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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
April 22, 2021

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of January 20, 2021, Enforcement and Compounding Committee Meeting Minutes.

A draft version of the minutes is provided in **Attachment 1.**

IV. Approval of the February 18, 2021, Informational Meeting on "White Bagging"

A draft version of the meeting minutes is provided in **Attachment 2**.

V. Presentation on the National Association of Boards of Pharmacy, Compounding Data Sharing Project

Relevant law

Federal law establishes provisions for pharmacy compounding in Section 503A of the FD&C Act. Further, as provided in this section, the FD&C Act directs the FDA to develop a standard Memorandum of Understanding (MOU), in consultation with the National Association of Boards of Pharmacy.

Background

In October 2020, the FDA finalized its draft MOU, that establishes an agreement between the respective state authority and the FDA regarding the distribution of inordinate amounts of

compounded human drug products interstate and the appropriate investigation by respective state authority of complaints of such products.

The MOU establishes various conditions that respective state authorities must adhere to as a condition of the agreement including:

1. **Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State**
   The state authority will investigate complaints of adverse drug experiences and product quality issues related to human drug products compounded at a pharmacy in its jurisdiction that is distributed outside of the state. As part of the investigation the state authority must assess whether there is a public health risk association with the compounding product. Further, the state agency must maintain records for at least three years, compels the state authority to report complaints involving serious adverse drug experience or serious product quality issues within five business days of receipt, and mandates reporting of investigation outcomes to the FDA. The state authority is also required to notify the appropriate regulatory authority of physicians in the jurisdiction, if the complaint involves product compounded by a physician and distributed interstate.
2. **Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate**
   Defines inordinate amount as the number of prescription orders that a pharmacy distributed interstate during any calendar year that is greater than 50 percent of the number of prescription orders sent out of state versus the total number of prescription orders dispensed. Requires the state authority to identify such compounding pharmacies and notify the FDA within 30 days of such a determination and requires the state authority to notify the appropriate regulator of physicians, if the state authority is aware of a physician distributing an inordinate amount.
3. **Submission and Disclosure Information**
   Prescribes the minimum information that must be provided, specifies that the information can be provided via the Information Sharing Network, and establishes authority for sharing such information under a separate agreement as provided for in 21 CFR 20.88.

During the meeting members will receive a presentation by NABP and the FDA on the Compounding Pharmacy Information-Sharing Project, which is intended to help facilitate some of the provisions of the MOU.

Attachment 3 includes a copy of the presentation slides information and summary information provided by the NABP.

VI. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products

Background

During its prior discussion, the Committee received significant public comment requesting the Board enter into the MOU. Further, the Committee requested that staff determine if an extension could be secured to allow for implementation of necessary provisions should the Board determine signing the MOU is appropriate. Staff is awaiting a response on this issue and will provide an update should one be available during the meeting.

Review of summary implementation information provided by NABP reveals that states are in various stages of consideration of the issue. To date, only one state has signed the MOU and several states have declined. Several states have concluded they are unable to participate in the MOU because of legal or technical reasons, while some are considering regulations. Seven states are in the process of entering the MOU, pending additional action.

Staff and counsel recently attended a listening session with FDA representatives. As part of the session, concern was raised about the implementation timeline and other challenges with satisfying the requirements of the MOU, including the need for statutory changes in California before it could enter into the MOU if deemed appropriate. Staff have requested a follow up discussion with the FDA that has not been scheduled yet.

<u>For Discussion and Consideration</u>
During the meeting members will have the opportunity to discuss the MOU. It is recommended that the committee consider larger questions as part of its discussion including:

1. Does the Board have the authority to enter into the MOU?
2. What are the potential benefits and negative impacts to California consumers for the Board to enter into this agreement?
3. What are the potential positive and negative impacts to compounding pharmacies and residents outside of California if the Board does not enter into the MOU?

Should the committee agree that entering into the MOU is appropriate, the following implementation issues need to be considered. Such changes will need to be facilitate through statutory changes.

1. Should the Board require as a condition of renewal, that a pharmacy advise the Board that it distributes compounded preparations outside of California?
2. Should the Board establish a requirement for such pharmacies to report sales to the Information Sharing Network as provided for in the MOU?
3. Should the Board establish a requirement for pharmacies to report adverse drug experiences and drug quality issues related to a drug compounded at a pharmacy?
   Note: Staff suggest harmonizing the language of BPC 4127.1(f) for sterile products to include mandatory reporting of all adverse drug experiences and compounded drug quality issues. Further either a statutory change would be required to establish the mandatory reporting for nonsterile products.
4. Should we require pharmacies that engage in interstate compounding to affirm their understanding of the conditions detailed in the MOU that must be fulfilled to engage in interstate compounding?
5. Should the Board establish confidentiality provisions for the information provided to the FDA directly or through the Information Sharing Network.
6. Should the Board develop education materials for pharmacies that distribute compounded product interstate.

Attachment 4 includes a copy of the MOU, questions and answers released by the FDA, a draft statutory proposal that provides an example of statutory changes that could be used facilitate implementation, and written comments received.

VII. Discussion and Consideration of Compounding with Components or Other Materials that Could Result in Insanitary Conditions as Established in the FDA Insanitary Conditions at Compounding Facilities Guidance for Industry

Relevant Law

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health . . ." Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b), compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs (including biological products) prepared, packed, or held (hereinafter referred to as "produced") under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the FD&C Act.

Section 503A of the Food, Drug & Cosmetic Act (FD&C Act), includes certain restrictions on the bulk drug substances that can be used in compounding and directs the FDA to develop a list of bulk substances that can be used in compounding under section 503A.

Under the conditions of the law, one of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist compounds the drug product using bulk drug substances that:

1. Comply with the standards of an applicable USP-NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary, or,
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.

Note: FDA has interpreted "an applicable USP or NF monograph to mean an official USP or NF drug substance monograph. **Accordingly, the FDA does not consider USP monographs for dietary supplements to be "applicable USP or NF monographs within the meaning of section 503A(b)(1)(A(i)(I)".**

Further, Section 503B of the FD&C Act directs the FDA to develop a list of bulk drug substances for which there is a clinical need. Drug products compounded using bulk drug substances on the 503B bulks list quality for certain exemptions from the FD&C Act provided the other conditions in section 503B are met. As provided in federal law, outsourcing facilities are subject to FDA inspections and other conditions that help to mitigate the risks of the drug products they compound. Further, bulk drug substances used by outsourcing facilities must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with the FDA under section 510 of the FD&C Act. In addition, if an applicable USP or National Formulary drug monograph exists,

bulk drug substances must comply with the monograph and will be taken off the bulk substances list.

Background

In November 2020, the FDA finalized and released its guidance document describing examples of insanitary condition that the FDA has observed. As indicated in the document, the guidance specifically addresses drugs (including biological products) produced in settings including pharmacies and outsourcing facilities that compound, mix, dilute or repackage drugs, including biological products.

The FDA notes in its guidance document the following:

> "In addition, to protect the public health, both FDA and state regulatory agencies may take action when compounding facilities produce drugs under insanitary conditions. Based on its inspections, FDA determines whether compounding facilities produce drugs under insanitary conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may initiate regulatory action. However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the states and, as explained above, generally are not routinely inspected by FDA. FDA strongly encourages state regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices, including those described below. Where insanitary conditions are identified, FDA encourages states to take appropriate action, consistent with state laws and regulations, and to contact FDA."

This issue of compounding a sterile preparation using a bulk ingredient is very complex, requiring pharmacies to understand and adhere to not only relevant USP Chapters and Board regulations, but also relevant provisions of federal law and related guidance documents, most notably the guidance documents released specific to bulk substances and insanitary conditions.

The committee has dedicated significant time to public discussion of outsourcing facilities operating under the authority of Section 503B for the FD&C Act and relevant sections of Pharmacy Law, as well as pharmacies compounding preparations pursuant to the authority of Section 503A of the FD&C Act relevant sections of Pharmacy Law and its regulations.

Both Pharmacy Law and federal law recognize the different requirements under which compounding must be performed in outsourcing facilities versus pharmacies, most notably that outsourcing facilities must perform compounding under current good manufacturing practices while compounding pharmacies follow 503A provisions, relevant USP Compounding Chapters and Board regulations.

During several meetings members have received public comment in support of compounded preparations provided by pharmacies using bulk ingredients that may not comply with legal provisions, including methylcobalamin. As discussed during these prior meetings, bulk substances such as methylcobalamin are generally graded as dietary grade or not graded at all. Use of such bulk ingredients in sterile compounded preparation could result in insanitary conditions.

Under the FDA's Interim Policy on Compounding Using Bulk Drug Substances under 503(A), the FDA provides that the FDA may not take enforcement action under specified conditions. It is important

to note, as with all FDA guidance, the guidance is not binding on the FDA or the public. As staff understand the document, it is important to note that such conditions require evaluation but generally include:

1. The bulk substance appears in 503A Category I on FDA's website - - https://www.fda.gov/media/94164/download
2. The original manufacturer and all subsequent manufacturers of the bulk substance are establishments are registered under section 510 (including foreign establishments that are registered under section 510(i)) of the FD&C Act)
3. The bulk substance is accompanied by a valid COA; and
4. The product compounded using the bulk drug substance is compounded with all other conditions of section 503A of the FD&C Act. (Note: This would include compliance guidance related to insanitary conditions)

Further, the FDA reinforces the need for compounders to know bulk suppliers and confirm if such suppliers are testing the drugs before a compounder purchased bulk substances for patient use. In February 2021, the FDA posted an advisory, FDA to compounders: Know Your Bulks Supplier In this release the FDA noted several issues over the past few years related to repackagers of bulk drug substances, used in compounded drugs. The FDA has issued alerts about safety issues with various bulk substances, including highlighting concerns with using dietary ingredient glutathione to compound sterile injectables. Further, the FDA has issued warning letter to API repackagers for significant violations of CGMPs, including the warning letter issued to Professional Compounding Centers of America, dba PCCA, that was issued January 27, 2021, and briefly discussed at the January 2021 Board Meeting.

During the Committee's January 2021 meeting, members encouraged staff to continue to educate licensees about the provisions of law, the risks associated with compounding from an inappropriately graded material, and steps that could be taken to mitigate such risks. In addition, staff were directed to discuss the issue with the FDA and report back to the Committee.

Subsequent to the meeting, Board staff discussed the issue with the FDA, who confirmed that compounding from inappropriately graded products could result in violations of the guidance regarding insanitary conditions. The FDA indicated that such a determination is made considering a number of factors, including consideration of the bulk substances guidance document and insanitary conditions guidance document. As part of the discussion, FDA representatives also referred staff back to compounding risk alerts that have been issued by the FDA including the alert, FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables. The alert includes the following conclusions:

1. The powder the pharmacies received was labeled with "Caution: Dietary Supplement" and should not have been used to compound sterile injectable drugs. Ingredients not intended to use in compounding sterile injectable drugs can be harmful when administered to patients because they may contain impurities and contaminants, including endotoxins.
2. It is critical that compounders understand that quality should be built into the drug production, and that testing alone should not be relied on to ensure drug quality. Therefore, compounders should ensure that all ingredients they use to produce sterile injectable drugs are manufactured under conditions and specifications appropriate for the intended route of administration.
3. FDA also urges manufacturers and repackagers to clearly label ingredients intended for use in dietary supplements. Additionally, repackagers should ask the manufacturer about the intended

use of the ingredient. Clarifying information on the ingredient labels and in the COA could help prevent compounders from using ingredients not appropriate for compounding sterile injectable drugs.

As part of its ongoing activities, Board staff continue to educate licensees about the relevant provisions of law when identifying compounding with components or other materials that could result in insanitary conditions. Education typically focuses on provisions of the law, understanding the quality of the ingredient prior to use, understanding the testing specification and information included in the COA and possible implications to patients when impurities or other contaminants are identified, the importance of working with a supplier to improve the quality of bulk ingredients as well as the possible need to independently test bulk ingredients prior to use. Additionally, inspectors may provide several resources to licensees including:

1. "FDA to Compounders: Know Your Bulks Supplies", which states: "For patient safety and supply chain transparency, repackagers must follow all quality standards pertaining to them, including clearly identifying the original API manufacturer to their customers who use them to make the finished drugs patients take every day."

https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-supplier

2. "Warning Letter: Professional Compounding Centers of America Inc. (PCCA)" (link below), for receiving and distributing adulterated and misbranded active pharmaceutical ingredients (APIs).

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/professional-compounding-centers-america-dba-pcca-597638-01272021

3. "Guidance Document: Insanitary Conditions at Compounding Facilities" (link below). FDA defines *Insanitary conditions* as "conditions that could cause a drug to become contaminated with filth or rendered injurious to health. The drug itself need not actually be contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substance is deemed to be adulterated under section 501(a)(1) of the FD&C Act (21 U.S.C. 351(a)(1))" One of the examples of Insanitary Conditions listed is following: "Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)"

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/insanitary-conditions-compounding-facilities-guidance-industry

4. "FDA highlights concerns with using dietary grade glutathione to compound sterile injectables" (link below). In the Conclusion portion of the letter it states, "It is critical that compounders understand that quality should be built into the drug production, and that testing alone should not be relied on to ensure drug quality. Therefore, compounders should ensure that all ingredients they use to produce sterile injectable drugs are manufactured under conditions and specifications appropriate for the intended route of administration. FDA also urges manufacturers and repackagers to clearly label ingredients intended for use in dietary supplements. Additionally, repackagers should ask the manufacturer about the intended use of the ingredient. Clarifying

information on ingredient labels and in the COA could help prevent compounders from using ingredients not appropriate for sterile injectable drugs.

https://www.fda.gov/drugs/human-drug-compounding/fda-highlights-concerns-using-dietary-ingredient-glutathione-compound-sterile-injectables

5. "USP – Guideline for assigning titles to USP Dietary Supplement Monographs" – See page 3 of this document. Specifically *"Paragraph 3(a) of DSHEA states that a DS shall be deemed to be a food (i.e., neither an over-the-counter nor prescription drug) within the meaning of this Act"*

https://www.usp.org/sites/default/files/usp/document/get-involved/submission-guidelines/guideline-for-assigning-titles-to-usp-dietary-supplement-monograph.pdf

6. "FDA Questions and Answers on Dietary Supplements" – ***"What is a dietary supplement?*** *Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994. A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement."*

https://www.fda.gov/food/information-consumers-using-dietary-supplements/questions-and-answers-dietary-supplements

Further, as part of its prior discussion, the Committee requested information on adverse events related to the use of methylcobalamin. Although the Board does not have access to Med Watch, the FDA maintains a public dashboard, FDA Adverse Events Reporting System. As indicated in the footnotes of this sytem, it is important to understand what the data includes, which is limited to voluntary direct reports submitted through the MedWatch program by consumers and healthcare professionals, mandatory reports and biological safety reports.

For Committee Discussion and Consideration
During the meeting members will have the opportunity to continue its discussion of the issue, including legal and safety issues.

VIII. Discussion and Consideration of Opportunities to Improve Naloxone Accessibility through Auxiliary Labels for Opioid Prescriptions

Relevant Law
Business and Professions Code (BPC) section 4076.7 requires that in addition to other labeling requirements, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, a notice that states "Caution: Opioid. Risk of overdose and addiction."

BPC section 4052.01 established the authority for a pharmacy to furnish naloxone hydrochloride

under specified conditions. Further, CCR section 1746.3, further defines that authority through regulation.

Background

July 23, 2020, the FDA issued a Drug Safety Communication recommending that health care professionals discuss the availability of naloxone, and consider prescribing it to patients who are at increased risk of opioid overdose. As part of the FDA News Release, FDA noted its work to help increase availability of naloxone and combat opioid overdoses.

As part of the October 27, 2020 Committee Meeting, members voted to agendize discussion of auxiliary labels used to assist with naloxone accessibility.

For Committee Consideration

During the meeting members will have the opportunity to discuss the issue and determine if any other action should be taken.

IX. Discussion and Consideration of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Relevant law

BPC section 688 establishes, on or after effective January 1, 2022, a requirement for health care practitioners (HCP) authorized to issue prescriptions to have the capability to transmit electronic data transmission prescriptions and would require pharmacies to have the capability to receive those transmissions. Further, this section provides several exceptions to the requirement. Specific exemptions include the following:

1. Prescriptions issued pursuant to HSC 11159.2.
2. An electronic data transmission is not available due to a failure of the computer system, application, or device; the loss of electrical power; or other service interruption.
3. The HCP is issuing a prescription to be dispensed by a pharmacy located outside of California
4. The prescription is issued in an ER or urgent care clinic and at least one of the following conditions are present.
    a. The patient resides outside of California.
    b. The patient resides outside of the geographic area of the hospital.
    c. The patient is homeless or indigent and does not have a preferred pharmacy.
    d. The prescription is issued when the patient's regular pharmacy is likely to be closed.
5. Prescriptions may be issued electronically, but do not require electronic transmission including:
    a. A prescription issued by a veterinarian.
    b. A prescription is for eyeglasses or contact lenses
    c. The prescribing HCP and dispenser are the same entity.
    d. The prescribing HCP determines such transmission would be impractical for the patient to obtain the substance in a timely manner.
    e. The prescription issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard
6. An HCP who does not transmit the prescription as an electronic data transmission shall document the reason in the patient's medical record within 72 hours of the end of the technological or electrical failure.
7. A pharmacy that receives the transmission but has not dispensed the medication shall, at the request of

the patient or other authorized individual, immediately transfer or forward the electronic data transmission prescription to an alternative pharmacy.

8. If a pharmacy, or its staff, is aware that an attempted transmission of an electronic data transmission failed, is incomplete, or it otherwise not appropriately received, the pharmacy shall immediately notify the prescribing HCP.
9. A pharmacist who receives a written, oral, or faxed prescription shall not be required to verify that the prescription falls within one of the above exceptions and may continue to dispense medications from legally valid written, oral, or fax prescriptions.

For Committee Consideration and Discussion

During the meeting members will have the opportunity to discuss the provisions and hear from stakeholders to determine if, as part of its education on the requirements, development of Frequently Asked Questions, would be helpful.

X. Discussion and Consideration of Federal Food and Drug Administration Final Rule Related to Importation of Certain Canadian Prescription Drugs

Relevant Law

21 CFR Parts 1 and 251 include the final rule to implement a provision of the FD&A Act to allow for the importation of certain prescription drugs from Canada.

Background

In September 2020, the FDA and the Department of Health and Human Services announced a final rule to implement the provision of federal law that allows FDA-authorized programs to import certain prescription drugs from Canada under specific conditions.

In October 2020, the FDA released its guidance document on the Importation of Certain FDA – Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act.

For Committee Consideration and Discussion

As states begin to consider implementation of the requirements of the final rule and guidance documents, it appears appropriate to begin education of the federal requirements. During the meeting members will receive a brief overview of the federal rule. As part of its discussion members will have the opportunity to provide feedback to staff on any additional information that may be helpful to the Committee in future meetings, if appropriate.

XI. Office of the Attorney General, Presentation on the Annual Report to the Legislature Pursuant to Business and Professions Code Section 312.2

Relevant Law

BPC section 312.2 requires the Attorney General to submit a report on an annual basis, specified data that includes summary enforcement related issues handled by the Office of the Attorney General.

For Committee Consideration and Discussion

During the meeting members will receive a presentation from Carl Sonne, Senior Assistant Attorney General on the summary information related to the Board.

A copy of presentation slides and relevant portion of the report is provided in **Attachment 5.**

XII. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Relevant Law

BPC Section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Further, the section states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Article 19 (BPC sections 4300 – 4313), and other various provisions of Pharmacy Law and its regulation, define the provisions for disciplinary proceedings and other enforcement actions, acts that constitute unprofessional conduct and other violations of law, mitigating factors, and other authorizing and notification requirements.

CCR section 1760 requires the Board, when reaching a decision on a disciplinary matter, to consider the Disciplinary Guidelines, which are incorporated by reference into this regulation.

The Administrative Procedure Act (Government Code section 1140, et seq.,) defines the administrative case process developed to ensure due process.

Background

The Committee and Board have previously contemplated development of an alternative enforcement model. The goal of the alternative model is to reduce the time and cost associated with resolving a disciplinary matter which must be balanced with also continuing to provide due process to licensees, as well as consumer protection. The original proposal developed and considered by the Committee and Board was based on a model used by the Physical Therapy Board, that provides an option for pre-pleading settlement of an administrative matter where the outcome of the matter is a Public Letter of Reprimand. The language for such authority is provided below:

> **BPC 2660.3.**
> In lieu of filing or prosecuting a formal accusation against a licensee, the board may, upon stipulation or agreement by the licensee, issue a public letter of reprimand after it has conducted an investigation or inspection as provided for in this chapter. The public letter of reprimand may include a requirement for specified training or education, and cost recovery for investigative costs. The board shall notify the licensee of its intention to issue the letter 30 days before the intended issuance date of the letter. The licensee shall indicate in writing at least 15 days prior to the letter's intended issuance date whether he or she agrees to the issuance of the letter. The board, at its option, may extend the time within which the licensee may respond to its notification. If the licensee does not agree to the issuance of the letter, the board shall not issue the letter and may proceed to file the accusation. The board may use a public letter of reprimand only for minor violations, as defined by the board, committed by the licensee. A public letter of reprimand issued

pursuant to this section shall be disclosed by the board to an inquiring member of the public and shall be posted on the board's Internet Web site.

Since its initial discussion, the Committee has considered various proposals to achieve the overall stated policy goals - - to reduce costs and case resolution time. As the various proposals have been considered, at times counsel has identified possible concerns, particularly with the involvement of Board Members as either part of the investigative or settlement process, as an example including Member(s) as part of a proposed oral conference as part of the alternative enforcement model.

Members have also reviewed statistical information regarding disciplinary cases including case outcome information, which indicates that in FY 2019/20, about 10% of all investigations resulted in referral of the matter to the Office of the Attorney General for possible disciplinary action. Additionally, of the administrative cases resolved, about 25 percent resulted in a default decision, 56 percent were resolved through a stipulated settlement, 10 percent were resolved through an administrative hearing and about 10 percent were withdrawn. When reviewing the outcome of the mail vote process, the Board voted to nonadopt less than 1 percent of stipulated settlements and about six percent of proposed decisions. Last, when evaluating the types of disciplinary outcomes about 30 percent result in revocation, which includes default decisions. In addition, about 23 percent result in the respondent voluntarily surrendering a license, about 30 percent result in a term of probation, and about 16 percent resulted in the license being publicly reproved.

Following discussion and consideration, including a proposal by stakeholders, the Committee directed staff to report back on possible solutions to meet the overall policy goal that do not require legislative changes. In preparation for this meeting staff have conferred with the Office of the Attorney General on possible changes that do not require legislative changes to implement. As part of this discussion, Board staff was advised about a pre-settlement conference used by the California Board of Accountancy, a brief description of which is provided below:

THE PRE-ACCUSATION REVIEW/CONFERENCE

Before an accusation is filed, unless public safety requires immediate action, you may be offered an opportunity to review a draft accusation and comment on its factual content. The accusation will be available for review only at a scheduled pre-filing review conference. No copies will be released to you until the actual filing of the accusation.

Based on staff understanding of this conference, respondents are provided another opportunity to provide mitigation and/or rehabilitation for consideration by the Agency. Respondents are not required to participate in this conference. Information received during this conference could result in several outcomes including amendments to the draft pleading prior to filing or withdrawal of the matter. In addition, the pre-filing conference allows an opportunity to earlier engagement in settlement where appropriate, which ultimately results in a reduction in resolution time. The Department of Managed Health Care (DMHC) uses its own Enforcement Division (as opposed to the Attorney General's Office) for resolution of its Enforcement Actions. As part of its process DMHC will sent a pre-accusation letter and allow the Licensee to response with information in its defense, or in mitigation. However, in the case of DMHC, if a settlement agreement is reached, the pre-accusation letter does not become public. If an agreement is not reached, a DMHC attorney will file an administrative accusation.

In addition, stakeholders were advised to contact the executive officer if interested in presenting a

proposal to members during the April meeting.

For Committee Discussion
During this meeting members will have the opportunity to consider proposals from stakeholder as well as discuss the pre-filing conference model used by other agencies.

As members continue its discussion, it is suggested that the focus remain on the overall policy goal -- reducing costs and overall completion times. In addition, several policy questions should be considered including:

1. Is the proposed change consistent with the Board's consumer protection mandate?
2. Should the proposed change be limited to certain types of cases?
3. Would such changes provide the appropriate balance of consumer protection and due process?
4. Would such a change increase or decrease the time for case resolution?
5. What are potential impacts on cost is such changes were made.

Attachment 6 includes the current administrative case process flow chart.

XIII. Review and Discussion of Enforcement Statistics

Since July 1, the board received 1,601 complaints and has closed 1,777 investigations. The board has issued 186 Letters of Admonishment, 736 Citations and referred 133 cases to the Office of the Attorney General. The board has secured 11 interim suspension orders. Further, the board has revoked 55 licenses, accepted the disciplinary surrender of 62 licenses, denied 6 applications, and imposed other levels of discipline against 139 licensees and/or applicants.

As of April 1, 2021, the board has 1,324 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

- 73 cases under review for assignment, averaging 13 days
- 572 cases under investigation, averaging 210 days
- 172 investigations under supervisor review, averaging 60 days
- 68 investigations under second level review, averaging 56 days
- 439 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 34 days

Attachment 7 includes the quarterly enforcement statistics.

XIV. Future Committee Meeting Dates

- July 15, 2021
- October 20, 2021

Attachment 1

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT COMMITTEE
Draft MEETING MINUTES

DATE: January 20, 2021

LOCATION: Teleconference Public Committee Meeting
Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member Chair
Jig Patel, Licensee Member Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth Admin. & Regulations Manager

I. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 9:01 a.m. Dr. Serpa advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's Executive Order. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments.

A roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Albert Wong, and Maria Serpa. A quorum was established.

II. Public Comment on Items Not on the Agenda, Matters for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were offered.

III. Approval of October 27, 2020, Enforcement and Compounding Committee Minutes

Members were provided an opportunity to provide comments on the draft

minutes. Members noted the need to correct reference to CPhA.

Motion: Approve the October 27, 2020, Committee meeting minutes including the correction identified.

M/S: Lippe/Wong

Members of the pubic were provided an opportunity to provide comments; however, no comments were made.

Support: 5 Oppose: 0 Abstain: 0 Not Present: 1

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Not present
Wong	Yes

IV. Presentation on the Pharmacists Recovery Program

During the meeting members received a presentation on the provisions of the Pharmacists Recovery Program (PRP). The presentation can be viewed as part of the webcast of the meeting posted on the Board's website.

Members were advised that the program was established in statute to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The statute also provides that the intent of the program is to return pharmacists and interns to the practice of pharmacy in a manner that will not endanger the public health and safety. Consistent with the provisions of the statute, the Board contracts with a qualified vendor to administer the program. The current contractor is MAXIMUS, Inc.

The presentation was provided by Virginia Matthews, Project Manager, for Maximus, California Health Professionals Recovery Program. During the

presentation Ms. Matthews, provided an overview of the program, including other DCA programs also under contract with Maximus for services.

Ms. Matthews provided an overview of alcoholism and addiction as well as the signs, symptoms and impact of substance abuse in the workplace. Ms. Matthews discussed the risks for healthcare professionals, noting that because of accessibility to controlled substances, are especially susceptible to substance use disorder. Ms. Matthews provided an overview of the recovery program highlighting the two primary goals of the program include protection of the public and returning healthcare professionals to safe clinical practice, through intervention and rehabilitation. Ms. Matthews reviewed program eligibility requirements and contractual performance requirements as well as general provisions for participation, including criteria for returning to work and the transition phase prior to completion.

Member Veale joined the meeting around 9:30 a.m.

At the conclusion of the presentation, members of the public were provided with an opportunity to provide public comment.

A representative from the California Society of Health Systems Pharmacists (CSHP) suggested that the PRP should be opened to pharmacy technicians and encouraged a future agenda item to discuss the opportunity to make such a change.

No action was taken on this item.

The meeting was in recess from 10:20 a.m. – 10:30 a.m. Following the recess roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Maria Serpa. Albert Wong was not present during the roll call.

V. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines

Chair Serpa, lead the committee in resuming its discussion on the Committee's evaluation of the Board's disclosure policy for citations and fines. Dr. Serpa referenced information included in the materials, noting that in July 2018, the Board referred this matter back to the committee for further consideration.

Member Wong returned to the meeting at 10:33 a.m.

As part of its discussion, the committee considered several policy questions including discussion on the larger policy goal of the Board. Members noted that the Board's current policy goal is to provide transparency on disciplinary actions

and noted the difference between disciplinary actions and citations. The committee drew a distinction between the two noting that routine citations or fines that may come up during routine inspections or investigations of complaints do not merit discipline.

Members noted that the Board's current policy is consistent with its consumer protection mandate and ensures the public is aware of discipline, while also releasing citations in response to requests for information.

Members also expressed concern with a potential change to the policy that would require posting of citations on the Board's website, noting such a change could have a chilling effect and unintended consequences, including the potential inference that a citation is discipline.

Members of the public stated agreement with committee discussion noting that non-disciplinary action should not be posted and described some unintended consequences including a misunderstanding of what the action represents.

No action was taken by the committee.

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

During the meeting members reviewed proposed changes to self-assessment forms. Chairperson Serpa and members discussed the importance of the self-assessment process, which is intended to be an education and self-monitoring tool for licensees to evaluate for compliance. Members were reminded that failure to complete the self-assessment form is among the top 10 violations identified during a routine pharmacy inspection.

Members also discussed the self-assessment process and considered if changes would be beneficial. The committee suggested additional opportunities for education on the requirements to complete the self-assessment forms, including additional opportunities to remind licensees of the requirements. The committee determined that further discussion on the process appears is appropriate and suggested that such discussion would be appropriate under the purview of the Communication and Public Education Committee.

Members first considered the proposed changes to the Community Pharmacy/Hospital Out-Patient Self-assessment form 17M-13. The committee reviewed the changes.

Motion: Accept the updated self-assessment forms with corrections to typographical errors as necessary.

M/S: Veale/Lippe

The members were advised through public comment that self-assessment forms are used as an educational tool for student in pharmacy school.

Support:6 Oppose:0 Abstain:0

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

Members also considered proposed changes to the Community Pharmacy and Hospital Out-Patient Pharmacy Compounding Self-Assessment Form 17M-14. The committee reviewed the changes, noting that the recommendation includes a repeal and replace of the self-assessment form.

Motion: Recommend initiation of a rulemaking to amend section 1735.2 of California Code of Regulations to update the Community Pharmacy and Hospital Out-Patient Pharmacy Compounding Self-Assessment Form 17M-14.

M/S: Lippe/Veale

Public comment sought clarification on the provisions related to temperature requirements included in regulation section 1751.4(k). Staff indicated the referenced section would be reviewed and corrected, as appropriate.

Support:6 Oppose:0 Abstain:0

Committee Member	Vote
Lippe	Yes
Patel	Yes

Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

Members also considered proposed changes to the Hospital Pharmacy Self-Assessment form 17M-14. The committee reviewed the changes.

Motion: Accept the updated self-assessment form with corrections to typographical errors as necessary.

M/S: Veale/Lippe

Members of the public were provided with the opportunity to provide public comment; however, none were provided.

Support:6 Oppose:0 Abstain:0

Committee Member	**Vote**
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

The committee deferred its consideration of the changes to the Wholesaler Dangerous Drugs and Devices Self-Assessment and Automated Drug Delivery Systems Self-Assessment.

VII. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Chairperson Serpa referenced information in the meeting materials including history of the committee's discussion on this issue. Further, Dr. Serpa reminded

the committee of the presentation it received in July 2020, on the administrative case process. As was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. Dr. Serpa noted that Deputy Attorney General Jarvis included as part of the presentation that the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Dr. Serpa reminded members that more recently, during the October 2020 meeting, the committee continued its discussion on an Alternative Enforcement model but did not reach a conclusion. The committee determined that additional consideration of the overall policy goal and proposed solution would be appropriate.

Members noted the need to make a decision based on data as opposed to responding to anecdotal information. Further, members were reminded of counsel's previous guidance that a licensee seeking to challenge the factual matters or the application of law to the facts should use the process under the administrative procedure act.

It was also noted that an alternative process is not possible under current legislative authority. Counsel previously raised a number of concerns about the potential for a preliminary hearing, including evidentiary issues and open meeting act considerations previously contemplated. Additionally, concerns were identified with Board members participation in the settlement process.

Members also referenced educational materials under development including FAQs and a Flow Chart on the administrative case process that could be published on the Board's website and included in the mailings to assist respondents in understanding the process and their rights.

Members of the public were provided the opportunity to provide information on proposals for an alternative enforcement model.

Daniel Martinez, CPhA, provided information in advance of the meeting which was provided to members and posted on the Board's website. The proposal offered by CPhA included changes to a proposal previously considered, but not accepted by the committee.

The committee also received public comment from Joseph Gracela, who indicated that Board members need to participate in the process to have oversight and transparency.

The committee noted that the issue is complex. Members discussed what problem was being solved noting a challenge because the problems

articulated through public comment appeared subjective, not objective. The committee indicated that benchmarking with other agencies might be helpful. The committee also indicated that a presentation on the investigation process would be helpful.

Members requested staff return to the committee with recommendations that would not require legislative changes.

The committee did not take action on this item.

The meeting was in recess from 12:45 p.m. – 1:15 p.m. Following the recess roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Maria Serpa and Albert Wong.

VIII. <u>Discussion and Consideration of Discrepancies Between the State and Federal Controlled Substances and Its Impact on Healthcare Services.</u>

Chairperson Serpa noted that the meeting materials provided a history of the Board's recent policy discussion on the issue, including prior legislative efforts. Dr. Serpa indicated that as discrepancies remain between the state and federal schedules, it is appropriate for the Committee to consider whether additional efforts should be undertaken to synchronize or otherwise address the discrepancies.

The Committee considered policy questions that were also displayed during the meeting. Chairperson Serpa suggested it was important for four specific drugs to be considered noting that Fioricet, Donnatal, Librax and Chlordiazepoxide were all included in the state schedule but not scheduled under federal law.

Motion: Recommend to the full Board that California match the federal schedule for the 4 identified drugs – Fioricet, Donnatal, Librax and Chlordiazepoxide. This would require legislative authority.

M/S: Lippe/Veale

Dr. Gray, representing CSHP, was concerned with the motion because it did not solve the problem. Dr. Gray suggested as an alternative, the committee consider using the schedules for different purposes, the state schedule for criminal purposes and the federal schedule for patient care systems**.**

Support:6 Oppose:0 Abstain:0

Committee Member	Vote
Lippe	Yes
Patel	Yes
Sanchez	Yes
Serpa	Yes
Veale	Yes
Wong	Yes

IX. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drug Products.

Chairperson Serpa reminded the committee that in October 2020, the FDA finalized its draft Memorandum of Understanding (MOU), that established an agreement between the respective state authority and the FDA regarding the interstate distribution of inordinate amounts of compounded human drug products.

Dr. Serpa noted that the agreement establishes provisions for investigation of complaints relating to the compounded human drug products distributed outside of California, defines and establishes reporting requirements for the distribution of inordinate amounts of such products, and mandates the submission and disclosure of information. Dr. Serpa informed the committee members that they received the supplemental meeting materials that included comments on this agenda item.

Dr. Serpa stated that she believed this is a very complex issue which cannot be resolved in a single committee meeting. She noted that staff has identified some significant challenges with the MOU and that counsel evaluated the MOU for legal issues. In the meeting materials provided, she noted two states had already decided not to enter into the MOU, and several other jurisdictions were still undecided.

Dr. Serpa asked DCA Counsel Smiley to provide the committee with her assessment of the legal issues surrounding the MOU.

Ms. Smiley stated that she was still in the process of reviewing the MOU, but at this point of her review she had concerns regarding confidentiality. Ms. Smiley indicated that the Board could not sign the MOU currently because it did not

have the required reporting mechanism in place. Ms. Smiley informed the committee that the Board has until October 2021 to make the necessary changes.

During public comment Daniel Martinez, CPhA, provided his support for the Board signing the MOU. Three representatives from Nutrishare also expressed their support of the Board signing the FDA's MOU. Ms. Christy Poindexter, TPN consumer, expressed her support of the board signing the MOU.

Dr. Serpa acknowledged the time constraints and the need for further discussion. The committee directed board staff request the National Association of Boards of Pharmacy (NABP) to provide a presentation on the Information Sharing Program at the next committee meeting.

The committee did not take action on this item.

X. <u>Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry</u>

Chairperson Serpa informed Committee Members, this issue was discussed in depth during the October committee meeting. She stated, under the Food, Drug, and Cosmetic Act, a drug is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions.

Dr. Serpa referred members to Attachment 6 of the meeting materials that included a copy of the guidance document. As indicated in the guidance document, the FDA encourages states to take appropriate action and to contact the FDA when it identifies a compounding facility that is engaged in poor practices and/or where insanitary conditions are identified.

The Committee heard public comment from Rod Okamoto, Nutrishare, who spoke about the federal inspection process; Ronald McGuff, of McGuff Pharmaceuticals, who suggested that the relevant sections of USP could be used to define "pharmaceutical grade"; and Danny Martinez, of CPhA.

The committee did not take action on this item.

XI. <u>Discussion and Consideration of the Compounding of Methylcobalamin</u>

Chairperson Serpa reminded members of previous discussions surrounding the compounding of methylcobalamin including as part of previous Compounding Committee meetings regarding USP Standards and impacts to Board compounding regulations. Dr. Serpa specified during those meetings, the Board has consistently pointed patients to potential sources to obtain such products. Dr. Serpa also referenced, Attachment 7 of the meeting materials with included

an example FDA 483 report which documents observations of a facility using non-pharmaceutical grade Methylcobalamin to compound sterile product.

Dr. Serpa noted other provisions must also be considered, specifically the compounding of Methylcobalamin, including the conditions described as constituting insanitary conditions the Committee discussed in the prior agenda item.

Dr. Serpa stated her belief that the FDA's position on the issue appeared clear from the public information it released and noted that from a patient safety perspective, the Board needs to balance product access with product safety.

Dr. Serpa specified one of the primary challenges experienced by some compounding facilities, is the lack of pharmaceutical grade Methylcobalamin. Inappropriately graded materials can contain lead, arsenic, and other compounds which create risk to patients when used in sterile products. Long-term it would be beneficial for one or more manufacturers to either produce pharmaceutical grade bulk ingredients or seek approval from the FDA.

As part of the Committee discussion, Member Veale expressed her concern regarding quality of product being compounded at 503A compounding pharmacies. President Lippe inquired as to supply shortages of Methylcobalamin.

Dr. Serpa stated that she believed moving forward, staff should focus on educating licensees and exercise appropriate enforcement discretion.

The Committee heard public comment from several members of the licensed community as well as from private consumers.

Daniel Martinez, CPhA spoke against prohibiting pharmacies from producing Methylcobalamin. In relation to statements made, EO Sodergren offered to work with DCA counsel offline to confirm the state of affairs with respect to outsourcing facilities distributing in California.

Ms. VanNess, a parent of a child currently using Methylcobalamin, testified she fears neuropsychiatric deterioration consequences if her son is no longer able to obtain Methylcobalamin.

R. Israel, professional and general counsel of a compounding pharmacy, spoke against limiting ability of 503A pharmacies to compound sterile Methylcobalamin injections.

Dr. Becker spoke of his experience and success in using Methylcobalamin in functional psychiatry for the past 15 years. He warned of costs becoming prohibitive and inaccessible to patients.

Mr. Pham, McGuff Pharmacies, spoke to methods of screening incoming material for the level of elemental impurities; he stated these tools are not unique to 503B outsourcing facilities.

Dr. Ashby spoke to her patients' extensive experience of using injectables. She states it has become progressively more difficult to find pharmacies that are still producing them.

Ms. Gardner urged the Board to allow pharmacies to compound Methylcobalamin. Based on her own experience using Methylcobalamin shots, this medication prevents her from having to take 11 pain pills per day.

Dr. Holstead spoke about his experience working with autistic children and people with mixed connective tissue disease. He shared that 25 of his patients were successfully using Methylcobalamin but he can no longer get the concentration he needs because the one pharmacy he used has shut down due to regulatory restrictions. He is unable to find any pharmacies that will produce Methylcobalamin.

Dr. Osbourne spoke to the benefits of Methylcobalamin compounded by pharmacies. She explained that the benefit of compounding by pharmacies is that only the specific amount needed is produced. Additionally, she remarked that costs would increase exponentially if pharmacies were not allowed to compound.

Dr. McGuff, McGuff Pharmacies spoke to a pharmacy's ability to review pharmaceutical grade raw materials. He encouraged the Board to use the generated reports created by independent FDA registered laboratories as evidence whether a pharmacy is using a pharmaceutical ingredient.

Ms. Alexander, parent of child who uses Methylcobalamin and a patient herself, testified to the success of using the injectables. She and her child have both used the product successfully for five years with no side effects.

Ms. Robinson, parent of an autistic child who could not speak at the age of 5, stated the day after his first injectable dose of Methylcobalamin, her son was able to speak. Now 18, her son continues to need preservative-free shots, which she does not believe can be obtained from an outsourcing facility.

Jillian, parent of an autistic son testified her son was non-verbal until almost 4 years old. After he started compounded Methyl B12 injections he started making noises and by 4½ years old he was speaking basic sentences. Her son's cognitive awareness and overall health greatly improved as a result of the Methyl B12 injections. Jillian believes without compounded Methyl B12 her son's condition would regress and he would become low-functioning.

Ms. Fingerhood spoke about product testing and asked board to engage 503A pharmacies with additional end-product testing recommendations.

Dr. Koshland spoke about his difficulty in finding outsourcing facilities to serve his patients who compound B12. He testified, out of 29 outsourcing facilities he researched, he only found one who supplied B12 in limited strengths, for office use only and preservative free. He informed the committee in his experience there are no outsourcing that can meet the needs of many patients that have specific needs, such as preservative free or specific strength.

A representative speaking on behalf of the National Community Pharmacists Association urged the board to acknowledge the need to maintain patient specific compounding of Methylcobalamin through pharmacies. He urged the committee to not set an unsettling precedent for the rest of the country.

Member Patel left the meeting at 2:03 p.m. and returned at 2:51p.m.

Dr. Serpa indicated that moving forward staff should continue to educate and exercise appropriate enforcement discretion. She recommended staff should also continue to review information from the FDA.

Member Wong thanked the professional and patient community for their feedback.

XII. Review and Discussion of Enforcement Statistics

Members were directed to the enforcement statistics in the meeting materials.

Members of the public were provided with the opportunity to provide public comment; however, no comments were provided.

XIII. Future Committee Meeting Dates

Chairperson Serpa directed the members to the Chair Report for future meeting dates.

Additionally, Dr. Serpa announced proposed meeting dates for an informational meeting on White Bagging, to be held either February 18, 2021 or March 4, 2021. Members of the public were directed to contact Executive Officer Sodergren if interested in providing a presentation during the meeting.

XIV. Adjournment

Chairperson Serpa adjourned the meeting at 3:20 p.m.

Attachment 2

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

TELECONFERENCE ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING
INFORMATIONAL MEETING
DRAFT MEETING MINUTES

DATE:	February 18, 2021
LOCATION:	Teleconference Public Committee Meeting Note: Pursuant to the provisions of Governor Gavin Newsom's Executive Order N-27-20, dated March 27, 2020, neither a public location nor teleconference locations are provided.
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member Chair Jig Patel, Licensee Member Vice-Chair Ricardo Sanchez, Public Member Greg Lippe, Public Member Debbie Veale, Licensee Member Albert Wong, Licensee Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Executive Officer Lyle Matthews, Assistant Executive Officer Eileen Smiley, DCA Staff Counsel Sheila Tatayon, DCA Staff Counsel Debbie Damoth, Administration Manager

I. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 1:05 p.m. Dr. Serpa advised all individuals observing or participating in the meeting that the meeting was being conducted consistent with the provisions of Governor Newsom's executive order. Members of the public were provided with general instructions for the WebEx meeting and process to provide public comments.

A roll call was taken. Members present included Greg Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale, Albert Wong, and Maria Serpa. A quorum was established.

II. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda; however, none were offered.

III. Presentations and Discussions on "White Bagging"

Dr. Serpa advised the Committee it would hear presentations from various stakeholders on the practice of white bagging. She noted the meeting was publicized and identified stakeholders contacted to participate with the goal of receiving various perspectives on this practice to ensure education on the matter is comprehensive. Dr. Serpa thanked all of the presenters for their time as well as all of the stakeholders that provided written comments. She noted written comments received are posted on the Board's website.

Dr. Serpa provided background on the practice of white bagging. She noted much of the information provided is included in the information published by the National Association of Boards of Pharmacy (NABP) report on the practice. A link to this report was included on the agenda and in the announcements regarding the meeting. Dr. Serpa noted that "white bagging" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital or clinic for administration. It is often used in oncology practices to obtain costly injectable and infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.

Dr. Serpa advised members that the focus of the meeting was on white bagging but noted another practice called "brown bagging" which refers to the dispensing of a medication for a pharmacy directly to a patient, who then transports the medication to the physician's office.

Dr. Serpa noted the practice of white bagging has become more frequent as payors more robustly require the practice to reduce medication costs. The NABP report details out some benefits to the practice of white bagging, including the potential for a greater opportunity for pharmacists to use their expertise to improve patient outcomes as well as the opportunity for physicians to reduce costs associated with purchasing and stocking expensive medications. From the payer perspective, benefits include cost savings through negotiated dispensing rates and increased transparency.

Dr. Serpa added safety concerns have also been identified including the special handling that is required for many of these medications which can pose

safety, operational and unexpected financial burdens. Additional challenges may arise as specialty pharmacies may not have access to patient medical records as well as unpaid expenses resulting from coordination, storage and handling of patients' medications until the drug is administered. She noted the practice could present some challenges in instances where a change in dosage or strength of transition to a different class of medication is common. Additionally, the potential for delays in patient care resulting from troubling acquiring or receiving the appropriate medication can occur.

Dr. Serpa noted as included the NABP's report, it may be incumbent on the Board to determine who is accountable for verifying the authenticity and integrity of the drugs before administration as well as who would be responsible when a delay in therapy occurs. These may be questions we need to answer but suggested only considering these and other issues that may be identified today after the education portion has been completed.

California Department of Managed Health Care

Sarah Ream, Chief Counsel, Department of Managed Health Care (DMHC), addressed the committee to share DMHC's mission, role and responsibilities as the regulator of licensed health care plans in California under the Knox-Keene Health Care Service Plan Act of 1975 including full-service and specialized plans; commercial and Medi-Cal Managed Care Plans; and Medicare Advantage Plans (limited regulation). DMHC operates a Help Center to assist health care consumers receive services they are entitled to receive. Ms. Ream advised the DMHC does not regulate health insures licensed by CA Department of Insurance or self-insured employers; does not regulate providers including hospitals and pharmacies; does not require plans to contract with particular providers; or does not set provider reimbursement rates.

Ms. Ream reported most full-service plans cover medically necessary prescription drugs with cost-sharing allowed up to $250 for a 30-day supply in most instances. The DMHC receives and reports prescription drug coverage on information regarding health care costs associated with prescription drugs. Ms. Ream provide from 2017 to 2019, prescription drug costs paid by plans increased by $1 billion and accounted for 12.8 percent of total health plan premiums in 2019. She added the DMHC tracks costs and expenditures on prescription drugs.

Ms. Ream advised DMHC does not have the authority to prohibit white bagging or brown bagging provided the practice does not harm or impact enrollees' ability to receive medically necessary care.

California Association of Health Plans

Charles Bacchi, President and Chief Executive Officer, California Association of Health Plans(CAHP), provided his organization is a statewide trade association that represents 45 full-service health care plans who provide coverage to more than 26 million Californians. Mr. Bacchi advised most of CAHP's members provide coverage through the individual and group markets as well as partnering with the state for health care programs. CAHP also contracts with Medi-Care. Coverage is provided through the HMO model, PPO model, commercial health plans, public health plans (including county organized health systems and local initiatives), regional plans and fully integrated health care systems.

Mr. Bacchi added CAHP focuses on the affordability of health care coverage as health care costs increase and are an issue for everyone. He noted employers who hire CAHP to provide coverage to their employees including labor trusts and government payers are pressuring health care costs to be lowered and made more affordable for their budgets.

Mr. Bacchi advised majority of health care expenses goes for services such as hospital/doctor visits, prescription drugs, lab tests, x-rays, and medical supplies/equipment. He stated health care plans are regulated and must comply with transparency requirements for how premiums are set. Mr. Bacchi noted inpatient drug costs are substantial and plans have to cover the cost of medication and administration. Drugs that are administered to the patient by a provider at a site other than the patient's home such as clinics, hospitals, infusion sites or physicians' offices can cost significantly more which can be due to other charges or significant mark up for the cost of the drugs being acquired by the facility. Mark ups beyond the acquisition cost are sources of revenue for the facility and can be purchased at a lower cost while still being administered in a safe and efficacious manner.

Mr. Bacchi provided as health plan benefits have evolved, some have moved the drug portion of these inpatient costs to the drug portion of the plan which allows the plans to negotiate directly with the specialty pharmacies to acquire the drugs at the actual cost plus a minor dispensing fee resulting in a substantial reduction of costs (e.g., thousands of dollars per dose or per treatment) known as white bagging. Plans and insurers believe this has been done and can be done safely while not being a new practice. This model should have the same safety profile as a drug shipped by a wholesaler or distributor just purchased at a different point and price.

Mr. Bacchi advised there are known efforts by pharmacy boards and stakeholders across the nation to either limit or prevent the practice of white bagging. He stated it was important to note for the Board in considering any action that would limit or prevent the use of white bagging that it will not change the coverage for the drug as that is determined by the insurance policy that the plan purchased on behalf of enrollees. The costs for these medications will be increased to payers and will result in increased premiums as well as likelihood to increase costs to patients through premiums, enrollee cost sharing, or out-of-pocket costs. He added while many DMHC regulated products have relatively modest caps on out-of-pocket costs, there are other non-DMHC regulated products on the market that do have high co-pays or cost sharings so if the cost of the drug is marked up, the enrollee will have to pay more out of pocket to access the treatment. In some non-DMHC regulated plans, this could happen in self-insured models that could require the enrollee to pay up front for the prescription and seek reimbursement from the plan if the plan does not have a contract with the provider who is providing the service. When this happens, the higher drug costs can impact medication compliance due to lack of resources.

Mr. Bacchi stated this is a contract issue between plans and providers. Contracts can be developed that allow or do not allow this process with a perspective to provide the most effective way to deliver medications to enrollees to relieve the health care system from the burden of higher health care costs and protect enrollees' safety. He noted taking action that would impact this practice in California could have negative impacts and should be considered in deliberations.

Member Lippe inquired if the issue is the facility is adding a markup and white bagging wouldn't be needed if there was no markup. Mr. Bacchi responded if the price differential was the same, there would be less incentive for this to happen. As part of a strategy to lower health care costs, health plans are looking for ways to drive volume through their purchasing and negotiating a lower price.

California Medical Association

Yvonne Choong, Vice President, Center for Health Policy, California Medical Association (CMA) advised the committee that CMA represents more than 50,000 California physician and student members. She stated white bagging practice impacts many physician practices including oncology and rheumatology practices. Ms. Choong noted CMA has serious concerns regarding policies that require physicians to obtain medications administered in the office through specified pharmacies designated by the health care plan or

other entity. She reported mandatory white bagging negatively impacts patient care by creating delays in treatment that can impact patient safety; increasing out-of-pocket costs for patients; and possibly accelerating physician practice closures and consolidation by increasing costs if physicians have to pay for unreimbursed medications.

Ms. Choong provided background on how physician administered medications are managed outside of a white bagging requirement. Generally, physicians purchase the medication from a vendor and bills the payer for the medication with appropriate storage on site and available for all patients regardless of payer type. She stated immediate availability of medications allow the physicians to provide the appropriate treatment for patients and make medical decisions at the point of care based on the individual patient's health care needs. She noted white bagging changes this process by requiring the physician to order these medications in advance of patient treatment from specified pharmacies.

Ms. Choong added CMA's biggest concern is the impact on patient safety. She noted some medications are sensitive to temperature and light fluctuations as well as require special handling and storage to maintain efficacy. White bagging has the potential for serious adverse impacts on patient safety and delays in care. By removing control of the sourcing, storage, preparation and handling of specialty medications, physicians become at risk for exposing patients to potentially serious harm and increasing administrative burdens and liability risks to their practices. When medication for each individual patient needs to come from specialty pharmacies and is not part of the physician's on hand medication inventory, patient care is subject to delays in treatment that can be caused by delivery errors (e.g., incorrect medication is delivered, medication shipped to the wrong address, medication out of stock, etc.). Patients requiring these medications often have serious and debilitating chronic conditions (e.g., cancer, multiple sclerosis, etc.) where delays in treatment can be catastrophic to their care. Due to severity of conditions and complexity of treatment, drugs and doses must often be modified at the point of care based on patient specific conditions (e.g., weight, renal function, bone marrow function, lab test results, etc.). The inability to make changes at the point of care can result in treatment delays but this doesn't happen when medication supplies are managed by the physician's office.

Ms. Choong provided an example of a patient who was receiving treatment and had to spend hours on the phone with pharmacy representatives and complete online forms/questionnaires to ensure the already well-established treatment plan could be continued through the specialty pharmacy. Despite this additional work, the patient's treatment plan was delayed by two weeks. When a new treatment was prescribed by the patient's oncologist, the

physician followed the requisite procedure but patient care was delayed by a week. Some of the drugs had to be mixed but the specialty pharmacy was not able to supply these drugs or the pump required to infuse the medication.

Ms. Choong stated there are instances when the patient requires multiple drugs but the specialty pharmacy cannot fill all of the required drugs so that they have to be ordered from multiple vendors. If shipping of drugs is not coordinated, patient care is delayed.

Ms. Choong noted white bagging requirements can lead to increased medication waste, patient inconvenience and lost treatment time if the medication does not arrive in time for the scheduled appointment. While patient safety is the most concerning issue, there are other issues such as out-of-pocket costs for patients if patient co-pay assistance isn't provided by the specialty pharmacy. Additionally, this could lead to physician practices closing. If the physician is unaware of the requirement to use a specialty pharmacy, reimbursement to the physician may be denied if the physician used the wrong pharmacy and the cost must be absorbed by the physician. She noted in addition to increases costs due to COVID-19, implementing white bagging requirements accelerates the financial stress for independent and medium sized practices. CMA's concern is that a new wave of consolidation could be seen that could broadly increase health care costs and decrease patient access to care.

Thomas Semrad, MD, MAS, FACP, Medical Director of Clinical Research, Gene Upshaw Memorial Tahoe Forest Cancer Center, provided to the committee summary information on how white bagging has impacted his practice and care provided in his area. Dr. Semrad is a medical oncologist at a critical access hospital in Truckee, California, to provide treatment to cancer patients in the remote region. The closest infusion center is over 60 miles away.

Dr. Semrad advised his practice is known for high quality of care and being able to treat patients on the day of their scheduled appointment due to the distance many patients have to travel. He noted in the mountainous area of Truckee, delivery issues are frequently a problem due to weather. When a dose change is required, it is managed by having the appropriate stock on hand. The requirement of an insurance plan to use a specialty pharmacy providing a specific dose for a specific patient generates a huge cost and staff issue.

Dr. Semrad noted that drugs must be properly handled and stored. Pharmacists are asked to certify a product that has been pre-leveled for a patient from an outside source and wonders if that is acceptable. Additional and separate storage requirements, practice requirements, management protocols and preparation protocols are required for items involved in white bagging process.

He stated the concept of minimizing variation to minimize error is part of a quality assurance program but preparing the same drug from different settings does not minimize error. This results in additional liabilities to staff and safety risk to the patient.

Dr. Semrad noted delivery delays for oncological treatment could result in a patient's cancer worsening if there are delays and identified additional issues to include psychological well-being of the patient if treatment is delayed.

Dr. Semrad added white bagging is not providing the same type of care for every patient. Distributive justice isn't being achieved when patients subject to an insurance specific white bagging policy are treated under a different and arguably riskier protocol than those with different insurance.

California Hospital Association

BJ Bartleson, RN, MS, NEA-BC, Vice President, Nursing & Clinical Services, California Hospital Association (CHA), advised the committee CHA takes care of policy and advocacy for over 400 hospitals in California. CHA shares the concerns of white bagging related to affordability, patient safety, financial stress, operational burden and distributive justice.

Ms. Bartleson advised current policy used frequently by hospitals is called the "buy and bill" method where providers buy and store drugs for general use and bill payers for the doses used when the drug is administered to the patient. She stated white bagging; however, requires payers to reimburse third-party pharmacies which then distribute the medications to outpatient medical providers.

Ms. Bartleson provided a brief history of the introduction of white bagging from different payers as brought to the attention of CHA ranging from July – October 2020. She noted notification to the hospitals was inconsistent and delayed; in some cases, members notified CHA.

Ms. Bartleson advised patient safety and treatment delays include medication integrity, medication adjustment/timely delivery of medication, and preparation/labeling. She stated these guardrails are critical for patient safety. She noted impacts on hospital operations include strain on hospital systems, increased administrative burden, lack of compensation for unused medications, management of inventory of drugs for each patient, and threats to 340B Drug Pricing Programs for hospitals.

Ms. Bartleson provided a background on CHA's advocacy on the white bagging issue from June 2020 – January 2021.

Ms. Bartleson provided a comparison of the Board of Pharmacy regulations and conflict with white bagging procedures. She noted a few items to determine what possible solutions might exist. Specifically, she noted a conflict with Business and Professions Code section (BPC) 4024 with the definition of dispense that requires the furnishing of drugs or devices directly to a patient. When white bagging processes are used, the medications are marked as dispensed by the payer-designated pharmacy but not furnished directly to the patient. She continued BPC 4059 provides an exception for furnishing dangerous drug or devices by a manufacturer, wholesaler or pharmacy to each other but with white bagging medications are not sold between the designated payer specialty pharmacy and receiving health-system pharmacy. She noted BPC 4119.5 allows for the transfer or repackaging of dangerous drugs of a reasonable supply from one pharmacy to another. However, white bagging medications are patient specific and not considered reasonable supply. Ms. Bartleson referenced conflict with federal regulations, Drug Supply Chain Security Act (DSCSA), and CA Health and Safety Code.

Ms. Bartleson referred to the Massachusetts Health Policy Commission of 2017 and 2018 NABP Survey/Study as other advocacy efforts as documents to be used as reference documents. She highlighted the NABP Survey/Study that referenced while 28-31 percent of drugs nationally are supplied through white/brown bagging processes yet few states define the concept. The NABP Survey/Study also identified legitimate patient protection issues when a specialty drug is distributed to an entity other than the patient.

Ms. Bartleson noted Massachusetts and Ohio are focused on dispensing/redispensing prohibiting a pharmacist shall not redispense any medication that has been dispensed and has left the physical premise. New Jersey and Georgia are focused on other issues such as diverting patients and pharmacy benefit managers.

Ms. Bartleson reviewed recent advocacy from the American Hospital Association (AHA) to CMS in February 2021 noting white bagging practice should only be allowed where the provider and health plan agree through standard negotiations that it is in the best interest of the patient. Providers should be permitted to decline any such arrangements based on quality of care concerns.

Ms. Bartleson posed options for white bagging posing questions about consumer protection and in relation to current regulations with Board of Pharmacy assisting with comparing the process to the regulations.

California Children's Hospital Association

Grace Magedman, PharmD, DPLA, Executive Director of Pharmacy Services, Children's Hospital of Orange County (CHOC), and Shabnam Gaskari, PharmD, BCPPS, Executive Director and Chief Pharmacy Officer, Lucile Packard Children's Hospital Stanford, provided information on the risks and failure points that white bagging introduces from a pediatric perspective.

Dr. Gaskari reviewed the different models (e.g., buy and bill, white bagging, brown bagging and clear bagging) highlighting the process and the insurance benefit billed. She reviewed a historical perspective of white bagging as well as the process. Dr. Gaskari noted the introduction of an external pharmacy to the treatment plan adds an additional entity that can lead to greater risk.

Dr. Gaskari reviewed the problems with white bagging at different stages in the medication management process. At the prescribing stage, the risk/failure point is that pediatric patients can experience weight changes during the growth process that requires a change in dose or therapy. If the patient arrives for an infusion and the dose is no longer appropriate due to changes, the patient is unable to receive the infusion and there is a delay in therapy.

Dr. Gaskari provided at the distribution stage, the risk or failure point is the inability to verify the authenticity or integrity of the drug due to lack of supply chain oversight. She noted recall management is difficult when the pharmacist is not involved in the purchasing. The DSCSA is disrupted from this process when the pharmacist isn't buying the drug or supplying the drug. She further noted redispensing introduces the risk of contamination. Dr. Gaskari added some of the infusions are a lifetime chance for a patient like with gene therapy where there is one chance to get purity. If the drug is not stored and handled properly, the one lifetime chance could be lost.

Dr. Magedman added additional risks exist because external pharmacies do not have access to the patient's medical records and do not have the ability to provide comprehensive medication management especially during prescription verification. There is often a lack of pediatric expertise in specialty chronic conditions (e.g., metabolic deficiencies and oncology) which can lead to error. She had numerous stories where therapy was significantly delayed due to logistics (e.g., delayed deliveries, lost shipments, lack of coordination between drug receipt and scheduling, dispensed drugs expiring prior to scheduled appointment/procedure, etc.). These delays negatively impact patients and their families.

Dr. Magedman stated staff cannot be asked to compound drugs where authenticity and integrity can't be assessed. She noted possible incompatibilities with safety protections such as closed system transfer devices which require workarounds to accommodate. Dr. Magedman stated it is not acceptable to eliminate these protections for staff and patients.

Dr. Magedman advised at the administration point, when there are administration related reactions, chain of custody must be maintained to ensure contamination or adulteration was not a contributing factor. Pediatric patients require a special skill set of care such as IV placement in small veins or pediatric emergency response. She added when a patient is transferred to another facility because of payer restrictions and that facility is not equipped to serve pediatric patients, the patient's care and outcomes could be compromised.

Dr. Magedman advised at the point of patient education and monitoring, the providers take on the responsibility of medication education and administration. She stated external pharmacies can't monitor as effectively as health system pharmacies for adverse effects, adherence and patient outcome. Additionally, health system pharmacies have direct access to providers to communicate more effectively and efficiently. External pharmacies cannot perform any required safety monitoring or clearance prior to dose administration of certain specialty medications. She offered it is a risky practice to dispense without the ability to validate the medication for safe administration.

Dr. Magedman provided an example of a patient who was receiving a white bagged supplement implant for their precocious puberty. The patient was in the procedure and under anesthesia when the physician opened the delivered medication to find that the medication kit was defective. It wasn't acceptable to not complete the procedures so the institution had to provide their own product they fortunately had in inventory.

Dr. Magedman provided another example of a patient who experienced delays from a specialty pharmacy located 2,600 miles away from the patient. The patient experienced multiple rescheduled treatments and infusions that were eight weeks late. Patients and families experience disease progression, additional anxiety and lack of information about the coordination of their care.

Dr. Gaskari provided an example of a patient who was developmentally delayed with veins that were difficult to access. The patient was required to be transferred to another facility due to payer restrictions. The patient became so stressed that the facility was not able to access the veins for treatment and the patient had to be transferred to the emergency room.

Dr. Gaskari provided another example where the patient and parents were at the facility for a procedure but the facility had not received the medication from the specialty pharmacy. The patient's mother had to coordinate with the specialty pharmacy on the day of the procedure. She stated this is another worry for the patient and families who shouldn't have to be worried about receiving patient medication.

Dr. Magedman expressed concern that "brown bagging" may be viewed as a solution if white bagging is eliminated. She emphasized this is not an acceptable solution because it results in medications being left on porches, in hot cars or in food refrigerators where temperature can't be regulated. She stated "clear bagging" is not a solution.

Ms. Veale asked if dosing changes made so close to the scheduled infusion is common. Dr. Gaskari explained patients taking medications for irritable bowel symptoms experience weight changes due to nutrition. For patients who get infusions every month, the medication is dispensed three to four weeks in advance. At the doctor's visit prior to the infusion, if the weight has changed, a new drug or change of dose may be required. Ms. Veale inquired if it was common that medications are shipped three to four weeks before a procedure. Dr. Magedman added that depends on the specialty pharmacy and payer but typically the specialty pharmacy is not aware of when the procedure is scheduled. She noted medication could come a few weeks or days before the procedure or it may not come at all.

Ms. Veale inquired if there was little communication between the physician's office and the pharmacy. Dr. Magedman explained communication plays a part but there is also the prior authorization process that differs from payer to payer. She noted there is lack of communication during the authorization process to know if it has been denied or not. Health system pharmacists are better able to bridge the communication gap and advocate for the patient.

Ms. Veale asked if the prior authorization would still be required when specialty pharmacies are not being used. Dr. Gaskari provided pharmacists are better equipped to explain why the patient needs the drug therapy.

Ms. Veale inquired why there is a higher chance of fraud or contamination if coming from a remote pharmacy. Dr. Magedman clarified she said adulteration rather than fraud. She noted the ability of the pharmacists to detect contamination or assess for authenticity and integrity is around the DSCSA where the pharmacist is required to receive transaction history which can't be done when it comes from another pharmacy.

Ms. Veale inquired if the drug pedigree would have to transfer with the drug from pharmacy to pharmacy. Ms. Sodergren indicated the issue may be when the drug is considered to be dispensed and would have to be further researched.

The committee took a break from 2:44 p.m. to 2:50 p.m. Roll call was taken. Committee members present included: Gregory Lippe, Jignesh Patel, Ricardo Sanchez, Debbie Veale and Maria Serpa. A quorum was established. Albert Wong joined the meeting at 2:53 p.m.

Rita Shane, PharmD, FASHP, FCSHP, Vice President and Chief Pharmacy Officer, Professor of Medicine, Cedars Sinai Medical Center

Rita Shane, PharmD, FASHP, FCSHP, Vice President and Chief Pharmacy Officer, Professor of Medicine, Cedars Sinai Medical Center, reported the issue of drug cost has been an issue for many years and white bagging is a reaction to the high cost of drugs and exponential increase of drug costs. She expressed concern that white bagging is a band-aid approach to the high drug costs noting it is an unknown process to patients who are now caught in the middle.

Dr. Shane reported the integrity of the drug is something pharmacists are responsible for and storage requirements do matter. Even though drugs are coming from another pharmacy, it is unknown how the drugs were sourced or stored appropriately prior to being received for infusion.

Dr. Shane advised the redispenseing issue has been address in Massachusetts and Ohio. In New Jersey and Georgia, the issue is framed around removing the patients' freedom of choice. Patients are supposed to have choice and patients are not aware of the process and how it could be affecting their care.

Dr. Shane reported safety concerns from multiple entities. Specifically, the American Society of Clinical Oncology (ASCO) recommends against brown or white bagging. The National Comprehensive Cancer Network (NCCN) Specialty Pharmacy Task Force recommends standardization of communication methods with the health care team.

Dr. Shane advised there are 57 checks when working with chemotherapy developed over 30 years ago as a result of Boston Globe reporter Betsy Lehman dying of an overdose of chemotherapy. Since that time, efforts have been made in systems and providers to ensure safety of chemotherapy. The death of Ms. Lehman and another patient at the University of Chicago underscore the importance of all of the checks put into place to ensure safety of

chemotherapy. Having the drugs available is important so all 57 checks can be performed. Having patient specific-chemotherapy for patients disrupts and fragments care. Dr. Shane noted dose changes are required for many types of patients (e.g., chemotherapy, inflammatory bowel disease, rheumatology, and transplant) who have chronic diseases that are debilitating. If not treated appropriately, the patients will end up back in the hospital resulting in increased health care costs or a delay in therapy resulting in disease progression and or death.

Dr. Shane stated there is data to support that delay in chemotherapy does result in disease progression. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) recommends standardizing processes to prevent error-prone aspects of the medication use process.

Dr. Shane provided patient safety challenges not previously discussed by colleagues. She stated there have been more delays than drugs coming in advance. She noted patients have visits the day of or day before they are scheduled for their medications. Changes in weight, labs, or bio markers could change the amount of drugs needed. Transplant patients may need a drug immediately or risk rejection of the newly transported organ, emphasizing there are many patient-specific factors that necessitate just-in-time drug inventory. For patients at discharge, the patient may not be able to be discharged from the hospital without receiving the drug from the specialty pharmacy.

Dr. Shane addressed how orders are built into electronic health records. Systems are spending time and resources making sure they have electronic health records that build out complex drug therapies. Drugs used for chronic disease typically affect the immune system. Patients must be evaluated and checks put into place (e.g., labs, recent infections, recent drugs that could be a contraindication) before these drugs are given. The courses of therapy including number and frequency of drugs are all integrated in the electronic health record. When a specialty pharmacy is used, questions arises about if a physician must call in the order? The systems were built to prevent deaths from incomplete or inaccurate orders. Providers who are critical to the care of the patients shouldn't have to call in the orders or have to remember to call in the next order. Depending on the disease there is a different frequency required for administration of drugs.

Dr. Shane provided master formulas are required by law for compounding. If different strengths of drugs are received, a new master formula is required which will further delay treatment.

Dr. Shane referenced the Louisiana Board of Pharmacy (8/27/2020) Legislative Action Letter that cited patients previously approved to receive medication

benefit were now being denied and forced to receive medication under the prescription benefit outside their healthcare organization resulting in severely delayed and abandoned pursuit of treatment. According to the letter, the payers are not assisting with helping patients when issues arise.

Dr. Shane provided examples of impacted patients. A patient who had multiple sclerosis since 2015 needed additional induction with periodic treatment. Treatment from the specialty pharmacy was significantly delayed and the patient had to make arrangements to get treatment elsewhere. A patient with hepatocellular cancer had a prior authorization denied and patient was administered for disease progression. High cost drugs should not impact patients when they are the most vulnerable.

Ms. Veale inquired if a prior authorization was necessary for the second patient regardless of the pharmacy. Dr. Shane indicated with white bagging additional prior authorizations are built in. Ms. Veale stated it seemed like communication with a pharmacy outside of the facility was the issue. Dr. Shane provided for complex care and pediatric patients, it is a team approach with the physician entering the treatment plan with the pharmacist and nurse workflow. She stated adding another pharmacy makes the pharmacy function as a wholesaler. The only purpose is to reduce the cost of health care to the insurance at the expense of the patient.

Ms. Sodergren inquired about chemotherapy patients taking multiple medications and if a single specialty pharmacy would provide all the medications or if multiple specialty pharmacies involved. Dr. Shane provided some medications had to be bought and some came from a specialty pharmacy.

Ms. Veale asked if Dr. Shane's organization is accepting white bagging. Dr. Shane indicated her organization is not and are helping the patients get redirected to other entities for treatment.

California Society of Health-System Pharmacists

Steven Thompson, Director of Pharmacy, Torrance Memorial Medical Center, and former president of the California Society of Health-System Pharmacist (CHSP) addressed the committee on behalf of CSHP.

Dr. Thompson advised CSHP has similar views on white bagging as other presenters and noted an increasing trend of white bagging. He noted many

states are addressing this issue such as Louisiana, Ohio, Texas and Massachusetts as well as associations such as AHA addressing the issue with CMS.

Dr. Thompson advised members that Torrance Memorial does not allow white bagging for many reasons. He noted concerns violating the DSCSA. He added delays in delivery due to weather or traffic. Dr. Thompson noted challenges in entering medications into the electronic health record. He noted the inability to take advantage of the vetting of medication order sets through multiple departments making sure supportive orders (e.g., labs, dietary, medications, etc.) are included with the medication orders to ensure safety for the patient. He indicated the inability to use barcode scanning on medication that provides for additional levels of safety for the patient. Dr. Thompson also stated many times dosage changes are needed after precursory appointments and indicated external pharmacies do not have access to patient history or medical profiles. He added when a hospital doesn't allow white bagging, it drives the patient out of the system and then the system doesn't have a complete medical history. He stated it also impacts costs of drugs but the real focus is that the patient is put in the middle of the process and makes it difficult to take care of the patient.

Keck Medical Center of USC

Krist Azizian, Chief Pharmacy Officer and Chief Regional Oncology Officer, Keck Medicine USC, presented to the Committee on the reasons white bagging is an issue now indicated that as a result of cost of care, payers are rolling out cost of care initiatives and policy changes. He noted vertical integration has occurred within the payers, PBM and specialty pharmacies. There is also a transition from the medical benefits to the pharmacy benefits where the specialty pharmacy buys and bills for the drug and the hospital or provider only bills for the administration. This adds another layer and is confusing to the patients and providers. Coordination is shifted to the providers and health systems. Providers should be taking care of patients and not focused on administrative coordination efforts. There is also impact to patient care and safety.

Dr. Azizian noted for the pharmacist and pharmacy teams there are major conflicts with regulatory requirements. He stated there were about eight regulatory/statutory and Joint Commission requirements that white bagging has a conflict with around procurement, storage and preparation of the medication. Shipment loss and delays will result in postponement of life saving therapies and increased waste. When examinations or laboratory results are required on the day of or day prior to infusion, the provider may need to change dose based on weight, delay or cancel dose or change regimen and the medication is wasted.

Dr. Azizian stated external pharmacies do not have the same capabilities to provide the same level of medication surveillance and safeguards, nor access to clinical information for the patient. Dr. Azizian noted DSCSA requires action on recalled products indicating without the appropriate pedigree information makes it difficult to act on recalled products.

Dr. Azizian provided examples of patient impact due to payer mandated white bagging including a patient with brain cancer and melanoma who had a one-week gap in treatment, a patient with colon and liver cancer who had a physician change treatment from infusion to oral therapy to avoid gaps in care. Further, Dr. Azizian highlighted a patient with neuroendocrine tumor had a two-month gap in treatment due to the patient's inability to afford their share of cost as a result of the conversion from medical benefit to pharmacy benefit due to payer mandate. A patient with liposarcoma was pending hospital discharge after a chemotherapy treatment was unable to receive medication from a mandated specialty pharmacy causing delays in discharge. In this case, the prescription was sent two-three weeks prior to discharge.

Dr. Azizian stated USC has a strict policy prohibiting white or brown bagging as they are not able to meet federal and state regulatory requirements. Letters are sent to patients with an option to file a complaint with DMHC. Coordination is required to educate providers because of the unilateral decision by payers.

Dr. Azizian requested the Board to advocate for patients, evaluate the public safety risk and take action. He suggested reviewing and revising regulations to prohibit unilateral mandated white bagging policies and to prohibit unilateral exclusion of health-system owned specialty pharmacies from payer network. If outside of the Board's jurisdiction, advocate and collaborate stakeholders for patients and provide guidance to profession on how to handle white bagging.

Ms. Veale asked for an explanation of what happens when medication coverage is switched from the medical benefit to the pharmacy benefit portion of insurance. Dr. Azizian explained the patient may have a high share of cost or be in a doughnut hole. In the example provided, the patient couldn't afford their share of cost and they were unsuccessful in finding price reduction plans so the patient decided to wait to continue treatment until the beginning of the new year when insurance could be changed. When the medical benefit is being used, the pharmacy on the facility site can be accessed but when the pharmacy benefit is being used, the specialty pharmacy has to be used with a different co-pay structure.

Ms. Veale inquired if Board regulations would allow redispenseing. Ms. Sodergren stated time would be needed to work with counsel. She noted Ohio is

prohibiting the redispenseing of a previously dispensed medication whereas Massachusetts is taking a different approach.

PIH Health

Diane McGowan, PharmD, BCSCP, Director of Pharmacy, PIH Health Whittier – Hospital, addressed the committee as a hospital run infusion center with drugs purchased through the hospital pharmacy.

Dr. McGowan advised there was no notification of the change in policies as white bagging just started occurring. She noted in addition to other regulation conflicts with white bagging, CCR 1735.3 (b) and (c) requires the pharmacy maintain records for the proper acquisition, storage and destruction of chemical drug products used in compounding. When received from a secondary source, they are unable to achieve the regulation.

Dr. McGowan commented standardization of delivery has been challenging as specialty pharmacies do not seem to know what to do. Some are calling patients asking if medications are needed, instructing the patients to pick up the medications, sending medication directly to the physician's office or delivering the medication to a desk at the front of the hospital. USP 800 requires many steps to receive hazardous drugs that are not being followed (e.g., wear chemotherapy rated gloves, drugs sealed in impermeable bags, receive in neutral air flow zones with a chemotherapy spill kit ready). Chain of custody of drugs are not reliable.

Dr. McGowan stated it has impacted the standard of care for patients. The lack of standardization allows for possible errors in the compounding process if the drugs are received in different concentration amounts. She reported eight patients who experienced delayed care because the drugs did not come in time.

Dr. McGowan noted with a small chemotherapy negative pressure room, there is not enough room to store each patients' medication. She commented with the electronic health record, these are added as a nonformulary drug which does not include checks for dose range, allergy, duplicate drug and the ability to have standardized order sets are lost as well as bar coding upon administration.

Dr. McGowan stated this is a variation from the prescription in violation of CCR section 1716. The physicians are writing an order for an IV administrable drug to be given to a patient over a certain amount of time. The specialty pharmacies

are deviating from the prescription when provided as vials to another pharmacy.

Dr. McGowan reported white bagging is not accepted at PIH Health Whittier – Hospital due to patient safety concerns; it is impacting the members. Some patients received their last dose while others decided to not receive their last dose. She requested the Board support current regulations that make white bagging illegal.

Chairperson Serpa advised the Committee public comment submitted can be found on the Board's website for public review.

The Committee took a break from 3:49 p.m. to 3:55 p.m. Roll call was taken. Members present included Greg Lippe, Jignesh Patel, Debbie Veale, Albert Wong and Maria Serpa. A quorum was established. Dr. Wong confirmed attendance after the last roll call.

Public Comment

Vu Phan, oncologist physician, highlighted a patient who had no issues with the new procedure but experienced a three-week delay in their treatment plan. Dr. Phan contrasted that experience to another patient who only received half of the medication and the practice had to supplement the medication with the risk of not being reimbursed. Dr. Phan provided a third patient who experienced a three-week delay and was so frustrated she paid for her own medication. A fourth patient couldn't afford the medication because it was run through the pharmacy benefit and not the medical benefit. Dr. Phan stated white bagging should be criminalized.

Becky Natali commented many HMOs are doing white bagging to reduce costs. Ms. Natali stated white bagging presents logistical issues, safety risks and delays in therapy due to the bifurcated system. She provided examples of patients arriving for treatment but the medication has not arrived. She stated it shouldn't be a pharmacy benefit because the patient cannot administer the medication that requires compounding and the provider is required to hold the medications. White bagging results in a lot of pharmaceutical waste and allows for fraud where the medication can end up in different channels.

Melissa Chase, Director of Pharmacy, Valley Children's Hospital, commented she has similar experiences with white bagging. Due to the limited access in the central valley of California, Valley Children's Hospital allows white bagging and has had to deal with the abrupt changes in policy. Ms. Chase provide written comment about a patient with Crohn's disease who had prior authorizations denied for Remicade but was able to get it approved through buy and bill for

two doses. After the second dose and weeks of delay, the second prior authorization was approved but the insurance required it be white bagged. Additional weeks went by as the specialty pharmacy was working on getting similar authorization. The specialty pharmacy was over 2,600 miles away from the hospital. The patient was able to receive great care initially but the implementation of the required white bagging by the insurance significantly delayed subsequent treatment.

Warren Fong, oncologist physician, representing the Medical Oncology Association of Southern California, commented the number of medication errors increase with the more people involved in the process. Dr. Fong stated the risk of contamination increases with time. He added another problem is centralization of prescription preparation increases the impact of error. He recalled the New England Compounding Center affected 14,000 doses in 23 states where 800 people became ill and over 100 people died. This does not happen then things are done locally. In Mississippi, a compounding pharmacist reduced the dose of Taxol to increase profit affecting thousands of people. Dr. Fong added when chemotherapy is provided, typically, it is provided with pre-medications and/or several chemotherapy drugs. If one medication is missing, the treatment can't be provided. He added oncology practices are in financial trouble and are closing because of this process. When chemotherapy is received, specialized equipment and nurses are needed that represent uncompensated costs when medications are received through the white bagging process. He added while this saves the insurance costs through vertical integration, the costs incurred by the providers is not represented.

Chad Morton provided a comment through the chat feature. Counsel Smiley provided it was allowable to read the comment to the record because of his audio issues. Dr. Serpa read his comment into the record, "How do we accommodate compassionate use medications that often times don't come directly from the manufacturer but from a vendor pharmacy?" Dr. Serpa indicated the question was not related to white bagging and encouraged him to contact via telephone to clarify his question.

Mark Johnston, CVS, commented white bagging has been in existence for decades and is not a new issue. He stated pharmacies, prescribers and hospitals have worked together without regulations to increase communication, modify policy and change operations to make white bagging work for the benefit of patients. He stated the accounts today are initial reactions to third-party changes. Medications from specialty pharmacies are considered dispensed. He stated CVS Specialty shipping pack out is much more scientific than the package utilized by the manufacturer shipping to wholesaler or the wholesaler shipping to the hospital or clinic. He stated cost, profitability and/or third-party billing is not within the jurisdiction of the Board. White bagging begins with

pharmaceutical manufacturering contract which is not within the Board's statutory authority. He stated the definition of the word dispensed is being twisted. He encouraged the Board and attorneys to assess board law relevance indicating President Lippe verified if hospitals accepted the same reimbursement, specialty pharmacy would not be needed. Third-party billing does cause delays but all parties try to prevent delays from happening. Removing costs from the discussion, he believes it can be resolved with increased communication and modification of inflexible operations.

Mr. Lippe clarified he asked a question if the facilities didn't mark up the drugs, would that take away the need for white bagging? He stated he wasn't endorsing any point of view for or against white bagging.

Sam Martinez commented on the Board's website the says it promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care. He stated we all agree this is not the highest quality of care with white bagging.

Dawn Holcombe, Medical Oncology Association of Southern California, stated members include hospitals and health care systems of all sizes as well as private medical groups and practices who provide cancer services. She noted additional information will be submitted for the record. Ms. Holcombe noted white bagging is not common place upon the county and if forced is in violation of California law – Health and Safety Code, Article 5, Standards 1367.22 (c) which requires plans purchase services in a manner providing continuity of care and demonstrate medical decision are made by qualified medical providers unhindered by fiscal or administrative management. White bagging puts both the providers and patients at risk and endangers patients. It creates added waste and violates California patient steering laws – Health and Safety Code, Division 1, Administration of Public Health 135 to 1179.102, part 1.9, Medical Referral Services 334-445.

Chad Morton commented a similar process exists for compassionate drug where patients are able to get essentially get free drugs from a manufacturer and it is sent to an infusion pharmacy as well. The process is used when a patient can't afford their medication and only available to private pay insurance patients and not Medicare or Medi-Cal patients.

Dr. Serpa thanked everyone for participation in the meeting today. She stated there certainly are issues with patient access to specialty medication and safety. She continued the issues between payers and providers are complex and noted considerations for opportunities available for the Board to address. She reported the committee will be providing a summary of this informational meeting as part

of the Board's April 29-30, 2021 meeting. She noted following the meeting, any addition activity by the Board will be announced.

IV. Adjournment

Chairperson Serpa adjourned the meeting at 4:26 p.m.

Attachment 3

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Preparing for FDA's Compounding MOU

Melissa Madigan, PharmD, JD
National Association of Boards of Pharmacy
Associate Executive Director, Professional Affairs

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FDA's Compounding MOU Has Raised Questions Among Boards of Pharmacy

- What information will boards be required to collect and share with FDA?
- What mechanism will be used to collect, manage, and share information?
- What IT and personnel resources will be needed?
- Do "prescription orders" include new and refill prescription orders?
- Does the MOU apply to nuclear pharmacies?
- When does the "receipt of a complaint" by a board occur when there is an umbrella agency receiving complaints that board is not aware of right away?
- If a state is prohibited from reporting complaints under investigation, how can that state comply with the MOU?

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Additional Questions:

- If a state prohibits disclosure of a complainant's name, how can the board comply with the MOU?
- Regarding submission of complaint information, should the board include PHI, such as patient names or other identifiers? Or should PHI be redacted?
- The MOU's mandate to investigate complaints of adverse drug experiences and product quality issues related to compounded products may be interpreted to remove the state's discretion to determine if a complaint warrants investigation. Is this the case?
- How does a state handle a prescribing compounder who is distributing compounded drugs interstate?

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Additional Questions:

- What will FDA do with submitted information?
- When it comes to state investigations, can states leverage any FDA resources?
- What happens if a state doesn't comply with the MOU?
- Will FDA delay enforcement of the 5% rule due to COVID?
- What resources will the board need to expend to comply with the MOU?

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What Will Boards that Sign the MOU need to do?

- Investigate certain compounding pharmacy complaints
- Report certain compounding pharmacy and compounding physician complaints to FDA
- Report certain information about compounding physician offices
- Identify and report to FDA certain compounding pharmacy data

How will NABP's Information Sharing Network help?

- Provide a tool for states to report complaint information to FDA
- Provide a tool for states to review compounding pharmacy data and, if needed, report it to FDA

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What Specific Information Do Boards Need to Report?

- **Pharmacies** that are compounding human drug products **and distributing inordinate amounts interstate***, including their compounding data
- Complaints of **serious adverse experiences or quality issues** relating to human drug products **compounded by pharmacies and distributed interstate**
- Complaints of **adverse experiences or quality issues** relating to human drug products **compounded by a physician and distributed interstate**
- **Information relating to the distribution interstate of any amount** of human drug products **compounded by physicians**

*The distribution of inordinate amounts interstate is a threshold for the board of pharmacy to identify and report certain information to FDA, not a limit on the distribution of compounded products interstate.

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Regarding “Inordinate Amounts:”

- Boards will determine if a pharmacy is compounding inordinate amounts using either:

  surveys, or
  reviews of records during inspections, or
  information-sharing network (NABP’s system), or
  other available mechanisms

- The MOU does not require the board to input compounding pharmacy data into the information-sharing network.
- The MOU allows the board to meet its obligation to determine compounding of inordinate amounts solely through use of the information-sharing network.

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NABP Develops System for Collecting and Sharing Information Specified in the MOU

- The information-sharing network is being developed using a grant provided by FDA to NABP
  - Grant is for a pilot project to build a network and evaluate its accuracy and usefulness
- FDA recognized there is no centralized system to collect and share data from compounding pharmacies distributing interstate, and thus the grant was established
- FDA agrees the network will be a key to assisting boards in their efforts to comply with the MOU, understanding the lack of board resources
- FDA is eager to partner with NABP and boards to protect patients from high-risk compounders

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How is NABP Building the New Information Sharing System?

- NABP is adapting its existing NABP e-Profile Connect data management system to meet the needs of the new information-sharing network
  - To enable the collection, management, and sharing of information pertaining to compounders
- e-Profile Connect provides state boards of pharmacy with information on each individual pharmacist, technician, student/intern, and facility in the system

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System Will Provide New Capabilities for Boards of Pharmacy

- Expands current e-Profile Connect system
- Adds data fields outlined in the MOU to the pharmacy facility profiles found in the e-Profile Connect system
- Allows both boards and pharmacies to enter data
- Boards will be able to review information provided by licensees and upload documents, including complaints and inspection forms

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System Will Flag Compounding Pharmacy Data for States and FDA

- The system will notify boards about pharmacies whose submitted data show that they are distributing inordinate amounts of compounded human drugs interstate
- The system will require boards of pharmacy to review and approve the submission of such data to FDA prior to it being transmitted

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What Information Will Be Collected From Pharmacies?

Regarding the distribution or dispensing of compounded human drug products, the system will collect the following information from the pharmacy for an identified calendar year:

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities:
    - Human drug compounding – sterile
    - Human drug compounding – nonsterile
    - Patient-specific compounding
    - Non-patient-specific compounding

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If a Pharmacy Is Compounding Sterile or Nonsterile Human Drug Products, the Following Information Will Also Be Collected or Calculated:

- Number of prescription orders for compounded drugs the pharmacy sent out (or caused to be sent out) of the facility (in state or out-of-state)
- Number of prescription orders for compounded drugs dispensed (e.g., picked up by the patient) at the facility
- Total number of prescription orders for compounded drugs sent out of or dispensed at the facility*
- Total number of prescription orders for compounded drugs distributed interstate
- Percentage of compounded drugs distributed interstate*

*Calculated by the system

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Also to Be Collected:

- Number of prescription orders for sterile compounded drugs distributed interstate
- Names of states in which pharmacy is licensed
- Names of states into which pharmacy distributed compounded drugs during the year
- Whether compounded drugs are distributed without patient-specific prescriptions

If the board has the compounding pharmacy data referenced here, the board will be able enter it into the facility's e-profile.

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Notifying FDA of Inordinate Amounts – What Information and When?

Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drugs interstate during the identified calendar year, and upon approval by the board, the system will provide FDA with the following information about such pharmacies:

1. Name and address of the pharmacy
2. The number of prescription orders for compounded human drugs that the pharmacy sent out of (or caused to be sent out of) the facility in which the drugs were compounded
3. The number of prescription orders for compounded human drugs that were dispensed (e.g. picked up by the patient) at the facility in which they were compounded

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Notifying FDA of Inordinate Amounts – What Information and When?

4. The total number of prescription orders for compounded human drugs distributed interstate
5. The total number of prescription orders for sterile compounded human drugs distributed interstate
6. The names of the states in which the pharmacy is licensed
7. The names of the states in which the pharmacy distributed compounded human drugs
8. Whether the board inspected for and found during its most recent inspection that the pharmacy distributed compounded human drugs without valid prescription orders for individually identified patients

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Notifying FDA of Pharmacy Complaints – What Information?

Regarding complaints involving a serious adverse drug experience or serious product quality issue related to human drug products compounded by a pharmacy and distributed outside the state, the board will enter into the system the following:

1. Name and contact information of the complainant, if available
2. Name and address of pharmacy that is the subject of complaint
3. Description of complaint, including description of any compounded human drug product that is the subject of complaint
4. The board's assessment of whether the complaint was substantiated, if available
5. Description of any actions the board has taken to address the complaint

The board will also be able to upload a copy of the complaint or other relevant documents.

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Notifying FDA of Pharmacy Complaints – When?

Transmission of complaint information from system to FDA:

- As soon as possible after, but no later than five business days after receiving the complaint, and upon approval by the board, the system will provide FDA with the information found in items 1 – 3.
- After the board concludes its investigation of the compliant, and upon approval by the board, the system will provide FDA with the information found in items 4 – 5.

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Notifying FDA of Complaints and Notifications about Physicians – What Information?

Regarding complaints involving an adverse drug experience or product quality issue related to human drug products compounded by a physician, or regarding the distribution of any amount of human drug products compounded by a physician and distributed outside a state, the board will enter the following information, if available, into the system:

1. Name and contact information of the complainant or notifier
2. Name and address of the physician who is the subject of the complaint or notification
3. A description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

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Notifying FDA of Complaints and Notifications about Physicians – When?

Transmission of Physician Complaint Information from system to FDA:

- Regarding complaints against physicians, as soon as possible but no later than five business days after receiving the complaint, and upon approval by the board, the system will transmit such complaint to FDA. In addition, the board must notify the state regulator of physicians.

Transmission of Physician Notification Information from system to FDA:

- Regarding the distribution of any amount of compounded products interstate by a physician, within 30 business days of identification of such physician, and upon approval by the board, the system will transmit this information to FDA. In addition, the board must notify the state regulator of physicians.

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Collection of Data From Pharmacies Will Be Through Two Pathways

1. Pharmacy accreditation program applications (*except* for the DMEPOS program) and the VPP inspection application. The pharmacy will pay the regular accreditation or inspection application fee.
2. The pharmacy e-profile. New data fields are being added to pharmacy e-profiles. The pharmacy will set up an e-profile or access its already-established e-profile, then insert the data. There is no charge for this.

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How will NABP Encourage Pharmacies to Provide Requested Information?

- During the pilot project, all pharmacies submitting the requested data will have the opportunity to receive a VPP inspection at no cost to them.
- If a pharmacy pays for a VPP inspection or accreditation application and is selected to be surveyed under the pilot project, the cost of the survey will be refunded.

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Feedback from Boards

- Vast majority of boards are in the process of determining whether to sign the MOU.
- So far:
  - One state has signed the MOU
  - Seven have said they will sign the MOU pending some other needed action.
  - Eight states have said they cannot or will not sign the MOU, five due to technical or legal issues with the document. FDA would like to work with states that have expressed technical or legal issues.
- Some boards have said they do currently require pharmacies to submit this data to their own systems or are considering requiring pharmacies to report data to the system.
- NABP is in conversations with several boards about sharing compounding pharmacy data they already collect.

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Feedback from Profession

- NABP is working with pharmacy groups to help inform members about the MOU and the Information Sharing Network
  - Alliance for Pharmacy Compounding
  - National Home Infusion Association
  - PCCA

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Informational Resources

NABP's new website has a page dedicated to this project

- Background and details on the project
- Link to MOU
- FAQs
- Map of state MOU decisions
- Slide deck

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Thank You!

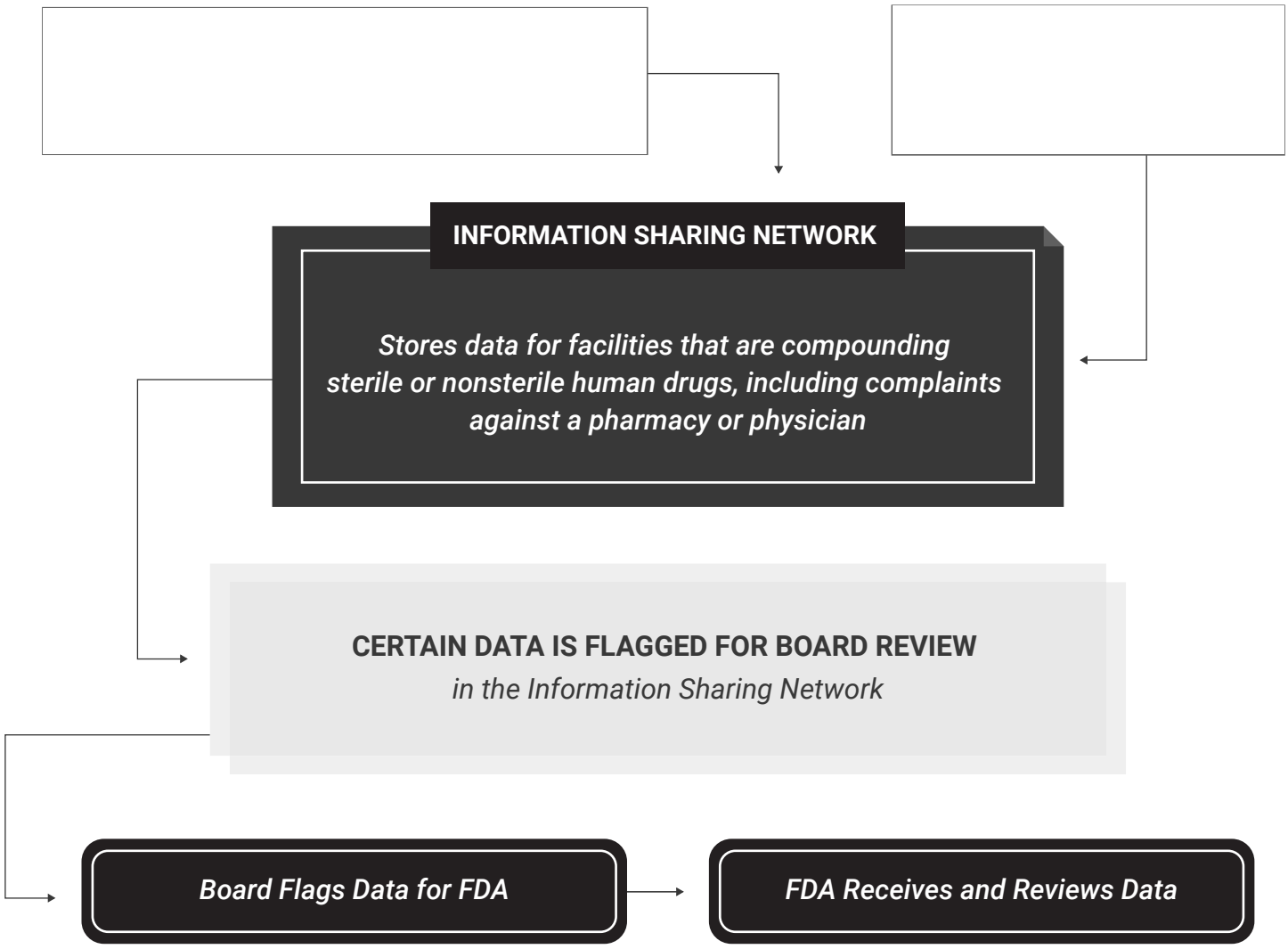
Collect and Share Compounding Data With NABP's Information Sharing Network

NABP's Information Sharing Network helps state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA). Access to the network is free and allows your board to meet the obligations outlined in the memorandum of understanding (MOU) on compounded human drug products.

PATHWAYS FOR DATA ENTRY

& the flow of data through NABP e-Profile Connect

Developed as an expansion of NABP e-Profile Connect, the Information Sharing Network will be available for boards of pharmacy to begin entering data in early 2021.



Visit *www.nabp.pharmacy/Compounding-Project* for more information on how the Information Sharing Network works or to access the FDA MOU.

Data Collected

The Information Sharing Network collects the following pharmacy and complaint data.

General Pharmacy Information – Entered by the Pharmacy or the Board

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
  - Human drug compounding — sterile or nonsterile
  - Patient-specific or non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, additional data is collected related to licensing, prescription orders, and distribution numbers

Complaint Information – Entered by the Board

Complaints of adverse drug experiences or product quality issues relating to human drug products that are compounded by a physician and distributed interstate are also entered by the board. Data collected includes:

- Name and contact information of the complainant or notifier
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

Complaints of adverse drug experiences, product quality issues, or distribution of human drug products that are compounded by a physician are also entered by the board.

For a complete list of data collected in the Information Sharing Network, visit ***www.nabp.pharmacy/Compounding-Project.***

Data for Board Review

The Information Sharing Network flags data for the boards of pharmacy to review based on certain criteria.

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate.
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate.

By logging in to e-Profile Connect, the boards can review and submit the information to FDA with the click of a button.

Sending Data to FDA

Boards must submit the required information to FDA in accordance with the timelines outlined in the MOU, which can be as little as five days depending on the type of complaint.

A list of the data transmitted to FDA and the associated timelines can be found at *www.nabp.pharmacy/Compounding-Project.*

NABP National Association of Boards of Pharmacy

Main Menu

Attention: NABP's e-Profile system will be unavailable due to system maintenance from 7-8 PM CDT on Wednesday, March 24, 2021. Thank you for your patience.

FDA Compounding MOU Project

Compounding Pharmacy Information Sharing Project

The Compounding Pharmacy Information Sharing Project was created in partnership with FDA to improve data sharing related to compounding pharmacies as outlined in the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU).

As part of this project, NABP developed the Information Sharing Network to help state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA) and meet the obligations of the MOU.

Understanding the MOU

FDA worked with NABP to develop a standard MOU for use by the state boards of pharmacy to aid with their compliance of section 503A(b)(3)(B)(i) of the Food, Drug and Cosmetic Act. As part of the MOU, boards must identify pharmacies that are compounding human drug products and distributing inordinate amounts of such products interstate and report those pharmacies to FDA. Boards can use the Information Sharing Network, accessible via e-Profile Connect, to meet the obligations outlined in the FDA MOU on compounded human drug products.

Learn more about the MOU and data collection for the project:

- Read the Compounding Pharmacy Information Sharing FAQs.
- Download our slide deck for details on preparing for the FDA MOU.
- Download the information sheet for a breakdown of the process for data entry and data flow through the Information Sharing Network.
- Contact prof-affairs@nabp.pharmacy if you have any additional

For more information about how the MOU can better position your board to address patient safety and improve communication between FDA and all boards of pharmacy, watch the recent webinar, *Preparing for FDA's Compounding MOU*.

Sign the FDA MOU

Meet MOU Obligations with the Information Sharing Network

Our Information Sharing Network makes it easy to report and review data about pharmacies compounding sterile or nonsterile human drugs, as well as complaints against a pharmacy or physician.

While signing the MOU does not require boards to enter data into the network, boards are encouraged to use the Information Sharing Network to create a uniform and streamlined reporting process with FDA. Boards can rely exclusively on the data reported through the network and easily transmit data to FDA electronically.

Easy Access to Data

All boards can access data in the Information Sharing Network by logging in to NABP e-Profile Connect.

Reduced Administration Burden

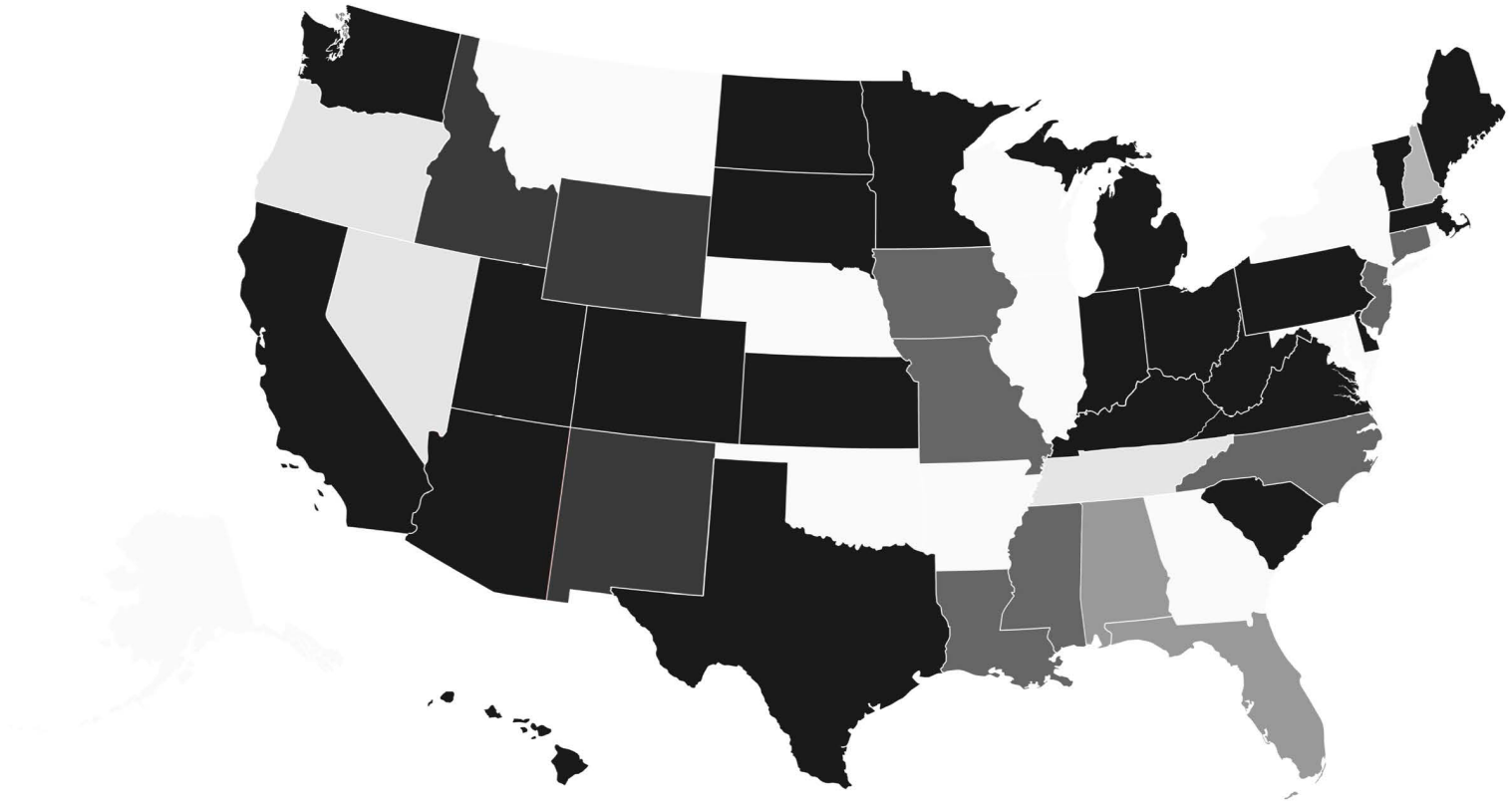
Compounding data is collected in the facility e-Profile, and will soon be collected on certain accreditation and the VPP application, and appears automatically in the system for board review, helping to reduce the amount of data entry required by the boards.

Simple Submission Process

Boards can review and submit data to FDA with the click of a button.

The Information Sharing Network is hosted in NABP e-Profile Connect, which has been expanded to accommodate the collection of compounding pharmacy data. Data in the system is accessible to all boards, even if they have not signed the MOU.

MOU PARTICIPATION



Yes | Yes, Pending Additional Action | Considering Signing

No | No, Due to Legal or Technical Reasons | No, Due to Legal or Technical Reasons. Considering Regulation

April 7, 2021

Attachment 4

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

    1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

[3] To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

(i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

(ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

facility in which they were compounded during that same calendar year.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information
    1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

        a. Complaints:

            i. Name and contact information of the complainant, if available;

            ii. Name and address of the pharmacy that is the subject of the complaint;

            iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

            iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

            v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

        b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

   a. Name and contact information of the complainant or notifier;

   b. Name and address of the physician that is the subject of the complaint or notification; and

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only "in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed" by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

[9] The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs: Questions and Answers

FDA is working to respond to questions from states regarding the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (/media/143283/download) between state boards of pharmacy or other state agencies and FDA. This web page will be updated as we receive additional questions. Please email questions to compounding@fda.hhs.gov (mailto:compounding@fda.hhs.gov).

1. **Will states have an opportunity to negotiate the language of the MOU?**

   No. FDA has made the standard MOU available for signature. Section 503A of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for use by states. Developing individualized MOUs would create a patchwork of regulation of distribution of compounded drugs interstate and it would be impractical to have individual MOUs with each state.

   The MOU describes, in brackets, the state in the agreement as "State Board of Pharmacy or other appropriate State agency." The bracketed language appearing in the MOU is intended to be substituted with the appropriate name and contact information of the state.

2. **Can the state solely rely on pharmacies entering information into an information sharing network to identify pharmacies that distribute inordinate amounts of compounded human drug products interstate under the MOU?**

   By signing the MOU, the state is agreeing to identify pharmacies that distribute inordinate amounts of compounded drugs interstate. However, the MOU provides flexibility in how the state does this, including use of tools like an information sharing network, such as the one established in cooperation with NABP. If a state that chooses to use an information sharing network is uncertain whether the information it contains is complete, the state may verify information through other means, such as during inspections. FDA will continue to work with states to address questions regarding reporting expectations under the MOU.

3. **What will FDA do with information submitted by the states under the MOU?**

   Protecting patients is our top priority. Information submitted by the states will help inform FDA about potential for patient harm, including whether additional federal oversight is warranted. The information submitted by the states also will help inform the agency's risk-based inspection priorities.

4. **What happens if a state does not fulfil the agreements under the MOU?**

   The MOU may be terminated upon a 60-calendar day notice of termination if a state does not adhere to the MOU provisions.

5. **Can states use their established processes to investigate complaints of adverse drug experiences and drug quality issues?**

Yes, states can use their established processes as long as those policies and procedures do not conflict with the terms of the standard MOU. The MOU indicates any state investigation will be performed according to the state agency's established investigatory policies and procedures, including those related to prioritizing complaints.

For example, using established procedures, a state board of pharmacy or other appropriate state agency may review an incoming complaint describing an adverse drug experience and determine the complaint does not warrant further investigation. In other cases, a state board of pharmacy or other appropriate state agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

Draft Statutory Proposal Related to the Interstate Distribution of Compounded Medications

Amend Section 4110 of the Business and Professions Code as follows:

4110.(a) License Required; Temporary Permit Upon Transfer of Ownership; Mobile Pharmacy Requirements (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually and shall include the matters identified by the board in the renewal application, including but not limited to, notification to the board regarding compounding practices, including compounded prescriptions distributed outside of the State. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) …

Add Section 4126.9 to the Business and Professions Code as follows:

4216.9 Distribution of Compounded Drugs in Interstate Commerce by Pharmacies Located in California

a) A pharmacy located in California may only distribute compounded preparations for interstate distribution under the following conditions.

1. Between January 1 and March 31 of each year, report all required data into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the federal Food and Drug Administration (FDA) to implement the Memorandum of Understanding established by the FDA Addressing Certain Distributions of Compounded Drugs.
2. On an annual basis, as a condition of renewal, the pharmacist-in-charge certifies that the reporting requirements established in section 1 have been satisfied.
3. Adverse drug experiences and product quality issues for all compounded products shall be reported to the board within 12 hours.

b) Confidential Treatment of Information Reported to the FDA Directly or Through the Information Sharing Network. All information reported by the board to the FDA directly or through the Information Sharing Network established in conjunction with the FDA is deemed to be confidential information as specified in California Government Code § 6254(f) if it relates to information regarding a complaint received or the investigation of any such complaint.

alliance for natural health USA

Alliance for Natural Health USA
1011 E Jefferson St #204
Charlottesville, VA 22902
(800) 230-2762
www.anh-usa.org

February 22, 2021

To the members of the California State Board of Pharmacy:

On behalf of the Alliance for Natural Health USA (ANH), I am writing to urge you to seriously consider deep flaws with the FDA's Memorandum of Understanding concerning compounded medications, and to contact the agency with your concerns.

ANH is a nonprofit organization representing one million consumers and healthcare practitioners across the U.S. ANH protects the right of natural health practitioners to practice, and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. We believe a system that is single-mindedly focused on "treating" sick people with expensive drugs, rather than maintaining healthy people, is neither practical nor economically sustainable.

Compounded medications are a key component of natural healthcare, as they are tailored to individual patient needs.

I'm writing to tell you that your decision, as the state board of pharmacy, about whether to sign FDA's Memorandum of Understanding with states has potentially catastrophic implications for access to compounded medications in your state.

The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency. In addition, FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

But there are also problems – potentially greater ones – for states that DON'T sign:

If your state board does not sign the MOU, compounding pharmacies will be limited to shipping NO MORE THAN 5% of compounded preparations out of state. For many, many compounders, that 5% cap will impede countless patients from getting their medications. It could well put some compounders out of business and result in lost jobs (and tax revenue) in your state. That's an unfortunate position state boards of pharmacy have been put in by FDA – making a decision that could hurt

local economies, not to mention patient care. (This 2020 op-ed by Virginia Congressman Morgan Griffith makes that point well.)

I urge you to consult with compounding pharmacy owners. The MOU is deeply flawed, and both NABP and FDA need to hear from you about your concerns now, not later. If they don't hear from you, there's no chance the MOU can be amended and improved. So please write to NABP and FDA.

What happens if FDA is unwilling to make changes? I'll be asking you to sign the MOU because that 5% cap on out-of-state shipments that will be imposed if you don't sign will be the death knell for many compounders. I do understand your role as a regulatory agency is to protect consumers. But when pharmacies can't stay in business, patients in-state and out-of-state can't access the medications they need. How does that protect consumers?

Thank you for your consideration.

Sincerely,

Gretchen DuBeau, Esq.
Executive and Legal Director
Alliance for Natural Health USA

Attachment 5

BPC Section 312.2

California State
Board of Pharmacy

April 22, 2021

Overview

- Background
- Data Collection Process
- All Agencies
- Board of Pharmacy

Background

- 2015: SB 467 is Passed
- 2016: BPC 312.2 Becomes Effective
- 1/1/2018: First Annual Report Published

  (data from Fiscal Year 2016-17)
- 1/1/2021: Fourth Annual Report Published

  (data from Fiscal Year 2019-20)

  1. 36 Agencies
  2. Licensing
  3. Health Quality Enforcement

How Data was Collected

- ProLaw is our Case Management System
- Approximately 200 ProLaw Users – HQE / Licensing
- Each Case Opened and Tracked in ProLaw
  - All Users Enter Data
  - Paralegals Audit and Validate Data

General Statistics – All Agencies
(Licensing and HQE Combined)

	FY 18-19	FY 19-20	Change
• Accusations	52%	52%	No Change
• Referrals	3,964	3,530	11% decrease
• Rejected	3%	5%	2% increase
• Further Inv	5%	7%	2% increase
• Adjudicated	3,929	3,377	14% decrease

BPC 312.2, subdivisions (a)(1) and (a)(2)

Accusation Matters Referred to the AG
Matters Rejected

	FY 2018-19	FY 2019-20
Accusations Referred to Attorney General	346	372 (8% increase)
Matters Rejected	8	9 (13% increase)

BPC 312.2, subdivisions (a)(3) and (a)(4)

Further Investigation Requested
Further Investigation Received

	FY 2018-19	FY 2019-20
Further Investigation Requested	13	24 (85% increase)
Further Investigation Received	11	18 (64% increase)

BPC 312.2, subdivision (a)(5)
Accusations Filed

	FY 2018-19	FY 2019-20
Accusations Filed	273	237 (13% decrease)

BPC 312.2, subdivisions (a)(6)and (a)(7)

Accusations Withdrawn
Accusation Matters Adjudicated

	FY 2018-19	FY 2019-20
Accusations Withdrawn	7	1 (86% decrease)
Accusation Matters Adjudicated	335	289 (14% decrease)

Average Days
BPC 312.2, subdivisions (b)(1) and (b)(2)
Accusation Received to Accusation Filed
Accusation Filed After Further Investigation

	FY 2018-19	FY 2019-20
Accusation Received to Accusation Filed	222 days (267)	214 days (221) 4% decrease
Accusation Filed After Further Investigation	385 days (21)	490 days (14) 27% increase

Average Days
BPC 312.2, subdivisions (b)(3) and (b)(4)
Accusation Filed to Settlement
Accusation Filed to Default

	FY 2018-19	FY 2019-20
Accusation Filed to Settlement	290 days (169)	368 days (173) 27% increase
Accusation Filed to Default	118 days (101)	117 days (80) 1% decrease

Average Days
BPC 312.2, subdivisions (b)(5) and (b)(6)
Accusation Filed to Hearing Requested
Hearing Date Received to Hearing Commenced

	FY 2018-19	FY 2019-20
Accusation Filed to Hearing Requested	149 days (66)	154 days (60) 3% increase
Hearing Date Received to Hearing Commenced	167 days (42)	146 days (21) 13% decrease
Total	316 days	300 days 5% decrease

Conclusions

- What can be Measured can be Improved
- CPEI Goal of 18 Months is Challenging
- Agencies Vary
- Speed versus Due Process

California State Board of Pharmacy

The Board of Pharmacy regulated 139,473 licensees in Fiscal Year 2018–19, with 28 license types. The board receives consumer complaints and routinely inspects pharmacies for compliance. Most complaints received by the board are investigated by the board's own inspectors, who are licensed pharmacists themselves. There were multiple respondents in about 41 percent of the board's accusation cases prosecuted by the Office of the Attorney General in Fiscal Year 2019–20. There is no statute of limitations within which to file accusations for this agency.

The tables below show data for Fiscal Year 2019–20.

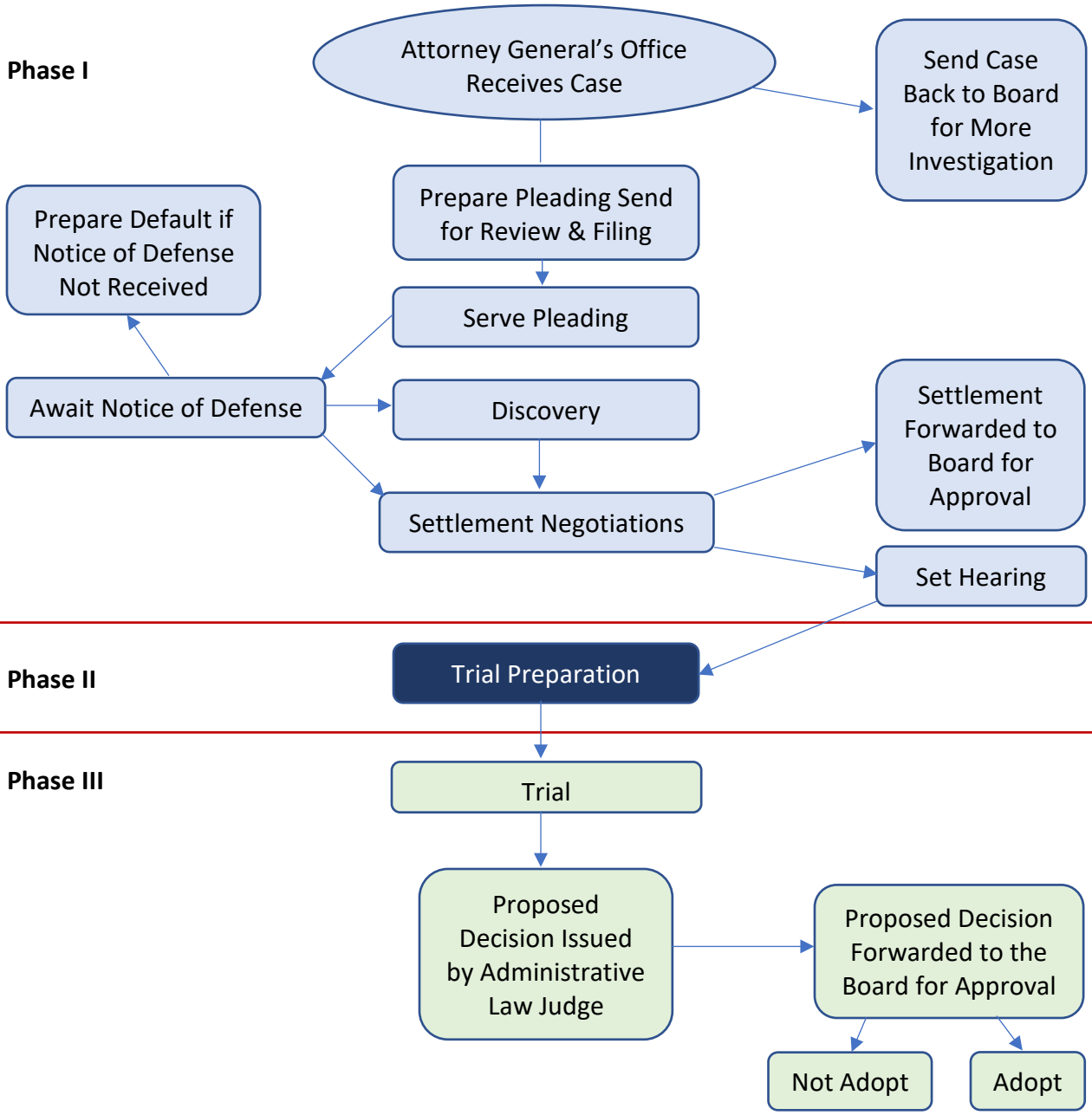
Table 1 – Business and Professions Code Section 312.2, Subdivision (a)	
Number of –	Count
(1) accusation matters referred to the Attorney General.	372
(2) accusation matters rejected for filing by the Attorney General.	9
(3) accusation matters for which further investigation was requested by the Attorney General.	24
(4) accusation matters for which further investigation was received by the Attorney General.	18
(5) accusations filed.	237
(6) accusations withdrawn.	1
(7) accusation matters adjudicated by the Attorney General.	289

Table 2 is based on the adjudicated accusation matters reported under Business and Professions Code section 312.2, subdivision (a)(7) in Table 1.

Table 2 – Business and Professions Code Section 312.2, Subdivision (b)				
Average number of days for adjudicated accusation matters –	Mean	Median	SD	Count
(1) from receipt of referral by the Attorney General to when an accusation is filed.	214	138	224	221
(2) to prepare an accusation for a case that is rereferred to the Attorney General after further investigation is received.	490	386	346	14
(3) from the filing of an accusation to when a stipulated settlement is sent to the agency.	368	277	329	173
(4) from the filing of an accusation to when a default decision is sent to the agency.	117	61	135	80
(5) from the filing of an accusation to the Attorney General requesting a hearing date.	154	106	136	60
(6) from the Attorney General's receipt of a hearing date to the commencement of a hearing.	146	124	152	21

Attachment 6

GENERAL CASE PROCESS



Attachment 7

Enforcement Workload Statistics FY 2020/21

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	592	481	528	0	1,601
Closed	561	627	659	0	1,847
Pending	1,649	1,776	1,642	0	1,642
Average Days for Investigation	227	257	223	0	223

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	820	661	524	0	524
Drug Diversion / Fraud	175	160	141	0	141
Prescription Drug Abuse	62	68	74	0	74
Compounding	67	75	64	0	64
Outsourcing	24	20	5	0	5
Probation / PRP	28	24	9	0	9
Enforcement	187	469	532	0	532
Criminal Conviction	286	299	294	0	294

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	51	64	62	0	177
Closed					
Approved	47	49	46	0	142
Denied	8	9	10	0	27
Total Closed (includes withdrawn)	***74***	***69***	***58***	***0***	201
Pending	89	85	89	0	89

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	124	168	177	0	469
Non-Jurisdictional	69	85	95	0	249
No Violation	70	44	88	0	202
No Further Action	47	47	48	0	142
Other - Non-Substantiated	6	7	10	0	23
Subject Educated	34	13	10	0	57

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	48	72	66	0	186
Citations Issued	226	262	248	0	736
Proof of Abatement Requested	53	64	88	0	205
Appeals Received	17	31	22	0	70
Dismissed	0	6	10	0	16
Total Fines Collected	***$204,815***	***$207,140***	***$199,225***	***$0***	***$611,180***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	48	36	49	0	133
Pleadings Filed	56	42	45	0	143
Pending					Quarter Ending
Pre-Accusation	117	105	108	0	108
Post-Accusation	205	180	153	0	153
Total Pending	**322**	**285**	**261**	**0**	**261**
Total Closed	50	71	80	0	201

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	2	5	0	8
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	9	15	16	0	40
Designated Representative	0	1	0	0	1
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	1	3	1	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***22***	***22***	***0***	***55***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	1	0	1
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***1***	***0***	***1***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	12	13	20	0	45
Intern Pharmacist	1	0	1	0	2
Pharmacy Technician	5	4	2	0	11
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	4	0	7	0	11
Sterile Compounding	0	0	2	0	2
Outsourcing	0	0	0	0	0
Total	***22***	***17***	***32***	***0***	***71***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	10	2	5	0	17
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	2	3	7	0	12
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	13	9	7	0	29
Sterile Compounding	0	0	1	0	1
Outsourcing	0	0	2	0	2
Total	***25***	***15***	***22***	***0***	***62***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	5	8	12	0	25
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	2	0	3
Designated Representative	1	0	0	0	1
Wholesaler	1	0	0	0	1
Clinic	0	0	1	0	1
Pharmacy	1	12	15	0	28
Sterile Compounding	0	0	2	0	2
Outsourcing	2	0	0	0	2
Total	***10***	***21***	***32***	***0***	***63***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	1	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***3***	***1***	***0***	***4***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	2	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Clinic	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	1	0	0	1
Total	***1***	***3***	***2***	***0***	***6***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$448,360***	***$439,165***	***$676,662***	***$0***	***$1,564,187***
Cost Recovery Collected	***$380,388***	***$405,001***	***$364,386***	***$0***	***$1,149,775***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	5	1	0	11
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	0	1	0	0	1
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	236	239	236	0	236
Intern Pharmacist	13	9	7	0	7
Pharmacy Technician	29	30	31	0	31
Designated Representative	2	2	2	0	2
Wholesaler	3	3	3	0	3
Pharmacy	73	70	70	0	70
Sterile Compounding	2	2	3	0	3
Total	***358***	***355***	***352***	***0***	***352***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	2	25	32	0	59
Probation Site Inspections	121	139	55	0	315
Probation Terminated / Completed	7	29	26	0	62
Referred to AG for Non-Compliance	0	2	1	0	3

As of 3/31/2021

Board of Pharmacy

Citation and Fine Statistics FY20/21

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	***Total***
Pharmacist with Fine	60	66	66	0	192
Pharmacist no Fine	38	77	43	0	158
Pharmacy with Fine	42	54	41	0	137
Pharmacy no Fine	47	65	59	0	171
Pharmacist-in-Charge with Fine*	29	35	25	0	89
Pharmacist-in-Charge no Fine	31	62	44	0	137
Pharmacy Technician with Fine	17	14	16	0	47
Pharmacy Technician no Fine	1	1	0	0	2
Wholesalers	3	1	0	0	4
Designated Representative	2	0	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	1	0	1
Hospital Pharmacy	6	2	1	0	9
Miscellaneous**	12	14	15	0	41
Unlicensed Premises	1	7	5	0	13
Unlicensed Person	0	0	0	0	0
Total Issued	289	398	316	0	1003

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	56%	1716 - Variation from prescription	57%	1716 - Variation from prescription	41%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	9%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	10%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	13%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	9%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	5%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice...	9%
1707.3 - Duty to review drug therapy	7%	1707.3 - Duty to review drug therapy	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	9%
1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	6%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	3%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	5%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	6%
4306.5(a) - Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist	3%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	4%	1711(d) - Quality assurance program finding shall be used to develop systems to prevent medication errors…	6%
1761(a)(b)/11164(a)/11152 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Sche	2%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	3%	1735.2(d)(3) - Compounding commericially available products	4%
1761 - Erroneous or uncertain prescriptions	2%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	2%	1714(d)/4113(c) - Operational Standards and Security; Pharmacist responsible for pharmacy security/Pharmacist in Charge shall be responsible for compliance with all state and federal laws pertaining to the practice of pharmacy	4%
1735.2(d)(3) - Compounding commericially available products	2%	4169(a)(4) - Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after or beyond use date on the label	2%	4301 - Unprofessional Conduct	4%

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

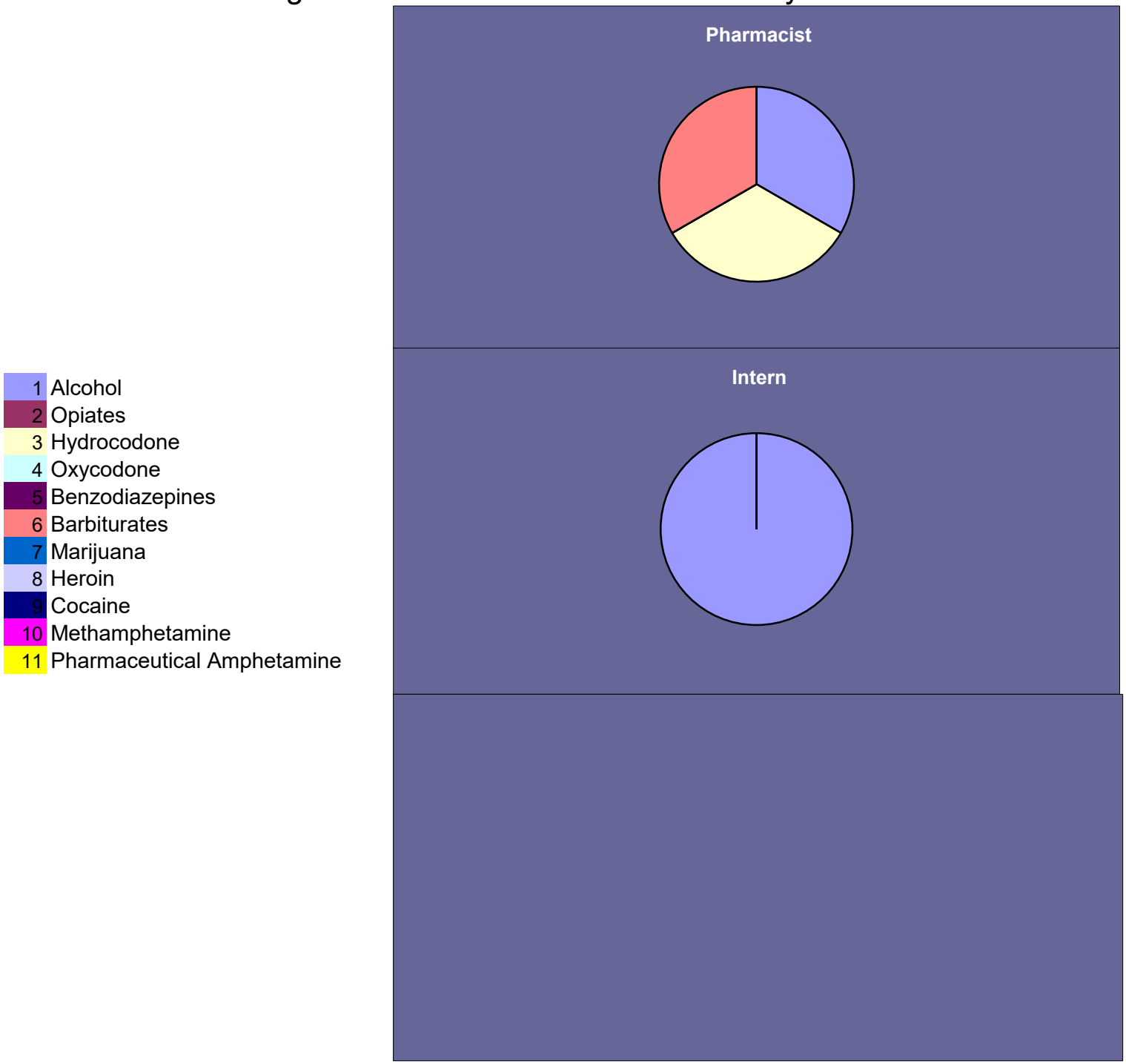
Board of Pharmacy	July Sep	Oct – Dec	Jan-Mar	Apr Jun	Total 20/21
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	2		2		4
PRP Under Investigation		1	1		2
PRP In Lieu Of (investigation conducted)			1		1
Total Number of PRP Intakes					
New Probationers					
Pharmacists	3		3		6
Intern Pharmacists	1		2		3
Pharmacy Technicians	2	3	1		6
Total New Probationers	6	3	6		15
PRP Participants and Recovery Agreements					
Total PRP Participants	58	55	56		N/A
Recovery Agreements Reviewed	56	53	48		157
Probationers and Inspections					
Total Probationers	80	76	75		N/A
Inspections Completed	53	62	58		173
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)			1		1
Drug Tests					
Drug Test Ordered (PRP and Probationers)	744	761	699		2204
Drug Tests Conducted (PRP and Probationers)	721	694	683		2098
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	1	2	1		4
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3	7	10		20
Termination from PRP	1	1			2
Probationers Referred for Discipline			1		1
Closure					
Successful Completion (PRP and Probationers)	1	5	5		11
Termination (Probation)			1		1
Voluntary Surrender (Probation)	4		2		6
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)		1			1
Non-compliance (PRP and Probationers)	23	14	14		51
Other (PRP)	2	1	1		4
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July Sep	Oct – Dec	Jan-Mar	Apr Jun	Total 20/21
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol			1		1
Ambien					
Opiates	1				1
Hydrocodone					
Oxycodone					
Morphine	1				1
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	2	2	1		5
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine		1			1
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2020 to March 2021



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