMORANDUM

DATE	April 21, 2022
TO	Members of the Board of Pharmacy
FROM	Eileen Smiley Attorney III
SUBJECT	**Proposed Federal Rule Setting National Licensing Standards for Wholesalers and Third Party Logistic Providers**

At the April 27, 2022 Board meeting, the Board will consider a matter approving the submission of a comment letter to proposed federal rules promulgated by the federal Food and Drug Administration (FDA) regarding third party logistics providers (3PLs) and wholesale distributors. 2022-01929.pdf (govinfo.gov).[1] The purpose of this memorandum is to summarize major areas of concern with the proposed rules.

Background

The Drug Quality and Security Act (DQSA) was signed into law on November 13, 2013. This Act consisted of two titles – Title I dealing with compounding of human drugs, and Title II dealing with drug supply chain security. The DQSA was enacted in response to the deaths and hospitalizations of many people across the United States caused by contaminated compounded drug products from a compounding pharmacy in New England. Title II of the DQSA amended the federal Food Drug and Cosmetic Act (FDCA) to require, among other things, the FDA to establish national licensing standards for wholesale distributors and third-party logistic providers (3PLs). On February 4, 2022, the FDA noticed proposed rules to establish these licensing standards. Comments are due on these proposed rules by June 6, 2022.

I. Preemption Provisions Applicable to Wholesaler and 3PL Licensure

The biggest area of concern is the FDA's announcement of the preemptive effect of these rules on the ability of states to require additional requirements beyond those set out in the proposed federal rules. Generally, states and the federal government have overlapping authority to regulate in most areas, including the area of public health. Congress can

[1] The proposed rules are detailed only in the Federal Register and the FDA's proposing release and proposed rules are located at 87 Fed. Reg. 6708 (Feb. 4, 2022). The proposed rules are listed on pages 6738-6757. All citations to sections beginning with 205.1 through 205.33 are references to the proposed federal rules.

preclude states from regulating in certain areas. If Congress chooses to preempt the ability of states to regulate in a specific area, it expresses its intent in a preemption statutory section. In interpreting Congress' intent, courts look primarily to the plain language of the preemption statutory section.

Section 585 of the FDCA is entitled Uniform National Policy. Section 585(b) states that:

> Beginning on the date of enactment of the Drug Supply Chain Security Act, no State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, *less stringent than*, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.[2] (emphasis supplied).

The plain language of this section is generally interpreted as establishing a "floor" or minimum standards but the states can impose additional requirements. In October 2014, the FDA issued for public comment a draft guidance document of the preemptive effect of both preemption sections.[3] In the 2014 Draft Guidance, the FDA stated its view that the preemptive effect of Section 585(b) would establish minimum standards or a floor for state regulations.[4] In contrast, the FDA interpreted the other preemption section applicable to the drug tracing laws differently as prohibiting any state requirements more stringent than, or in addition to the federal requirements. Both of these interpretations were consistent with the different language used in each section. The Board of Pharmacy submitted a comment letter in support of the FDA's interpretation of the preemptive effect of the final licensing rules in the 2014 Draft Guidance. This letter is attached as Attachment 2.

As part of the proposed rules, the FDA withdrew its 2014 Draft Guidance regarding the preemptive effect of the licensing rules, and now takes the view that the federal rules will establish "both a 'floor' and a 'ceiling' to state regulation. This change is important because it would render any additional California requirements in the licensing area preempted and unenforceable. California's existing law has additional requirements beyond the proposed federal rules. The FDA did not explain why, given the wording differences in these two different preemption sections, that they now will be interpreted in precisely the same way.

Our main problems with FDA's new announced preemptive effect of its rules are:

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[2] Section 585(a), applicable to the preemption of state requirements for drug tracing, is phrased differently and preempts State laws that are inconsistent with, *more* stringent than, or in addition to, any requirement for product tracing or waiver granted under federal law. (emphasis added).

[3] *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* (Oct. 8, 2014) (2014 Draft Guidance).

[4] See 2014 Draft Guidance, Section B.1 at page 4. The Draft Guidance is attached as Attachment 1.

- It is inconsistent with the statutory language in Section 585(a).
- The proposed federal rules go beyond licensing standards to operating standards which are not preempted by Section 585(b). For example, the proposed federal rules establish recordkeeping requirements[5] and details a federal disciplinary process, among others, that are hard to justify as licensing standards.
- The proposed federal rules cover a lot of subject areas but don't provide a lot of substantive requirements in required policies and procedures. The lack of detail in the proposed federal rules is more consistent with a floor than a ceiling.[6]

For these reasons, a comment letter objecting to the new preemptive interpretation announced by the FDA is warranted on statutory grounds and the potential impact to existing California law. It is also consistent with the earlier comment letter submitted by the Board in response to the FDA's 2014 Draft Guidance. We believe that it is prudent to comment on specific areas that the FDA rules do cover that differ substantively from California requirements to give the FDA an opportunity to address those concerns. For this reason, the staff seeks the Board authorization to file a comment letter to these proposed federal rules covering both the preemptive effect of the rules and the major differences from existing California law.

The following sections details only the major areas of concern with the proposed federal rules, and unless otherwise noted, the identified concerns apply to both the licensing of 3PLs and wholesale distributors.

III. Major Issues with Federal Rules

A. Licensing Authorities for Non-Resident 3PLs

Under the proposed federal rules, California can require licensure of 3PL entities if the 3PL conducts its 3PL activities (warehousing etc.) in California provided that California's licensing regime meets federal standards with no additional requirements.[7] If a state has not established a licensing regime consistent with the final federal rules, the licensing entity for a 3PL in that state would be the FDA.[8] States can require licensure of non-resident 3PLs shipping product into their State if their law requires a license but not if the non-resident 3PL is licensed by the FDA. If a non-

[5] The Board has not adopted specific regulations regarding 3PL operations. The Board has adopted limited regulations regarding the operations of wholesale distributors in Cal. Code Regs. Tit. 16 § 1780 (governing minimum standards for wholesalers, including recordkeeping requirements); § 1782 (reporting of dangerous drugs subject to abuse upon Board request) and § 1784 (requiring a self-assessment of a wholesaler to be completed every odd year).

[6] The federal rules also only cover the licensing of entities involved in dangerous drug distribution. 3PLs and wholesale distributors also must be licensed to engage in licensed activities with respect to dangerous devices. California could choose to implement similar rules for 3PLs or wholesale distributors of dangerous devices or continue its existing licensure requirements for those licensed activities related to dangerous devices.

[7] See § 205.4(a)(1).

[8] See § 205.4(a)(2).

resident 3PL is licensed by the FDA, the FDA would be the sole licensing authority for those non-resident 3PLs shipping products into California. The Board of Pharmacy would have **no** role in licensing, inspecting, or enforcing operative law against these FDA-licensed non-resident 3PLs even if their activities threaten the public health of California residents.

This impact is more concerning given that the FDA is proposing using approved third-party organizations (AOs)[9] to conduct initial licensure review and perform inspections without establishing minimum standards for their qualifications.[10] It is questionable whether the FDA will have the resources or the same sense of urgency to address problems with its licensees particularly if a licensee's activities impact only a few States. If the FDA relies upon AOs to do inspections and licensure reviews, it also is questionable whether employees of non-governmental private parties, that will likely be governed by a profit motive, would have the same interest or responsibility in protecting the citizens of a State as would employees of a State governmental agency entrusted with public safety.

This defect applies solely to non-resident 3PLs. The Board would have the ability to license, inspect and enforce laws against non-resident wholesalers licensed by the FDA, provided that California law requires the licensure of non-resident wholesaler distributors and its law is consistent with the final federal rules.

B. Separate Licenses Per Facility/Number of Licenses per Facility Initial Licensure

Similar to California law, the proposed federal rules will require each facility to be licensed, and licenses are owner- and location-specific and non-transferable.[11] However, California law generally prohibits a place of business from having more than one license issued to a location.[12] The federal rules are silent as to any limitation on the number of licenses that can be issued to one location. Existing law allows for a license to be issued to a wholesale distributor and 3PL under common control at the same location subject to certain conditions, including maintaining separateness of records and prohibitions on the commingling of products.[13] However the proposed federal rules only require that licensees at the same location maintain separate systems and processes.[14] There is no express federal requirement for the products of distinct licensees at the same location to be maintained separately. Under California

[9] These AOs will be private entities approved by the FDA.
[10] For example, Board inspectors are all licensed pharmacists and there is no requirement under the proposed federal rules governing the minimum qualifications of AO inspector personnel.
[11] See § 205.4(a) and (c) of the proposed federal rules. California law is generally in line with this federal requirement.
[12] Bus. & Prof. Code § 410(c)(1).
[13] Bus. & Prof. Code § 410(c)(2).
[14] See § 205.10(b).

law, maintaining the separateness of products of each licensee is statutorily required and Board staff does not approve multiple licenses at the same location without separate ingress and egress and product separation. These requirements could viewed as additional licensing requirements that would be preempted.

C. Treatment of Corporate Owners and Officers and Background Checks of Relevant Personnel

Under the proposed federal rules, the application will have to include the name of any owners or operators of the applicant except that the federal rules do not require the identification of any corporate owners even if the corporation is closely held.[15] Under the proposed federal rules, the Board could not require the identification of any owners of corporations, even closely held corporations. Owners of closely held corporations have both the ability and direct financial interest to control operations of the corporation they own.

Also, the proposed federal rules do not require background checks or criminal conviction screening of any corporate owner, or officer with the exception of the facility manager or designated representative.[16] A person cannot be a facility manager or designated representative of a 3PL or wholesale distributor if convicted of a felony relating to prescription drug distribution or any conviction related to drug tampering.[17] The limitation on screening owners and other officers that can control the operations of corporate 3PLs and wholesale distributors risks allowing bad actors to hire clean managers and still control the operations of a new facility. California law allows the Board to discipline and limit owners and officers of facilities subject to discipline from owning or operating more facilities.[18] There are no comparable provisions in the federal rules. The lack of provisions to hold owners or officers accountable for the operations of facilities could render enforcement against bad actors difficult and lead to sequential disciplinary actions against new facilities.

Finally, the identified criminal convictions that may result in denial or revocation of licensure under the federal rules is too narrow. Under California law, the Board looks to convictions in areas that are substantially related to the qualifications of the license, and can include misdemeanors, crimes of dishonesty, including insurance

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[15] See §§ 205.5(b)(6)(iii) (3PL applications must include corporate officers and directors) § 205.22(c)(6)(iii) (wholesaler applications must contain same information. Under California law, applications are required to list the underlying owners of corporations. See Bus. & Prof. Code § 4201(b)(2).

[16] See § 205.11(g) (requiring facility managers and designated representatives of 3PLs to submit fingerprints for criminal background checks for felony convictions related to product tampering or criminal violations of certain provisions of Food Drug and Cosmetic Act) and § 205.25(g) (requiring any facility manager or designated representative of a wholesale distributor to submit full fingerprints for screening of criminal convictions for felony violations regarding product tampering or violations of certain provisions under Food Drug and Cosmetic Act or cited two or more times for certain violations in the past seven years.)

[17] See §§ 205.11(g) (3PLs) & 205.25(g) (wholesale distributors).

[18] See Bus. & Prof. Code §§ 4307 & 4308.

fraud, theft, diversion of drugs, and convictions regarding substance abuse.[19] It is also unclear if a person with other convictions not included in the proposed federal rules would pass a DEA background investigation for access to controlled substances.[20]

D. Changes in Control Triggering New License Requirement

The proposed federal rules, similar to California law, require a new license for a change in location or control of an entity.[21] The proposed federal rules defines a change in ownership similar to California law, except when the entity is a corporation.[22] Under the federal rules, a change in control of a corporation includes only the merger of the licensed corporation into another corporation or the consolidation of two or more corporations resulting in the creation of a new corporation. A transfer of corporate stock is expressly excluded from the definition of a corporate change in control.[23] Although this might make sense with owners of a widely traded public corporation, for a closely held corporation, the transfer of stock of a 52% owner to another person would not trigger the need for a new application under the federal rules from the new owner even though a change in control has occurred.[24]

The proposed federal rules also need to be tightened up in other areas, including for sole proprietorships. Transfer of control of sole proprietorship means the transfer of title and property to another entity but does not deal effectively with partial transfers of control. For example, a change in control should be deemed to occur if drug property is transferred to a new owner but title is not transferred over the location of the facility. Any comprehensive rule should include the effective transfer of operations or drug inventory of a licensed entity and not give loopholes to avoid triggering the requirement for a new application and scrutiny of the operations of the new entity and its new owners or officers.

E. Required Inspections

The proposed federal rules will require the licensing authority to complete an inspection of the facility prior to issuing the license and then periodically after initial

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[19] See Bus. & Prof. Code § 4301(j)-(k).

[20] § 205.11(f) provides that licensure can be denied for a 3PL if the facility manager or designated representative in the past manufactured or distributed controlled substances but there was no similar provision for wholesale distributors.

[21] See § 205.4(c).

[22] § 205.3(b).

[23] § 205.3(b)(3).

[24] See § 205.3(b).

licensure.[25] If the FDA is trying to preempt state law in this area, it also should specify that for cause inspections can occur at any time. The States can do their own inspection of facilities or, in some instances, rely on the inspection of the State in which the entity is located or a third-party certification entity approved by the FDA. This new requirement will impact Board staffing and potentially the amount of licensing fees for these entities.

F. Process for License Denial, Suspension and Revocation

The proposed federal rules detail the federal process for denial, suspension, and revocation of licenses. Although there are indications that the FDA does not believe that these standards would preempt State law, it is not entirely clear.[26] California has already developed comparable processes in its Administrative Procedure Act. Our biggest objections to the federal processes, if states are to design comparable or consistent processes, are:

- These provisions are very bureaucratic and establish a linear disciplinary progression with at least two notices to licensees with time to correct compliance failures that can give bad actors more time to continue doing bad acts before the Board could finally discipline the license.
- There does not appear to be the ability to move for revocation first in a disciplinary hearing depending on the gravity of the situation.
- The detailed federal process does not speak to fines, citations, or other lesser forms of disciplinary or administrative action (such as failure to notify licensing authorities of changes to key personnel or changes in control).
- The proposed federal rules permit the voluntary termination of licensure by 3PLs and wholesale distributors and requires the licensing authority to terminate the license upon the licensee's request. There is no flexibility for the licensing authority to reject the license surrender or retain jurisdiction to adjudicate any cause for discipline. This flexibility is important particularly if the FDA, similar to California, chooses to implement the flexibility to discipline owners and officers of these licensees and bar them from acting in a similar capacity again. This flexibility is necessary to avoid an enforcement "whack a mole" game against new entities set up by the same bad actors.

If the FDA's preemption interpretation extends to the whole license denial and discipline area, changes would be necessary to the Government Code, as well as Board internal operating procedures.

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[25] The initial inspection will be required prior to licensure (including for new licenses triggered by change in location or control) and periodically. The routine inspection must be done every three years for both licensees but the 3PLs renewal cycle is every three years while the wholesale distributor renewal cycle is every two years.

[26] The FDA in the proposing release encouraged states to develop comparable processes.

G. Wholesaler Licensing Proposed Rules- Proposed Exemptions

The proposed federal rules also contain nineteen exemptions from the definition of wholesale distribution which would preclude the Board from requiring licensure, or regulating the activities, of entities engaged solely in such exempted activities. Some of the proposed exemptions are concerning, as discussed below.

1. **Intracompany distribution of any drug between members of an affiliate or within a manufacturer**

California law does not require the licensing of manufacturers if they are distributing solely their own products as they are regulated by the FDA.[27] However, if the manufacturer is warehousing and distributing dangerous drugs/devices manufactured by an affiliate, the Board has required the manufacturer to obtain a wholesaler or 3PL license. The proposed federal rules do not define an affiliate. We believe that this exemption should be limited to the distribution of a drug owned by the manufacturer.

2. **The distribution of a drug or an offer to distribute a drug among hospitals or other health care entities under common control**

This exemption does not define what "other health care entities" means and therefore it is impossible to gauge the entire impact of this proposed exclusion. California already permits transfers of drugs between pharmacies under common control which would apply to hospital pharmacies under common control without requiring licensure as a wholesale distributor.[28] We note that frequently hospitals that purchase drugs and devices through central supply departments[29] often have a warehouse located off the hospital campus to store dangerous drugs and devices, including IV solutions, sterile solutions, and irrigations. Currently, the Board requires licensure of these offsite warehouses as wholesale distributors to ensure that dangerous drugs and devices stored offsite are stored appropriately with appropriate security. This exemption should be so narrowed.

3. **The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act**

In the proposing release, the FDA explained that this exemption would apply in three situations involving emergencies. In each situation, California already addresses this

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[27] Bus. & Prof. Code § 4160(h) (exempts a manufacturer from licensing as a wholesale distributor or 3PL if it distributes drugs of its own manufacture).
[28] See Bus. & Prof. Code § 4126.5(a)(7).
[29] Use of a central supply facility is permitted under existing California law. See Bus. & Prof. Code BPC § 4057(d); Cal. Code Regs., tit. 16, § 1714.5.

need through existing law. By exempting these activities from the definition of wholesale distribution it would permit unlicensed persons, other than licensed pharmacies or other licensed entities, to furnish such drugs in a State with no ability for the State to determine minimal or alternative safeguards.

Under the proposed rules, this exemption would apply during a declared federal public health emergency, such as exists now with respect to COVID-19. Under federal law, the federal Health and Human Services Agency can issue PREP Act declarations to respond to federally declared public health emergencies. This proposed exemption, if it is intended to bypass the restrictions Congress imposed on when and how federal agencies can respond to a public health emergency using PREP Act declarations, it is an overreach. The Legislature has already given the Board of Pharmacy extensive power to waive provisions of pharmacy law during a declared state, local or federal emergency.[30] The Board has used this waiver authority extensively during the COVID public health emergency and other declared emergencies to respond to emergency situations while still ensuring public protection. In exercising its waiver power, the Board can impose conditions on such waivers. If distribution of drugs during an emergency are viewed as not engaging in wholesale distribution, the Board would lack the power to impose conditions on activities by unlicensed entities during public emergencies.

This exemption also would apply to distribution of drugs to first responders or other authorized individuals administering drugs to acutely ill or injured persons. California law already addresses the ability of different licensed persons to furnish drugs to first responders within an emergency medical services system,[31] and allows pharmacies and licensed wholesalers to stock dangerous drugs into an emergency medical services automated drug delivery system.[32]

Finally, the FDA also stated that this exemption would govern the distribution of drugs to a long-term care facility to receive an emergency kit to treat patients when drugs cannot be obtained from a dispenser. California law already addresses this issue subject to conditions.[33] Existing law also permits a pharmacy to have a licensed ADDS at a long-term care facility for emergency or immediate administration, subject to conditions.[34]

4. Distribution of minimal quantities of a drug by a licensed pharmacy to a licensed practitioner for office use.

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[30] Bus. & Prof. Code § 4062(c).

[31] See Bus. & Prof. Code § 4119(b) (allows a pharmacy to furnish drugs to an approved service provider within an emergency medical services system for storage in a secured emergency supplies container); Health & Saf. Code § 1261.5.

[32] See Bus. & Prof. Code § 4119.01.

[33] See Bus. & Prof. Code § 4119(a); Health & Saf. Code § 1261.5.

[34] See Bus. & Prof. Code § 4427.3(b)(2); Health & Saf. Code § 1261.6(e).

California law already permits pharmacies to furnish drugs to a health care provider for office use.[35] Under the proposed federal rules, a minimal quantity would mean the total annual volume of prescriptions drugs sold by a retail pharmacy to a practitioner for office use does not exceed 5% of the total dollar volume of that retail pharmacy's annual prescription drug sales. In the proposing release, the FDA noted that some states have expanded this definition to include sales to other persons besides licensed practitioners and the FDA notes that this is not permissible under federal law.[36] California law permits a licensed pharmacy to transfer a drug to another pharmacy or wholesaler, without being a licensed wholesaler, to alleviate a temporary shortage of a dangerous drug that could result in denial of health care.[37] Based on the FDA's statement, it appears that this authority would be preempted and the pharmacy would need to be licensed as a wholesale distributor. If adopted, the Board will need to consider requiring pharmacies to calculate their annual revenue to ensure that their sales of office use drugs does not exceed 5% of their overall prescription drug revenue for a given year.

5. The purchase or acquisition by a dispenser, hospital or other health care facility of a drug for use by the dispenser, hospital or other health care entity.

Section 4057(b)(2) of the Business and Professions Code generally exempts from further licensure requirements the furnishing of specific dangerous drugs to a clinic, hospital, institution, or establishment holding a license under the Health and Safety Code. A board regulation lists the drugs that are exempt from the licensing provisions of pharmacy law where the furnishing is made to a clinic, hospital, or other institution.[38] Because the proposed federal rule is a broader exemption, this regulation would need to be amended to conform.

6. Saleable Drug Returns when conducted by a dispenser

California law permits pharmacies to return dangerous drugs without additional licensure but only to a wholesaler (or one under common control) from which the drug was acquired, to the manufacturer, or to a wholesaler acting as a reverse distributor.[39] The federal exemption does not limit the entities to which a dispenser could return drugs, and it is unclear whether these California limitations would be enforceable. Given the FDA's announced preemptive effect of the rules, the FDA should clarify that the

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[35] Bus. & Prof. Code § 4126.5(a)(6) (allows pharmacies to furnish drugs to a health care provider that can purchase dangerous drugs) and § 4052(a)(1) (permits a pharmacist to furnish a reasonable quantity of a compounded drug product to a prescriber for office use by the prescriber). Ca. Code Regs., tit. 16, § 1735.2(c) (defines reasonably quantity of compounded drugs that may be furnished that is tied to a 120-hour supply).
[36] 87 Fed. Reg. at p. 6714.
[37] Bus. & Prof. Code § 4126.5(a)(4).
[38] Cal. Code Regs., tit. 16, § 1714.5 (drugs listed in this regulation).
[39] Bus. & Prof. Code § 4126(a)(1)-(3).

rules do not impact licensure of entities involved in the reverse distribution of drugs (i.e., licensing requirements for entities to remove dangerous drugs from the drug supply).

7. The distribution of certain dangerous drugs

The proposed federal rules would exempt from the definition of wholesale distribution any distribution of:

- an IV drug that is intended for replenishment of fluids and electrolytes (such as sodium, chloride, and potassium).
- an IV drug used to maintain equilibrium of water and minerals in the body.
- a drug intended for irrigation or sterile water; and
- distribution of medicinal gases.[40]

All of these items are designated as dangerous drugs by the FDA that require proper storage to maintain safety of the product. It is not clear why the FDA would exempt from licensure entities that distribute these dangerous drugs where proper storage is required and how permitting unlicensed entities to distribute such products would facilitate tracing of contaminated products. It is also hard to fathom how these exemptions would be consistent with public health.

H. Determination of Compliance of States Licensing Regime

The proposed federal rules require that State licensing regimes be consistent with, not identical to, the proposed federal rules. If a State's licensing scheme is not consistent with the federal rules, or has additional requirements, then those laws would be unenforceable and the licensing authority for 3PLs and wholesale distributors in such a State will be the FDA. Given the draconian effect of a state statutory regime being deemed inconsistent with the federal rules, the FDA should establish a review provision for state licensure regimes. Otherwise, the potential for license-related litigation increases and delays in licensing reviews and issuance would occur as those questions are litigated in an adversarial proceeding.

I. Lack of Specific Requirements that Will Not Lead to Consistency or Transparency in Requirements Approved

The proposed federal rules require that both 3PLs and wholesale distributors have specified policies and procedures but do not detail many specific requirements. For example, 3PLs must have policies and procedures detailing, among other areas, their inventory practices including regular inventories, but does not specify the frequency of such inventories.[41] The lack of specificity could result in one licensing authority reviewing a licensee's policies and procedures with annual inventories as sufficient and a later licensing authority could deem

[40] § 205.3(n)(14)-(17).
[41] See § 205.12(c).

that frequency inadequate. When AOs are reviewing policies and procedures as part of a licensure decision, there is also concern that approval of licensure is a de facto approval of the sufficiency of every operational step detailed in those policies and procedures. The lack of specificity in the federal rules is further grounds that such rules should establish a floor and not a ceiling to further regulation by the States.

J. Time Period for Compliance

The FDA stated that it would give two years from the adoption of final federal rules for States to come into compliance. If the federal rules establish a floor, and not a ceiling, statutory and regulatory compliance might be achievable in that time period.[42] However, the FDA also expects that new licenses (and required inspections) would be issued during this compliance period and physical inspections will need to be done prior to issuance. It would not be feasible to complete required inspections and issue new license to existing licensees during this same time period.

If the federal rules establish a ceiling that require the elimination of additional requirements the time period is too short. To implement these federal rules as a ceiling would require substantial changes to statute, regulations, applications, instructions, and operating procedures, and issuing new licenses to existing licensees. The statutory changes alone will not be an easy substitution based on the different structures of California pharmacy law and the proposed federal rules. The comment letter will include lengthening the time for compliance to allow the Legislature to enact conforming changes in the course of a normal legislative cycle (without resorting to emergency measures), and then give the Board a chance to adopt other necessary changes and issue new licenses to existing licensees after a physical inspection. Finally, the implementation deadline might need to be furthered lengthened if the FDA issues other rules and guidance in the areas of compounding and drug supply chain security before the final rules are adopted.

IV. CONCLUSION

The proposed federal rules have some positive elements by clearly establishing what areas must be covered by policies and procedures but only if the federal rules establish a floor and not a ceiling to additional state regulation.

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[42] I have identified two instances where existing California law is less stringent than the proposed federal rules. California's record retention period is three years and the federal rules are the same except that documents related to suspect, illegitimate, destroyed, returned, and recalled products is six years. Compare Cal. Code Regs. Tit. 16 §1780(f)(2); with § 205.13(b) (3PL records) & §205.27(d)(wholesaler records). Existing law permits a person to act as a designated representative or facility manager for more than one entity unless the entities are located at the same location. The proposed federal rules would limit persons to acting in that role for one licensed entity. See § 205.11(b)(2) (3PL provision) & § 205.25(f)(1) (wholesaler provision). California law does not contain a similar limitation except the same person cannot be the designated representative of a wholesaler or 3PL entity at the same location. Bus.& Prof. Code § 4160(c)(2)(C).

Attachment 1

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

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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

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

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Procedural

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

Guidance for Industry

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

Guidance for Industry[1]

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

I. INTRODUCTION

The Food and Drug Administration (FDA) is issuing these questions and answers to assist industry and State and local governments in understanding the effects of section 585 (Uniform National Policy) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[2] added by Title II of the Drug Quality and Security Act (DQSA), which was enacted on November 27, 2013. Title II, which is also referred to as the Drug Supply Chain Security Act (DSCSA), establishes a Federal system for tracing prescription drug products through the pharmaceutical distribution supply chain and requires trading partners to pass, receive, and maintain certain product and distribution information. The DSCSA also requires FDA to establish Federal standards for licensing of wholesale drug distributors and third party logistics providers; the Agency is currently drafting these regulations. Section 585 sets forth a uniform national policy preempting States[3] from establishing or continuing in effect certain standards and requirements.

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

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

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

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

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

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

II. BACKGROUND

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

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

> (a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—
>
> (1) any waiver, exception, or exemption pursuant to section 581 or 582; or
>
> (2) any restrictions specified in section 582.
>
> (b) Wholesale Distributor and Third-Party Logistics Provider Standards—
>
> (1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.
>
> (2) State Regulation of Third-Party Logistics Providers.—No State shall regulate third-party logistics providers as wholesale distributors.

III. QUESTIONS AND ANSWERS

A. Product Tracing

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

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

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

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

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

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

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

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

4. Which State requirements are preempted?

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

B. Wholesale Drug Distributor Standards and Licensing

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

Beginning on November 27, 2013, States were preempted from establishing or continuing any standards, requirements, or regulations with respect to wholesale distributor licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards[4] or requirements applicable under section 503(e) of the FD&C Act (as amended by the DSCSA). Thus, States may not impose standards, requirements, or regulations with respect to wholesale drug distributors that fall below the minimum standards established by Federal law.

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

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

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

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

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

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

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

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

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

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

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

Beginning on November 27, 2013, States are preempted from establishing or continuing any standards, requirements, or regulations with respect to 3PLs that are inconsistent with, less stringent than, directly related to, or covered by the standards[6] or requirements applicable under section 584 of the FD&C Act. Thus, States may not impose standards, requirements, or regulations with respect to 3PLs that fall below the minimum standards established by Federal law.

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

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

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

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

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

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

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

206 **4. Can States license 3PLs using their licensing program for wholesale drug**
207 **distributors?**
208
209 Section 585(b)(2) does not permit states to license 3PLs as wholesale drug distributors. States
210 would need to establish separate licensing programs for wholesale drug distributors and 3PLs.
211

Attachment 2

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STATE BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
EDMUND G. BROWN, JR., GOVERNOR

November 14, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. FDA-2014-D-1411
The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers – Guidance for Industry

To Whom It May Concern:

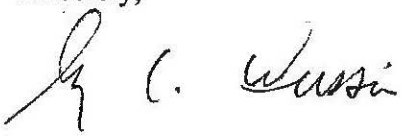
I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to submit comments on Docket No. FDA-2014-D-1411, titled "The Effect of Section 585 of the FD&C Act on Drug Product Tracing and Wholesale Drug Distributor and Third-Party Logistics Provider Licensing Standards and Requirements: Questions and Answers – Guidance for Industry." We will be brief. We strongly support this Draft Guidance. We believe it accurately conveys the effects of section 585 (Uniform National Policy) of the Federal Food, Drug and Cosmetic Act (FD&C Act) added by Title II (the Drug Supply Chain Security Act, or DSCSA) of the Drug Quality and Security Act (DQSA), enacted November 27, 2013. We also support this effort to clarify and settle the impacts of section 585 on federal and state laws.

We concur with your conclusions regarding the preemptive effect of the DSCSA on state prescription product tracing requirements, and the more limited preemptive effect of the DSCSA provisions regarding uniform national standards for wholesale drug distributors and third party logistics providers. California has already acted in conformity with your proposed interpretation. For instance, California has acknowledged the preemption of its state pedigree (track and trace) laws, and has effected their repeal. And California has set up a separate licensing category for third party logistics providers that distinguishes them from wholesale distributors yet holds them to similar standards of registration and safety to protect the drug supply. We look forward to the development of the minimum licensure standards and requirements for wholesale distributors and third party logistics providers that will be forthcoming under sections 583 and 584, and we pledge our commitment that California's licensure of these entities will never fall below those minimum standards to be established by the forthcoming regulations. In fact, we expect that we will continue to be an industry leader in how these entities are regulated.

We also concur with your conclusion that section 503(e)(1)(A) (as amended) requires that a wholesale distributor "be licensed by the State from which the drug is distributed or else by the Secretary of Health and Human Services if the distributing wholesale drug distributor's State chooses not to have a licensing program" and, '[i]n addition, . . . by the State into which the drug is distributed (if required by that State)." We presume the effect of identical language in section 584, as to third party logistics providers, is the same (licensure may be required by both states). It may be helpful to also have that specified in the final version of the Guidance document.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia.Herold@dca.ca.gov.

Sincerely,



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