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

Enforcement and Compounding Committee Report

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a. Updates to Frequently Asked Questions Related to Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Background

Assembly Bill 1286 included several significant patient safety elements. As part of the Committee's prior discussion on implementation of Assembly Bill 1286, members requested that staff prepare a list of Frequently Asked Questions (FAQs) that the Board could release to assist stakeholders in gaining an understanding of the requirements of the measure. The FAQs were approved by the Board during its February 2024 meeting. As part of the Board's discussion, members requested that additional questions be added to the FAQs. More recently, additional questions were submitted for inclusion.

This issue was considered during the Committee's July 17, 2024 meeting and was originally agendized for consideration by the Board during its July 31-August 1, 2024 meeting; however, discussion and consideration did not occur at that time.

Summary of Committee Discussion and Action

During the Committee's July 17, 2024 meeting, members reviewed two additional proposed FAQs and provided feedback to staff. The new questions sought to address questions received regarding the reporting requirements for nonresident pharmacies and the authority for pharmacy technicians to initiate prescription transfers. Concern was expressed specifically about the question and response related to authority for pharmacy technicians to initiate prescription transfers. The statute only speaks to receiving a transferred prescription. Committee members expressed concern that this does not reflect the practice of prescription transfers where the request is typically initiated or requested by the receiving pharmacy. Public comment was also received reminding the Committee that this was not an oversight in the statute but purposeful. Some felt that a technician should not initiate a prescription transfer without a pharmacist involvement to avoid diversion. Another commenter suggested that a technician still doesn't have the authority to receive transfers for controlled substances.

Following discussion, the Committee determined it appropriate to remove the question addressing technicians and prescription transfers for the time being and to ask staff to research this issue. If the Board is seeking clarification of technician qualifications for AB 1286 activities, perhaps this issue can be clarified in the statute during sunset review.

> **Committee Motion**: Recommend approval of the additional FAQs related to Assembly Bill 1286 consistent with the Committee's discussion.

Attachment 1 includes a copy of the updated FAQs.

b. <u>Presentation on Distribution of Controlled Substances, Wholesalers Perspective, Provided by Leah Lindahl, Vice President State Government Affairs, Healthcare Distribution Alliance and Sara Watson, CPhT, Manager, State Regulatory Outreach, Cardinal Health</u>

<u>Background</u>
At the April 2024 Committee meeting, members received a presentation on drug shortages including information on DEA's response to stimulant shortages. As part of the presentation, members were advised about actions taken by the DEA to change allocation quotas and steps taken to increase manufacturer transparency. During this meeting, as well as in other meetings, members have received public comments from patients and chronic pain advocates about impacts to patients that cannot receive controlled substances medications.

<u>Summary of Committee Discussion and Action</u>
During the committee's October 16, 2024 meeting, members received a presentation on controlled substances distribution from the wholesalers' perspective from representatives of the Healthcare Distribution Alliance and Cardinal Health. The presentation discussed Controlled Substances Monitoring Programs, including requirements established in federal law as well as requirements imposed through the national opioid settlement involving the big three drug wholesalers.

The presentation included information related to the required use of thresholds and suspicious order reporting. Members were advised that wholesalers are constrained by the settlement agreement in how they interact with their customers about thresholds. Members also learned that threshold changes are possible and wholesalers generally have a process to allow customers to make such a request.

Members discussed some of the challenges pharmacies experience with thresholds that extend beyond opioids, to other controlled substances such as hormones, as well as challenges with thresholds impacting access to medication for opioid use disorder (MOUD). Members also noted challenges that are created by thresholds when patient care needs of a pharmacy change, for example when a pharmacy closure occurs and patients need to receive their controlled substances medications from a new pharmacy, or in the instance of a terminal patient that may require larger doses or amounts of controlled substances to manage pain. Members noted that requests to

increase a pharmacy's threshold can take five to seven days, which delays patient care.

Public comment similarly expressed concern about barriers to care that occur with the established thresholds.

Following discussion and public comments, members requested that staff undertake a number of actions, including development of a policy statement and educational materials on the provisions related to wholesaler thresholds, including information to disseminate via the Board's listserve as well as in *The Script*. Members also requested that staff explore opportunities to collaborate with the Medical Board of California and other programs within the Department of Consumer Affairs to explore potential solutions.

The Committee will continue to monitor development of these items through future agenda items.

Following the meeting, staff received additional information from the presenters specifically related to MOUD.

- Expanding Access to Medications for Opioid Use Disorder (MOUD)
- HDA Comments on MOUD Guidelines
- HDA Comments on SAMHSA Proposed Rule on Medications for the Treatment of Opioid Use Disorder

The presentation slides are available here. The webcast is available on the Board's website. All Board members were sent the link to the webcast and encouraged to watch this very informative presentation.

c. Discussion and Consideration of Draft Report to the Legislature on Automated Drug Delivery Systems as Required by Business and Professions Code Section 4427.8

Relevant Law
Business and Professions Code (BPC) section 4427.8 requires the Board to report on the regulation of automated drug delivery system (ADDS) units as part of its sunset review process.

Background
To ensure the Board could respond appropriately and fully to the Legislature on the use of ADDS, the Board amended its quality assurance regulations at California Code of Regulations, title 16, section 1711, to establish mandatory reporting requirements for medication errors related to the use of an ADDS.

The Committee has previously received presentations on the data and findings from these medication error reports, most recently during its July 2024 meeting. As was noted,

the information learned from this reporting would be included as part of the legislative report required.

Summary of Committee Discussion and Action
During the committee's July 17, 2024 meeting, Supervising Inspector Janice Dang provided a presentation describing updated information related to quality assurance records received pursuant to 16 CCR section 1711(f). Members noted that the information in the presentation will help to inform the legislative report that will be required as part of the Board's sunset review. The Committee did not take action on this item. The webcast from the July 17, 2024 meeting is available on the Board's website.

During the committee's October 16, 2024 meeting, members considered the draft legislative report. Members received public comment on the report suggesting that the report did not meet the legislative intent, though the commenter noted that the report did answer all of the questions posed. Further, public comment suggested that, given the report is completed, the Board should no longer require submission of separate medication error reports related to the use of an ADDS.

Members noted the gap in medication error reporting and the need to continue requiring such reports.

Committee Motion: Recommend approval of the draft legislative report.

Attachment 2 includes a copy of the draft legislative report.

d. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy at the Committee's October 16, 2024 [1]meeting

i. Assembly Bill 1842 (Reyes, Chapter 633, Statutes of 2024) Health Care Coverage: Medication-Assisted Treatment
Summary: Will prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder.
Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*.
Summary of Committee Discussion and Action: Members noted agreement with the staff-recommended implementation activities. No public comment was received on this item.

ii. Assembly Bill 1902 (Alanis, Chapter 330, Statutes of 2024) Prescription Drug Labels: Accessibility

[1] Senate Bill 1451 was not discussed during the October 16, 2024 meeting.

Summary: Will require a pharmacy to provide translated directions for use on prescription labels, in the languages made available by the Board, and will also require a pharmacy to provide a person, at no additional cost, an accessible prescription label affixed to the container that meets specified conditions. Further, the provisions require a dispenser to ensure that a prescription label is compatible with a prescription reader if provided. The measure requires the Board to promulgate regulations necessary to implement this section.
Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *The Script,* and updates to the community pharmacy self-assessment form. Further, staff suggest that it may be appropriate to determine if the language of the statute is sufficient for self-execution or if regulations are necessary to provide clarity to the regulated public.
Summary of Committee Discussion and Action: Members considered if regulations are necessary and requested that staff develop information detailing out more specifically what is required in the statute and what could be proposed in regulations. Members noted the need to provide education and the Board should consider developing materials to assist pharmacies with information on how to operationalize the requirements. Members also suggested that during the implementation phase staff exercise enforcement discretion and focus on achieving compliance through education.

Public comment suggested that regulations are not necessary but agreed that some definitions may not be clear and that the Board should provide flexibility regarding "timeliness" of impacted prescriptions.

iii. Assembly Bill 2115 (Haney, Chapter 634, Statutes of 2024) Controlled Substances
Summary: Will authorize a nonprofit or free clinic to dispense a 72-hour supply of schedule II controlled substances for the purpose of relieving acute withdrawal symptoms while arrangements are being made for referral for treatment. Will allow for the dispensing of a C-II from a hospital pharmacy inventory not to exceed a 72-hour supply for purposes of initiating maintenance treatment and provides that no more than a 3-day supply may be dispensed at one time, while such arrangements are being made.
Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, information in the upcoming issue of *The Script,* and updates to the inpatient pharmacy self-assessment form.
Summary of Committee Discussion and Action: Members noted agreement with the implementation activities. Public comment noted the importance of the legislation.

iv. Assembly Bill 3063 (McKinnor, 2024) Pharmacies: Compounding
Summary: Would have exempted from the definition of compounding the addition of a "flavoring agent that is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor" if the flavoring agent does not alter the

medication's concentration beyond the level of variance accepted in the United States Pharmacopeia. This measure was vetoed by the governor. The veto message is available here.

While the legislation was pending, the Board conveyed amendments that would have facilitated implementation of USP standards related to flavoring. Regrettably, the Board's amendments were not accepted. Given the governor's recent action, it may be appropriate for the Committee to consider if it should sponsor legislation to facilitate implementation of the USP standards in line with the amendment sought during the legislative process. Provided below is the amendment language offered.

> *A flavoring agent may be added to a prescribed FDA approved drug in an oral liquid dosage form at the request of a patient or patient's agent without consultation with the prescriber or their authorized agent. A pharmacist performing such action must provide documentation on the prescription record.*

Summary of Committee Discussion and Action: Committee members discussed the issue and questioned if the Board should sponsor legislation in this area. The suggested legislation would not conflict with USP but still assist pharmacists to offer flavoring within the Board's authority. Members suggested the need to develop educational materials to help pharmacies operationalize the USP nonsterile requirements related to flavoring agents. This would be in addition to the USP FAQ on flavoring. Members also referenced information from the FDA that makes clear the adding of a flavoring agent is compounding.

Public comment suggested that the barrier pharmacies experience related to flavoring is the Board's position that flavoring is considered compounding with some suggesting that the possible legislation would have negligible effect. Other public comment appeared to support a statutory change while noting that additional changes may be necessary beyond notification to the prescriber.

Following public comment and additional discussion, members are offering the following recommendation.

> **Committee Motion**: Recommend that the chairperson and staff work together to develop potential statutory language related to flavoring agents and prescription requirements.

Attachment 3 includes a copy of the communication from the FDA related to this issue and an example. In addition to the FDA and USP's determination that adding a flavoring agent is compounding, several other entities have similarly reached this conclusion including the American Pharmacists Association and the American Veterinary Medical Association.

v. **Senate Bill 164 (Committee on Budgets, Chapter 41, Statutes of 2024) State Government**

Summary: As related to Board licensees, will increase the CURES fee from $9 annually to $15 annually. These new fees impact licenses expiring on or after April 1, 2025.
Implementation: The Board anticipates that the Department of Justice will begin providing education to impacted licensees about the fee increase. The Board will share education through its listservs as appropriate. In addition, staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. The Board's licensing systems will also require programming changes and renewal application forms will require updates.
Summary of Committee Discussion and Action: Members noted agreement with the implementation activities. No public comment was received.

vi. **Senate Bill 954 (Menjiva, 2024) Sexual Health**

Summary: As related to the Board's jurisdiction, would have included provisions prohibiting a retail establishment from refusing to furnish nonprescription contraception to a person solely on basis of age. This measure was vetoed by the governor. The veto message is available here.
Summary of Committee Discussion and Action: Members requested that education on this topic, including information on the current law regarding rights to contraceptive care, be provided in the upcoming issue of *The Script* and included in the Board's annual webinar regarding pharmacy law. Public comment also spoke in support of the development of education.
Recent Update: The Board will recirculate the subscriber alert about rights to contraceptive care that was sent out in February 2024. A copy of the alert is in **Attachment 4.**

vii. **Senate Bill 966 (Wiener, 2024) Pharmacy Benefits**

Summary: Would have established the regulation of Pharmacy Benefit Managers (PBMs) within the California Department of Insurance, including actions that are prohibited by a PBM. This measure was vetoed by the governor. The veto message is available here.

Specifically related to the Board, staff note that one such prohibition would have prohibited a pharmacy benefit manager from unreasonably obstructing or interfering with a patient's right to timely access to a prescription drug or device that has been legally prescribed for a patient at a contract pharmacy of their choice. Such practice has been identified during investigations completed by the Board.

Staff note that one of the sunset issues under consideration by the Board is payor practices that negatively impact patients. It may be appropriate to explore the feasibility of the Board pursuing a statutory change to address this patient care issue.

Summary of Committee Discussion and Action: The Committee did not discuss the measure. No public comment was received.

viii. **Senate Bill 1067 (Smallwood-Cuevas, 2024) Healing Arts, Expedited Licensure Process: Medically Underserved Area or Population**
Summary: Would have required the Board (and other DCA healing arts boards) to develop a process to expedite the licensure process by giving priority review to applications for which the applicant demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population. This measure was vetoed by the governor. The veto message is available here.
Summary of Committee Discussion and Action: The Committee did not discuss the measure. No public comment was received.

ix. **Senate Bill 1089 (Smallwood-Cuevas, Chapter 625, Statutes of 2024) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures**
Summary: As related to the Board's jurisdiction, will require a covered establishment, which includes a pharmacy, to provide 45-days advance notice of any closure to the Board.

Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Further, staff note that the Board previously voted to pursue amendment to 16 CCR section 1708.2 related to Discontinuance of Business requirements. As included in the proposed regulation text, a pharmacy would be required to provide notice to patients at least 30 days in advance of a proposed closure and provide the Board with a copy of the notice. It may be appropriate to consider if the Board wishes to make changes to the proposed rulemaking text to align the timeframe for notification with the statute.

Summary of Committee Discussion and Action: The Committee requested that staff work with counsel on the best process to update the Board's proposed regulation text to align with the 45-day notification established in SB 1089. No public comment was received.

x. **Senate Bill 1451 (Ashby, Chapter 481, Statutes of 2024) Professions and Vocations**
Summary: As related to the Board's jurisdiction, extends provisions for pharmacists to furnish COVID-19 oral medications until January 1, 2026. Further, the measure will require a pharmacist that dispenses a prescription for an animal patient, to at the request of the customer, provide documentation specifically designed for veterinary drugs.

Implementation: Staff recommend that implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of The Script. Information received from an expert with the Veterinary Medical Board indicates

there are veterinary specific monographs generally used to provide consultation information. Staff have been advised that Plumb's appears to be the most comprehensive and widely used by veterinarians, however, it was noted that the Plumb Monographs are not 100% California compliant. Should members agree with the implementation efforts, staff will again seek guidance from the Veterinary Medical Board in the development of the newsletter and educational information on the Board's website.

Summary of Committee Discussion and Action: The Committee did not discussion this measure as it was identified after the meeting.

xi. Senate Bill 1468 (Ochoa Bogh and Roth, Chapter 488, Statutes of 2024) Department of Consumer Affairs

Summary: Will require the Board, and other DCA healing arts boards that license prescribers, to develop and biannually disseminate to each licensee information and educational materials regard the federal "Three Day Rule."

Implementation: Staff recommend implementation activities focus on education on the provisions including highlighting the provisions in the Change in Pharmacy Law webinar, and information in the upcoming issue of *The Script*. Board staff contacted the Department of Consumer Affairs to learn if the Department will be assisting with the development of the required materials for use by the various impacted programs.

Summary of Committee Discussion and Action: The Committee suggested that if the Board is responsible for development of the required education materials, such efforts should be done under the purview of the Communication and Public Education Committee if the Department of Consumer Affairs does not coordinate such development. No public comment was received.

e. Discussion and Consideration of FDA Actions Related to Implementation of the Drug Supply Chain Security Act

Relevant Law

Title II of the Drug Quality and Security Act outlines the legal framework for the Drug Supply Chain Security Act, including definitions, requirements for stakeholders, and provisions related to enforcement.

Background

The Drug Supply Chain Security Act (DSCSA), enacted in 2013 as part of the Drug Quality and Security Act, aims to enhance the security of the pharmaceutical supply chain and prevent counterfeit drugs from entering the drug distribution channel. The DSCSA established requirements for drug manufacturers, repackagers, wholesale

distributors, and dispensers, focusing on the serialization and traceability of prescription drugs.

The DSCSA provided a phased in approach, with several key milestones already required. Most recently, by November 27, 2023, the DSCSA required all prescription drug packages to be serialized with a unique identifier.

The FDA has published several draft and final guidance documents to assist stakeholders in understanding and implementing the requirements of the DSCSA including topics such as product tracing, verification, and interoperability.

As part of the Board's November 2023 meeting, the Board received a presentation from Josh Bolin, Associate Executive Director, Government Affairs/Innovation on the DSCSA. As part of the presentation, Mr. Bolin shared information about FDA "Stabilization Period" guidance and provided an overview of a "pulse" solution developed by the NABP to facilitate interoperability. A number of important resources were also provided. The presentation slides are available here.

More recently, the FDA released information that it is issuing exemptions to small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This exemption provides small dispensers additional time to stabilize their operations to fully implement some of the requirements of the DSCSA. The FDA noted that information received suggests that small business dispensers have described challenges related to the time, costs, and resources needed to further develop the technologies and processes to enable data exchange with trading partners. Additional information is available here.

Summary of Committee Discussion and Action: At the committee's October 16, 2024 meeting, Members noted that the information was provided for informational purposed only. No public comments were received.

Discussion and Consideration of Enforcement Statistics

During the first quarter of the new fiscal year, July 2024-September 2024, the Board initiated 706 complaints and closed 764 investigations. The Board has issued 44 letters of admonishment, 156 citations, and referred 43 cases to the Office of the Attorney General. The Board has revoked 25 licenses, accepted the disciplinary surrender of 8 licenses, formally denied five applications, and imposed other levels of discipline against 36 licensees and/or applicants.

As of October 1, 2024, the Board had 1,918 field investigations pending. Following is a breakdown providing more detail in the various investigation processes:

	Oct. 1, 2023		Jan. 1, 2024		Mar. 1, 2024		July. 1, 2024		Oct. 1, 2024	
	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days	Vol.	Avg. Days
Awaiting Assignment	88	22	152	15	107	7	44	6	63	14
Cases Under Investigation	982	138	1,037	146	1,061	134	1,005	136	908	146
Pending Supervisor Review	183	47	286	77	355	85	223	74	147	74
Pending Second Level Review	82	22	81	21	115	26	99	22	229	26
Awaiting Final Closure	34	13	26	19	24	3	56	8	34	14

I. Summary of Committee Discussion and Action: at the committee's October 16, 2024 meeting, Information was reviewed. There were no comments from the Committee or the public.

Attachment 5 includes the enforcement statistics.

Attachment 1

Frequently Asked Questions – Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023)

Assembly Bill 1286, which becomes effective January 1, 2024, includes several patient safety provisions. Given the encompassing nature of the measure, the Board is releasing this FAQ to assist licensees with understanding the bill. To facilitate use of this document, short titles will be used to reference the various topics.

Medication Error Reporting

1. Q: What types of licensees are required to report medication errors under AB 1286?

A: A community pharmacy licensed pursuant to Article 7 of Chapter 9 of Division 2 of the Business and Professions Code (BPC) is required to report medication errors under AB 1286. For purposes of the measure, the term "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, including both resident and nonresident pharmacies, but not including facilities of the California Department of Corrections and Rehabilitation.

[Reference: BPC 4113.1(a), (c), and (e)]

2. Q: What is considered a medication error for purposes of AB 1286 reporting?

A: For purposes of AB 1286 reporting, the term "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration, but does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

[Reference: BPC 4113.1(d)]

3. Q: AB 1286 requires a community pharmacy to report medication errors to an entity approved by the Board. What is the name of the approved entity?

A: The Board is in the process of identifying an entity to receive AB 1286 medication error reports. Until the Board has approved the entity, medication errors do not need to be reported under BPC 4113.1. The Board reminds licensees, however, that provisions for documenting medication errors as established in California Code of Regulations (CCR), title 16, section 1711 (relating to quality assurance programs) remain effective. AB 1286 does not impact the quality assurance documentation requirements.

[Reference: BPC 4113.1(a); 16 CCR 1711]

4. **Q: Given the delay in implementation for reporting medication errors under AB 1286, how will I know when the medication error reporting becomes effective?**

A: The Board will use a variety of means to announce the approval of the entity and the implementation timeframe, including through the Board's subscriber alert system and posting information on its website.

Note: As a reminder, all licensees are required to enroll in the Board's subscriber alert system. Additional information is available here.

[Reference: BPC 4013]

5. **Q: I work in an outpatient hospital pharmacy. Do AB 1286's requirements for medication error reporting apply to our pharmacy?**

A: Yes. However, pursuant to subdivision (e) of BPC 4113.1, an outpatient hospital pharmacy shall not be required to report to the Board-approved entity a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to section 1279.1 of the Health and Safety Code (HSC). The State Department of Public Health may share any such report with the Board.

[Reference: BPC 4113.1(e)]

6. **Q: I work in an outpatient hospital pharmacy. Am I required to report all medication errors to the Board-approved entity under the provisions of AB 1286?**

A: It depends. AB 1286 generally requires a community pharmacy licensed by the Board to report, either directly or through a designated third party, all medication errors to an entity approved by the Board; however, subdivision (e) of BPC 4113.1 establishes a limited exemption from the reporting requirements, and specifies that an outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event that has been reported to the State Department of Public Health pursuant to HSC 1279.1.

[Reference: BPC 4113.1]

7. **Q: If I am reporting medication errors to an entity approved by the Board, am I still required to complete a quality assurance review and report?**

A: Yes. The Board's quality assurance regulations remain in place and pharmacies are still required to comply with those regulations.

[Reference: 16 CCR 1711]

8. Q: Are nonresident pharmacies required to report all medication errors to the Board-approved entity under the provisions of AB 1286? (New Question)

A: Yes. BPC 4113.1 states that a community pharmacy licensed pursuant to Article 7 of the Pharmacy Law (which includes nonresident pharmacies) shall report "all medication errors."

[Reference: BPC 4113.1]

Minimum Staffing Provisions

9. Q: What minimum staffing requirements does AB 1286 establish?

A: Effective January 1, 2024, a chain community pharmacy subject to BPC 4113.5 is required to be staffed at all times during normal business hours (defined as 8:00 am to 7:00 pm) with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services, unless any of the following conditions apply:

- The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
- The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm, in which case the minimum staffing requirement does not apply during the hours before 8:00 am and after 7:00 pm.
- The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, CLIA-waived tests, or any other ancillary services provided by law, this exemption does not apply.

In addition, where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

Note: Additional minimum staffing requirements are detailed under "Pharmacy Technician Expanded Duties" below.

[Reference: BPC 4113.6]

10. Q. If a pharmacist is solely scheduled with an intern, does that meet the minimum staffing requirement established in BPC 4113.6(a)?

A: AB 1286 is silent about the impact to the minimum staff requirement when interns are present. As stated in the prior question, a pharmacist on duty may waive the BPC 4113.6(a) minimum staffing requirement during specified hours based on workload need.

[Reference: BPC 4113.6(a)]

Staffing Decisions

11. Q: I am the pharmacist-in-charge (PIC) of a pharmacy. What changes does AB 1286 make as far as my ability to make staffing decisions?

A: Effective January 1, 2024, the law explicitly provides that the PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. The Board recommends that the PIC document their efforts to ensure sufficient staff are present.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

12. Q: I am the pharmacist on duty and the PIC is not available. Do I have the authority to adjust staffing?

A: Effective January 1, 2024, if the PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed. The Board recommends that the pharmacist on duty document their efforts to adjust staffing.

Note: These provisions do not apply to facilities of the Department of Corrections and Rehabilitation.

[Reference: BPC 4113(c)(2)]

Unsafe Pharmacy Conditions

13. Q: I am concerned that the working conditions of the pharmacy are harmful. What should I do?

A: Effective January 1, 2024, the pharmacist-in-charge or pharmacist on duty is required to immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:

- Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

The Board recommends that the PIC or pharmacist on duty document any such notification made by them to store management. The Board also recommends that

pharmacies establish policies and procedures for the notification process to ensure reporting personnel and store management have a common understanding of the process to be used.

[Reference: BPC 4113(d)]

14. Q: Is store management required to take action based on my report?

A: Yes. Effective January 1, 2024, store management is required to take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. The pharmacy owner may also close a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.

[Reference: BPC 4113(d)]

15. Q: I made a report, but the conditions remain. What should I do?

A: Effective January 1, 2024, the law states that if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified.

[Reference: BPC 4113(d)]

16. Q: How do I make a report to the Board?

A: The Board has established a dedicated email for such reporting: –– PharmacyAlert@dca.ca.gov. The Board requests that the following information be provided with the notification:

- Name and license number of pharmacy,
- Name and contact information for reporting party,
- Name and contact information for store management that received the initial notification,
- Copy of the notification provided to store management,
- Documentation of the conditions including photographs, temperature logs, etc.

[Reference: BPC 4113(d)]

17. Q: Do these requirements apply to all pharmacies?

A: No, facilities of the Department of Corrections and Rehabilitation are exempt from these requirements.

[Reference: BPC 4113(d)(6)]

Pharmacy Technician Expanded Duties

18. Q: What are the expanded duties pharmacy technicians may perform pursuant to AB 1286?

A: Effective January 1, 2024, qualified pharmacy technicians may perform the following duties under specified conditions:

- Prepare and administer influenza and COVID-19 vaccines via injection or intranasally
- Prepare and administer epinephrine
- Perform specimen collection for tests that are classified as waived under CLIA
- Receive prescription transfers
- Accept clarification on prescriptions

[Reference: BPC 4115(b)]

19. Q: What are the specified conditions that must be met for a pharmacy technician to perform the expanded duties?

A: The law establishes several conditions, as follows:

- The duties are performed under the direct supervision and control of a pharmacist.
- The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in BPC 4115(a) (*i.e.*, packaging, manipulative, repetitive, or other nondiscretionary tasks).
- The pharmacy technician is certified pursuant to the provisions of BPC 4202(a)(4) and maintains the certification.
- The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education that includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.
- The pharmacy technician is certified in basic life support.

[Reference: BPC 4115(b)(1)]

Unprofessional Conduct

20. Q: As a pharmacist, I know I am responsible for using professional judgment when taking care of patients. I believe my employer has implemented a policy that undermines my professional judgment. Does AB 1286 address this?

A: Yes. Effective January 1, 2024, the unprofessional conduct code was amended to expand the list of specified actions that constitute unprofessional conduct to include

actions or conduct that would subvert the efforts of a pharmacist or PIC to comply with laws and regulations, or exercise professional judgment.

[Reference: BPC 4301(v) and (w)]

21. Q: If I believe the pharmacy is violating the law, how do I file a complaint with the Board?

A: A consumer or licensee may file a complaint with the Board online. Fill out the boxes on the form that apply to your complaint. The Board requests that documentation or other evidence that support your allegations be retained and provided to the Board if requested.

22. Q: Can I file a complaint anonymously?

A: Yes. The Board welcomes and investigates complaints received, including anonymous complaints. However, anonymous complaints may limit the Board's ability to investigate.

Surgical Clinic Provisions

23. Q: Under new requirements established by AB 1286, our surgical clinic is required to complete a Surgical Clinic Self-Assessment Form. Where can I find that form?

A: The Surgical Clinic Self-Assessment Form is currently being developed. Upon approval, the Board will release a subscriber alert and post the form on its website. The form will be available here.

[Reference: BPC 4192(b)]

24. Q: It is my understanding that AB 1286 makes changes to the renewal requirements for surgical clinics. Please provide me with an explanation of the changes.

A: Effective January 1, 2024, as part of the renewal process for a surgical clinic, the consulting pharmacist must certify compliance with the quarterly inspections as required by BPC 4192. Further, as part of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in BPC 4192 must be provided to the Board.

[Reference: BPC 4204(c)]

25. Q: How does the consulting pharmacist certify compliance with the quarterly inspection requirements?

A: The renewal application form includes a statement that must be completed by the consulting pharmacist as part of the renewal process. As a reminder, the Board has a policy to accept digital signatures. The policy is available here.

[Reference: BPC 4192(b), 4204(c)]

26. Q: How do I submit a copy of the completed self-assessment form with our renewal application?

A: A copy of the completed self-assessment form can be mailed along with the renewal application form and renewal fee. It is recommended that licensees consider mailing the renewal application form, fee, and self-assessment form to the Board's office for handling, 2720 Gateway Oaks Drive, Suite 100, Sacramento, CA 95833.

[Reference: BPC 4204(c))

Draft Rev. July 23, 2024

Attachment 2

Automated Drug Delivery Systems

CALIFORNIA STATE
BOARD OF PHARMACY

CALIFORNIA STATE BOARD OF PHARMACY

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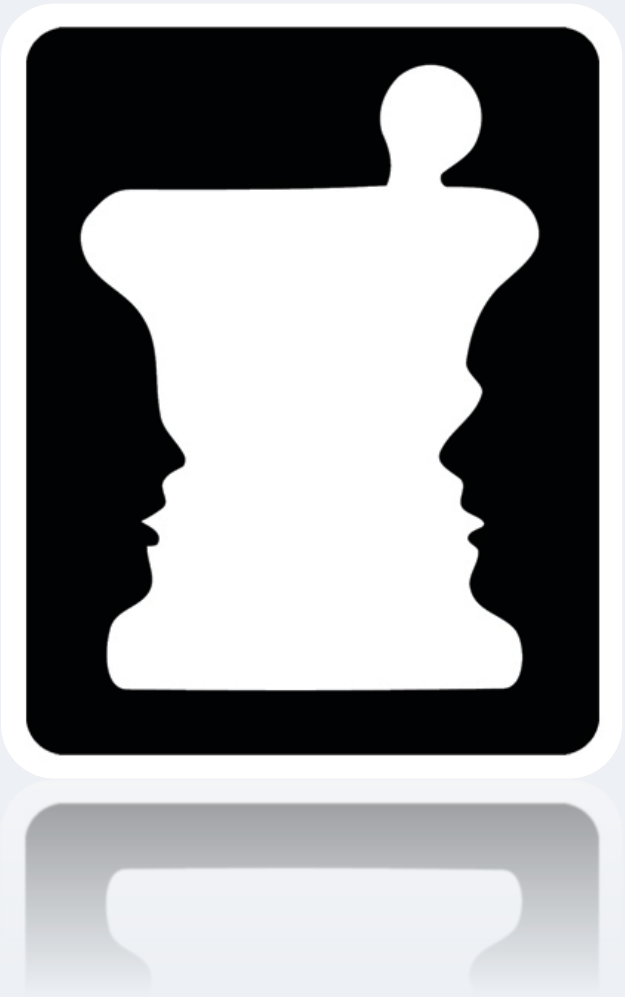
Vision

Healthy Californians through quality pharmacist's care.

Mission

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation and enforcement.



January 6, 2025

Summary

As required in Business and Professions Code section 4427.8, the California State Board of Pharmacy (Board) is pleased to report to the Legislature its efforts in regulating Automated Drug Delivery System (ADDS) units. This report will

- Summarize the specified information and recommendations offered at the conclusion of the report,
- Describe the use and dispersion of ADDS throughout the health care system,
- Highlight the number of ADDS prelicensure inspections conducted by the Board and its findings from these inspections,
- Discuss public safety concerns related to the use of ADDS.

Background

A pilot study conducted by the University of California, San Diego (UCSD) and Sharp Memorial Hospital in San Diego sought to evaluate the use of an ADDS for the dispensing of the hospital employee's prescriptions and their dependents. The study results presented to Board concluded that the ADDS was a convenient and safe extension of the hospital's pharmacy, with similar prescription pick up and consultation patterns at the regular pharmacy counter.

Given the results, the Board sponsored legislation to expand the use of automated drug delivery systems to include provisions to allow patients who choose to do so, to pick up their prescriptions from an ADDS, as well as, to develop licensing requirements for such devices while also expanding the settings where ADDS may be utilized. Many of the current statutory requirements were included in Senate Bill 1447 (Chapter 666, Statutes of 2018) and Assembly Bill 1533 (Chapter 629, Statutes of 2021).

Types of Technology

Business and Professions Code section 4017.3 defines an ADDS as a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, dispensing, or distribution of drugs. As required by law, the ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. Further, the law defines two subcategories of ADDS including "automated unit dose system" (AUDS) and "automated patient dispensing system" (APDS).

An AUDS is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions, such as a nurse within a hospital or skilled nursing facility. An APDS is an ADDS used for storage and dispensing of prescribed drugs directly to patients pursuant to a prior authorization by a pharmacist, such as at a pharmacy, medical office or clinic. The provisions for licensure and legal requirements vary based on the specific type of ADDS.

The law establishes provisions for licensure of ADDS operated by pharmacies while also allowing for use of unlicensed ADDS operated by pharmacies under specific conditions.

Further, the law allows for the use of ADDS by an Emergency Medical Services (EMS) provider agency for the restocking of secured emergency pharmaceutical supplies containers.

Licensed locations where the ADDS is operated by a pharmacy include:

- Adjacent to a pharmacy
- A health care facility licensure pursuant to Health and Safety Code 1250
- Clinics, including primary care and specialty clinics, free clinics, surgical clinics and correctional clinics
- Medical offices
- Locations where patients are regularly seen for purposes of diagnosis and treatment and patients of the practice
- Licensed facilities with the statutory authority to provided pharmaceutical services such as psychiatric health facilities.
- Jails, youth detention facilities and other correctional facilities
- "Covered entities" or affiliated sites as established in 42 United States Code 256b
- On the premises of a fire department headquarters, fire station or EMS provider agency location.

Unlicensed locations where licensure is not required include:

- Licensed hospitals used solely to provide doses administered to patients in an acute care hospital or licensed acute psychiatric hospital facility.
- ADDS used within the secured licensed premises of a pharmacy, used for the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

Licensing and Inspection Activities:
Following enacted of Senate Bill 1447 and related measures, the Board undertook a number of implementation activities including education on the requirements. Although the provisions for licensure became effective July 1, 2019, the Board implemented its application and inspection process in advance of the July 1, 2019, effective date to ensure those entities interested in using the technology were positioned to do so immediately. As of July 1, 2024, the Board has licensed 1,832 ADDS in California. This includes:

- 376 automated unit dose devices operated by the California Department of Corrections and Rehabilitation.[1]
- 735 automated unit does devices used in other health care facilities including hospitals, skilled nursing facilities, jails, etc.[2]
- 15 automated patient dispensing devices[3].
- 1 automated delivery device used to restock ambulances[4].
- 1 automated patient dispensing device used in a 340B clinic[5].

[1] Business and Professions Code section 4187.5
[2] Business and Professions Code sections 4427.2 & 4427.3
[3] Business and Professions Code section 4427.6
[4] Business and Professions Code section 4119.01
[5] Business and Professions Code section 4119.11

The Board has performed 2,004 pre-licensure inspections. These pre-licensure inspections provide a better window in to understanding the unique issues facing various settings. As the Board learned about some of these challenges, it sought changes in Assembly Bill 1533 expanding authority for use of ADDS.

Board inspector staff have provided significant education based on the various settings and unique challenges. As examples.

1. The use of an ADDS in an emergency department of a hospital requires licensure by the Board, while ADDS used within the hospital for administration to patients is exempt from licensure. This has led to some confusion. In such an instance, the Board provides education about labeling requirements for medications that are dispensed from the ADDS for patients discharged from the emergency department and well as the requirements to report to CURES if the prescription is for a controlled substance.
2. The placement of ADDS is important as some of the dispensing devices are in the waiting area of a medical office, creating challenges in maintaining patient confidentiality. Inspector staff offered recommendations such as reposition devices or utilization of privacy screens.
3. In some instances, the ADDS was placed in a closet which lacked ventilation and temperature control. Inspector staff offered recommendations to modify the room or closet to allow better circulation to ensure appropriate storage of medications that must be maintained within specific temperature ranges.
4. Some facilities were not familiar with DEA requirements for controlled substances in an ADDS. In addition to providing education, at times, reinspection was necessary to ensure compliance was achieved.
5. Many inspections revealed either insufficient policies and procedures or failure to adhere to policies.

Quality Assurance Requirements

To ensure the Board was positioned to respond to the questions posed by the Legislature, the Board amended its Quality Assurance Regulations, to require reporting of medication errors stemming from the use of ADDS. Although the regulations became effective July 1, 2021, the Board did not receive reports from many of the entities as required. The Board undertook significant educational activities to try to gain compliance with the reporting requirements including as part of the Board's FAQs and newsletters, in licensure renewals and self-assessments, education through the inspection process and through phone calls. The significant increase in reporting as noted in the tables below for FY 2023/24 demonstrates the impact of the Board's educational efforts.

Medication Errors Reported by Type of ADDS FY 2023/2024

Type of Device	Number of reports
ADDS (used inside a pharmacy for counting, etc.)	280
AUD (used for unit dose administration)	1,929

APD (patient-dispensing device)	0
Unknown	3

ADDS Medication Error Reports Received

Operated By	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Pharmacies	252	305	53	770
Hospitals	0	0	151	294
Exempt Hospitals	0	0	0	101
Licensed Correctional Facilities	1	11	66	1047
Total	253	316	270	2,212

*Includes reports submitted through March 1, 2024.

ADDS Medication Errors Reported by Location Type

Operated By	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Adjacent to Pharmacy	0	0	0	0
Medical Office	0	0	0	0
Clinic	0	0	0	2
Correctional Clinic	1	11	63	1,034
Skilled Nursing Facility	0	0	0	340
Intermediate Care Facility	0	0	3	0
Inside the Pharmacy	252	305	49	281
Other	0	0	155	555, including 395 at hospitals
Total	253	316	270	

Types of ADDS Medication Errors Reported

	FY 20/21	FY 21/22	FY 22/23	FY 23/24*
Wrong Drug	28	39	37	200
Wrong Strength	0	6	21	141
Wrong Quantity	210	258	55	583
Wrong Patient	0	1	8	321
Labeling Error	15	4	1	4
Duplicate Therapy	0	0	6	24
Expired Drug	0	0	1	6

Unauthorized Dispensing	0	0	139	924
Unknown	0	8	2	598
Total	253	316	270	2,801**

** a medication error report may have into more than one category

Based on reports received, the data suggests that access to medications directly from an APDS device as allowed under the law, does not appear to create additional patient safety concerns from ADDS medication errors. This is consistent with the findings of the initial study of APDS conducted by UCSD. However, the data does reveal a concerning number of errors, some with the potential of causing patient harm or death stemming from the use of AUDS.

The data reveals that unauthorized dispensing accounts for the greatest number of ADDS medication errors reported. This occurred most frequently with the use of AUDS devices in hospitals, skilled nursing facilities and correctional clinics where authorized individuals (registered nurses, licensed vocational nurses, etc.) accessed a medication that was not ordered for a patient or removed medication without authorization by utilizing the device's override function. Further, almost 25% of the errors reported were patients receiving the wrong medication or a medication intended for another patient. ADDS medication errors involving duplicate therapy and the wrong medication strength also have the potential of causing patient harm or death depending on the type of medication.

ADDS medication errors related to the quantity dispensed into a prescription can, but generally would not, result in potential patient harm. Quantity errors can lead to interruptions in therapy when a patient receives less than their full quantity and runs out medication. Such errors are typically related to the use of an ADDS located inside a pharmacy used for purposes of selecting, counting, packaging, and labeling prescriptions.

The Board further notes that, over 25% of the ADDS medication error reports received did not provide sufficient data for evaluation and to understand the type of error.

Conclusions:
The use of ADDS for medication distribution is found throughout a variety of health care settings. ADDS offer medication security and the opportunity to improved patient care. Risks exist with the use of technology that is not appropriately implemented and utilized. After review and discussion of the data, the Board finds ADDS have many technological safeguards available, but some facilities elect not to use some features or allow staff to override the safeguards. Further, review of the ADDS medication error reports suggests that failure to follow a facility's established policies and procedures related to the use of an ADDS can lead to medication errors.

The Board has presented these findings during a public meeting and intends to release further education materials and best practices on the use of ADDS. Since ADDS medication error reporting to the Board has been limited and to ensure there is data necessary to perform ongoing assessment of ADDS medication errors, it is anticipated the Board will continue to require ongoing submission of reports for the foreseeable future. The Board may consider developing a standardized report template to assure sufficient information is included in the ADDS medication error report for evaluation.

Further, the Board notes that while recently enacted legislation requires the reporting of medication errors that occur in specified community pharmacies, that reporting requirement does not extend to all environments where ADDS are in use.

State of California

Governor Gavin Newsom
Kimberly Kirchmeyer, Director, Department of Consumer Affairs

California State Board of Pharmacy Executive Staff

Anne Sodergren, Executive Officer
Julie Ansel, Deputy Executive Officer

Additional Copies of this report can be obtained from
www.pharmacy.ca.gov

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

Attachment 3

From: Acosta, Christine@DCA
To: Sodergren, Anne@DCA; Kalantar, Anna@DCA; Panella-Spangler, Peg@DCA
Subject: Fwd: FDA and adding a flavoring agent
Date: Tuesday, August 15, 2023 6:49:43 AM

Thank you,

image
Christine Acosta PharmD, Supervising Inspector
California State Board of Pharmacy
(619) 818-7255 | FAX (760) 796-4610 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!
Useful links:
2023 law book: **https://pharmacy.ca.gov/laws_regs/lawbook.pdf**

Get Outlook for iOS

From: DoNotReply_CDER@fda.hhs.gov <DoNotReply_CDER@fda.hhs.gov>
Sent: Tuesday, August 15, 2023 6:08:55 AM
To: Acosta, Christine@DCA <Christine.Acosta@dca.ca.gov>
Cc: Compounding@fda.hhs.gov <Compounding@fda.hhs.gov>
Subject: RE: FDA and adding a flavoring agent

Dear Ms. Acosta:

Thank you for your inquiry asking if the Food and Drug Administration (FDA) considers adding a flavoring agent to a manufactured drug product to be compounding. You also ask if FDA agrees with the United States Pharmacopeia's (USP) statement in its USP Chapter <795> Frequently Asked Questions document that states: "Flavoring a manufactured product is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act. Compounding standards apply to the assembly of premeasured kits."

FDA has not issued guidance addressing the specific question of whether FDA considers adding flavoring to the drug to be compounding under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The addition of a flavoring by a pharmacy to a drug generally would be considered

compounding under section 503A of the FD&C Act.

However, we note that section 503A(e) of the FD&C Act states that “the term “compounding” does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in [FDA-]approved labeling provided by the product’s manufacturer and other manufacturer directions consistent with that labeling.” Therefore, if the labeling for an FDA-approved drug includes directions to do so, adding flavoring to the drug in accordance with these directions would not be considered compounding under section 503A of the FD&C Act.

We hope this responds to your inquiry. Should you have additional questions or require additional information, please contact Compounding@fda.hhs.gov.

Sincerely,

Compounding Policy Branch

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AUGMENTIN ES-600®, safely and effectively. See full prescribing information for AUGMENTIN ES-600®.

AUGMENTIN ES-600® (amoxicillin and clavulanate potassium) for oral suspension
Initial U.S. Approval: 2001

----------RECENT MAJOR CHANGES----------
Warnings and Precautions (5) 6/2022

----------INDICATIONS AND USAGE----------
AUGMENTIN ES-600 is a combination of amoxicillin, a penicillin-class antibacterial and clavulanate potassium, a beta-lactamase inhibitor, indicated for the treatment of pediatric patients with

- Recurrent or persistent acute otitis media due to *S. pneumoniae* (penicillin MICs less than or equal to 2 mcg/mL), *H. influenzae* (including β-lactamase-producing strains), or *M. catarrhalis* (including β-lactamase-producing strains) characterized by the following risk factors (1):

  - Antibacterial exposure for acute otitis media within the preceding 3 months, and either of the following: 1) age 2 years, or younger or 2) daycare attendance

Limitations of Use
Acute otitis media due to *S. pneumoniae* alone can be treated with amoxicillin. AUGMENTIN ES-600 is not indicated for the treatment of acute otitis media due to *S. pneumoniae* with penicillin MIC greater than or equal to 4 mcg/mL. Therapy may be instituted prior to obtaining the results from bacteriological studies when there is reason to believe the infection may involve both *S. pneumoniae* (penicillin MIC less than or equal to 2 mcg/mL) and the β-lactamase-producing organisms listed above. (1)

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of AUGMENTIN ES-600 and other antibacterial drugs, AUGMENTIN ES-600 should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. (1)

----------DOSAGE AND ADMINISTRATION----------
- Pediatric Patients less than 40 kg: 90 mg/kg/day divided every 12 hours, administered for 10 days. (2)

----------DOSAGE FORMS AND STRENGTHS----------
For oral suspension: 600 mg/42.9 mg per 5 mL. (3)

----------CONTRAINDICATIONS----------
- History of a serious hypersensitivity reaction (e.g., anaphylaxis or Stevens-Johnson syndrome) to AUGMENTIN ES-600 or any other beta-lactams (e.g., penicillins or cephalosporins). (4.1)
- History of cholestatic jaundice/hepatic dysfunction associated with AUGMENTIN ES-600. (4.2)

----------WARNINGS AND PRECAUTIONS----------
- Serious (including fatal) hypersensitivity reactions: Discontinue AUGMENTIN ES-600 if a reaction occurs. (5.1)
- Severe Cutaneous Adverse Reactions (SCAR): Monitor closely. Discontinue if rash progresses. (5.2)
- Hepatic dysfunction and cholestatic jaundice: Discontinue if signs/symptoms of hepatitis occur. Monitor liver function tests in patients with hepatic impairment (5.3)
- *Clostridioides difficile*-associated diarrhea (CDAD) (ranging from mild diarrhea to fatal colitis): Evaluate patients if diarrhea occurs. (5.4)
- Patients with mononucleosis who receive AUGMENTIN ES-600 develop skin rash. Avoid AUGMENTIN ES-600 use in these patients. (5.5)

----------ADVERSE REACTIONS----------
The most frequently reported adverse reactions were diaper rash (4%), diarrhea (3%), vomiting (2%), candidiasis (1%), and rash (1%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact USAntibiotics, LLC at 1-844-454-5532 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- Co-administration with probenecid is not recommended. (7.1)
- Concomitant use of AUGMENTIN ES-600 with oral anticoagulants may increase the prolongation of prothrombin time. (7.2)
- Co-administration with allopurinol increases the risk of rash. (7.3)
- AUGMENTIN ES-600 may reduce efficacy of oral contraceptives. (7.4)

----------USE IN SPECIFIC POPULATIONS----------
- Pediatric 3 months to 12 years old: Modify dose according to weight. (2.2, 8.4)
- Adults and pediatric patients weighing more than 40 kg: The safety and effectiveness of AUGMENTIN ES-600 has not been established. (8)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 9/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the Full Prescribing Information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AUGMENTIN ES-600 is indicated for the treatment of pediatric patients with

- Recurrent or persistent acute otitis media due to *S. pneumoniae* (penicillin MICs less than or equal to 2 mcg/mL), *H. influenzae* (including β-lactamase-producing strains), or *M. catarrhalis* (including β-lactamase-producing strains) characterized by the following risk factors:

  - Antibacterial drug exposure for acute otitis media within the preceding 3 months, and either of the following: 1) age 2 years, or younger or 2) day care attendance *[see Microbiology (12.4)]*.

Limitations of Use
Acute otitis media due to *S. pneumoniae* alone can be treated with amoxicillin. AUGMENTIN ES-600 is not indicated for the treatment of acute otitis media due to *S. pneumoniae* with penicillin MIC greater than or equal to 4 mcg/mL. Therapy may be instituted prior to obtaining the results from bacteriological studies when there is reason to believe the infection may involve both *S. pneumoniae* (penicillin MIC less than or equal to 2 mcg/mL) and the β-lactamase-producing organisms listed above.

Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of AUGMENTIN ES-600 and other antibacterial drugs, AUGMENTIN ES-600 should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

To minimize the potential for gastrointestinal intolerance, AUGMENTIN ES-600 should be taken at the start of a meal. Absorption of clavulanate potassium may be enhanced when AUGMENTIN ES-600 is administered at the start of a meal.

2.2 Dosage in Pediatric Patients

Pediatric patients 3 months and older: Based on the amoxicillin component (600 mg/5 mL), the recommended dose of AUGMENTIN ES-600 is 90 mg/kg/day divided every 12 hours, administered for 10 days (see chart below). This dose provides 6.4 mg/kg/day of the clavulanic acid component.

Body Weight (kg)	Volume of AUGMENTIN ES-600 for oral suspension providing 90 mg/kg/day

8	3 mL twice daily
12	4.5 mL twice daily
16	6 mL twice daily
20	7.5 mL twice daily
24	9 mL twice daily
28	10.5 mL twice daily
32	12 mL twice daily
36	13.5 mL twice daily

Pediatric patients weighing 40 kg and more: Experience with AUGMENTIN ES-600 in this group is not available.

2.3 Dosage in Adult Patients

Experience with AUGMENTIN ES-600 in adults is not available and adults who have difficulty swallowing should not be given AUGMENTIN ES-600 in place of the 500 mg or 875 mg tablet of AUGMENTIN.

2.4 Dosage in Patients with Hepatic Impairment

Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals *[see Warnings and Precautions (5)]*.

2.5 Preparation of the Oral Suspension

Directions for Mixing Oral Suspension: Prepare a suspension at time of dispensing as follows: Tap bottle until all powder flows freely. Measure the total amount of water (see chart below) to be added in two parts. Add approximately 2/3 of the total amount of water for reconstitution, replace cap and shake vigorously to suspend powder. Add remainder of the water (that had been measured), replace cap and again shake vigorously.

AUGMENTIN ES-600, USP	
Bottle Size	Amount of Water Required for Reconstitution
75 mL	70 mL
125 mL	110 mL
200 mL	180 mL

Each teaspoonful (5 mL) will contain 600 mg of amoxicillin as the trihydrate, and 42.9 mg of clavulanic acid as the potassium salt.

Shake oral suspension well before each use. Suspension must be refrigerated. Discard after 10 days. Suspension is off-white at time of reconstitution; some color change is normal during the dosing period.

***Flavoring Information*:** For patients who wish to alter the taste of AUGMENTIN ES-600, immediately after reconstitution 1 drop of FLAVORx™ (apple, banana cream, bubble gum, cherry, or watermelon flavor) may be added for every 5 mL of AUGMENTIN ES-600. The resulting suspension is stable for 10 days under refrigeration. Stability of AUGMENTIN ES-600 when mixed with other flavors distributed by FLAVORx has not been evaluated for flavors other than the 5 flavors listed above.

2.6 Switching between Dosage Forms and between Strengths

AUGMENTIN ES-600 does not contain the same amount of clavulanic acid (as the potassium salt) as any of the other suspensions of AUGMENTIN. AUGMENTIN ES-600 contains 42.9 mg of clavulanic acid per 5 mL, whereas the 200 mg/28.5 mg per 5 mL suspension of AUGMENTIN contains 28.5 mg clavulanic acid per 5 mL and the 400 mg/57 mg per 5 mL suspension of AUGMENTIN contains 57 mg clavulanic acid per 5 mL. Therefore, the 200 mg/28.5 mg per 5 mL and 400 mg/57 mg per 5 mL suspensions of AUGMENTIN should not be substituted for AUGMENTIN ES-600 as they are not interchangeable.

3 DOSAGE FORMS AND STRENGTHS

Augmentin ES-600 for oral suspension, USP:

- **600 mg/42.9 mg per 5 mL:** Strawberry cream-flavored for oral suspension (each 5 mL of reconstituted suspension contains 600 mg of amoxicillin as the trihydrate, and 42.9 mg of clavulanic acid as the potassium salt).

4 CONTRAINDICATIONS

4.1 Serious Hypersensitivity Reactions

AUGMENTIN ES-600 is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis or Stevens-Johnson syndrome) to amoxicillin, clavulanate, or to other beta-lactam antibacterial drugs (e.g., penicillins and cephalosporins).

4.2 Cholestatic Jaundice/Hepatic Dysfunction

AUGMENTIN ES-600 is contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with treatment with Amoxicillin and Clavulanate Potassium.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Allergic Reactions, including Anaphylaxis

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam antibacterials, including AUGMENTIN ES-600. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. Before initiating therapy

with AUGMENTIN ES-600, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, discontinue AUGMENTIN ES-600 and institute appropriate therapy.

5.2 Severe Cutaneous Adverse Reactions

AUGMENTIN ES-600 may cause severe cutaneous adverse reactions (SCAR), such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP). If patients develop a skin rash, they should be monitored closely, and AUGMENTIN ES-600 discontinued if lesions progress.

5.3 Hepatic Dysfunction

Use AUGMENTIN ES-600 with caution in patients with evidence of hepatic dysfunction. Hepatic toxicity associated with the use of AUGMENTIN ES-600 is usually reversible. Deaths have been reported (fewer than one death reported per estimated four million prescriptions worldwide). These have generally been cases associated with serious underlying diseases or concomitant medications *[see Contraindications (4.2) and Adverse Reactions (6.2)]*.

5.4 *Clostridioides difficile*-Associated Diarrhea (CDAD)

Clostridioides difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including AUGMENTIN ES-600, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.5 Skin Rash in Patients with Mononucleosis

A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash. Thus, AUGMENTIN ES-600 should not be administered to patients with mononucleosis.

5.6 Potential for Microbial Overgrowth

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Pseudomonas* spp. or *Candida* spp.), the drug should be discontinued, and appropriate therapy instituted.

5.7 Phenylketonurics

AUGMENTIN ES-600 contains aspartame which contains phenylalanine. Each 5 mL of suspension of AUGMENTIN ES-600 contains 7 mg phenylalanine.

5.8 Development of Drug-Resistant Bacteria

Prescribing AUGMENTIN ES-600 in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

6 ADVERSE REACTIONS

The following are discussed in more detail in other sections of the labeling *[see Warnings and Precautions (5)]*:

- Anaphylactic reactions *[see Warnings and Precautions (5.1)]*
- Severe Cutaneous Adverse Reactions (SCAR) *[see Warnings and Precautions (5.2)]*
- Hepatic Dysfunction *[see Warnings and Precautions (5.3)]*
- *Clostridioides difficile*-Associated Diarrhea (CDAD) *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Two clinical trials evaluated the safety of a 10-day treatment course of AUGMENTIN ES-600 90/6.4 mg/kg/day, divided every 12 hours, in pediatric patients with acute otitis media *[see Clinical Studies (14)]*. The first trial involved 521 pediatric patients (3 months to 50 months) and the second trial involved 450 pediatric patients (3 months to 12 years). In the intent-to-treat population of the first trial of 521 patients, the most frequently reported adverse events were vomiting (7%), fever (6%), contact dermatitis (i.e., diaper rash) (6%), upper respiratory tract infection (4%), and diarrhea (4%). Protocol-defined diarrhea (i.e., 3 or more watery stools in one day or 2 watery stools per day for 2 consecutive days as recorded on diary cards) occurred in 13% of patients.

The primary objective of the second study was to compare the safety of AUGMENTIN ES-600 (90/6.4 mg/kg/day, divided every 12 hours) to AUGMENTIN (45/6.4 mg/kg/day, divided every 12 hours) for ten days. There was no statistically significant difference between treatments in the proportion of patients with 1 or more adverse events. The most frequently reported adverse reactions for AUGMENTIN ES-600 and the comparator of AUGMENTIN were coughing (12% versus 7%), vomiting (7% versus 8%), contact dermatitis (i.e., diaper rash, 6% versus 5%), fever (6% versus 4%), and upper respiratory infection (3% versus 9%), respectively. The frequencies of protocol-defined diarrhea with AUGMENTIN ES-600 (11%) and AUGMENTIN (9%) were not statistically different. Two patients in the group treated with AUGMENTIN ES-600 and one patient in the group treated with AUGMENTIN were withdrawn due to diarrhea.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following have been identified during postmarketing use of AUGMENTIN products, including AUGMENTIN ES-600. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to AUGMENTIN.

Gastrointestinal: Diarrhea, nausea, vomiting, indigestion, gastritis, stomatitis, glossitis, black "hairy" tongue, mucocutaneous candidiasis, enterocolitis, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment *[see Warnings and Precautions (5)]*.

Immune: Hypersensitivity reactions, anaphylactic/anaphylactoid reactions (including shock), angioedema, serum sickness-like reactions (urticaria or skin rash accompanied by arthritis, arthralgia, myalgia, and frequently fever), hypersensitivity vasculitis *[see Warnings and Precautions (5.1)]*.

Skin and Appendages: Rashes, pruritus, urticaria, erythema multiforme, SJS, TEN, DRESS, AGEP, exfoliative dermatitis *[see Warnings and Precautions (5.2)]*.

Liver: A moderate rise in AST (SGOT) and/or ALT (SGPT) has been noted in patients treated with ampicillin-class antibacterials. Hepatic dysfunction, including increases in serum transaminases (AST and/or ALT), serum bilirubin, and/or alkaline phosphatase, has been infrequently reported with AUGMENTIN or AUGMENTIN ES-600. It has been reported more commonly in the elderly, in males, or in patients on prolonged treatment. The histologic findings on liver biopsy have consisted of cholestatic, hepatocellular, or mixed cholestatic-hepatocellular changes. The onset of signs/symptoms of hepatic dysfunction may occur during or several weeks after therapy has been discontinued. The hepatic dysfunction, which may be severe, is usually reversible. Deaths have been reported *[see Contraindications (4.2), Warnings and Precautions (5.3)]*.

Renal: Interstitial nephritis and hematuria have been reported. Crystalluria has also been reported *[see Overdosage (10)]*.

Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. There have been reports of increased prothrombin time in patients receiving AUGMENTIN and anticoagulant therapy concomitantly.

Central Nervous System: Agitation, anxiety, behavioral changes, aseptic meningitis, confusion, convulsions, dizziness, insomnia, and reversible hyperactivity have been reported.

Miscellaneous: Tooth discoloration (brown, yellow, or gray staining) has been reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

7 DRUG INTERACTIONS

7.1 Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with AUGMENTIN ES-600 may result in increased and prolonged blood levels of amoxicillin. Co-administration of probenecid is not recommended.

7.2 Oral Anticoagulants

Abnormal prolongation of prothrombin time (increased international normalized ratio [INR]) has been reported in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

7.3 Allopurinol

The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. It is not known whether this potentiation of amoxicillin rashes is due to allopurinol or the hyperuricemia present in these patients. There are no data with AUGMENTIN ES-600 and allopurinol administered concurrently.

7.4 Oral Contraceptives

AUGMENTIN ES-600 may affect intestinal flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

7.5 Effects on Laboratory Tests

High urine concentrations of amoxicillin may result in false-positive reactions when testing for the presence of glucose in urine using CLINITEST®, Benedict's Solution, or Fehling's Solution. Since this effect may also occur with AUGMENTIN ES-600, it is recommended that glucose tests based on enzymatic glucose oxidase reactions be used.

Following administration of amoxicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Reproduction studies performed in pregnant rats and mice given AUGMENTIN (2:1 ratio formulation of amoxicillin:clavulanate) at oral dosages up to 1200 mg/kg/day revealed no evidence of harm to the fetus due to AUGMENTIN. The amoxicillin doses in rodents (based on body surface area and assuming a 20 kg child) were approximately 2 times (rats) or equal to (mice) the recommended clinical AUGMENTIN ES-600 dose of 90/6.4 mg/kg/day. For clavulanate, these dose multiples were approximately 15 times and 7.5 times the recommended daily dose of AUGMENTIN ES-600.

8.2 Labor and Delivery

Oral ampicillin-class antibacterial drugs are generally poorly absorbed during labor. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions, and duration of contractions. However, it is not known whether the use of AUGMENTIN in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary. In a single study in women with premature rupture of fetal membranes, it was reported that prophylactic treatment with AUGMENTIN may be associated with an increased risk of necrotizing enterocolitis in neonates.

8.3 Nursing Mothers

Ampicillin-class antibacterial drugs are excreted in human milk; therefore, caution should be exercised when AUGMENTIN is administered to a nursing woman.

8.4 Pediatric Use

Safety and efficacy of AUGMENTIN ES-600 in infants younger than 3 months have not been established. Safety and efficacy of AUGMENTIN ES-600 have been demonstrated for treatment of acute otitis media in infants and children 3 months to 12 years *[see Clinical Studies (14)]*.

The safety and effectiveness of AUGMENTIN ES-600 have been established for the treatment of pediatric patients (3 months to 12 years) with acute bacterial sinusitis. This use is supported by evidence from adequate and well-controlled studies of AUGMENTIN XR™ Extended Release Tablets in adults with acute bacterial sinusitis, studies of AUGMENTIN ES-600 in pediatric patients with acute otitis media, and by similar pharmacokinetics of amoxicillin and clavulanate in pediatric patients taking AUGMENTIN ES-600 *[see Clinical Pharmacology (12)]* and adults taking AUGMENTIN XR.

10 OVERDOSAGE

Following overdosage, patients have experienced primarily gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhea. Rash, hyperactivity, or drowsiness have also been observed in a small number of patients.

In case of overdosage, discontinue AUGMENTIN ES-600, treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed. A prospective study of 51 pediatric patients at a poison control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms and do not require gastric emptying.[1]

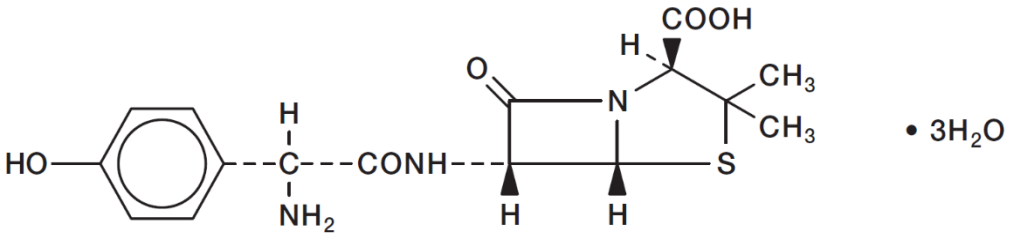
Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and clavulanate. Both amoxicillin and clavulanate are removed from the circulation by hemodialysis *[see Dosage and Administration (2)]*.

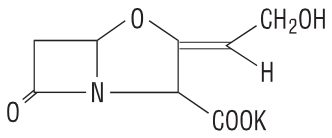
11 DESCRIPTION

AUGMENTIN ES-600, USP, is an oral antibacterial combination consisting of the semisynthetic antibacterial amoxicillin and the β-lactamase inhibitor, clavulanate potassium (the potassium salt of clavulanic acid). Amoxicillin is an analog of ampicillin, derived from the basic penicillin nucleus, 6-aminopenicillanic acid. The amoxicillin molecular formula is $C_{16}H_{19}N_3O_5S•3H_2O$, and the molecular weight is 419.46. Chemically, amoxicillin is (2*S*,5*R*,6*R*)-6-[*(R*)-(-)-2-Amino-2-(*p*-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3.2.0] heptane-2-carboxylic acid trihydrate and may be represented structurally as:



Clavulanic acid is produced by the fermentation of *Streptomyces clavuligerus*. It is a β-lactam structurally related to the penicillins and possesses the ability to inactivate a wide variety of β-lactamases by blocking the active sites of these enzymes. Clavulanic acid is particularly active against the clinically important plasmid-mediated β-lactamases frequently responsible for transferred drug resistance to penicillins and cephalosporins. The clavulanate potassium molecular formula is $C_8H_8KNO_5$ and the molecular weight is 237.25. Chemically,

clavulanate potassium is potassium (*Z*)-(2*R*,5*R*)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate and may be represented structurally as:



Following constitution, each 5 mL of oral suspension contains 600 mg of amoxicillin as the trihydrate and 42.9 mg of clavulanic acid (equivalent to 51.1 mg of clavulanate potassium).

Inactive Ingredients: Aspartame, colloidal silicon dioxide, strawberry cream flavor, xanthan gum, sodium carboxymethylcellulose, and silicon dioxide *[see Warnings and Precautions (5.7)]*.

Each 5 mL of reconstituted AUGMENTIN ES-600 contains 0.23 mEq potassium.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

AUGMENTIN ES-600 is an antibacterial drug *[see Microbiology (12.4)]*.

12.3 Pharmacokinetics

The pharmacokinetics of amoxicillin and clavulanate were determined in a study of 19 pediatric patients, 8 months to 11 years, given AUGMENTIN ES-600 at an amoxicillin dose of 45 mg/kg q12h with a snack or meal. The mean plasma amoxicillin and clavulanate pharmacokinetic parameter values are listed in the following table.

Table 1. Mean (±SD) Plasma Amoxicillin and Clavulanate Pharmacokinetic Parameter Values Following Administration of 45 mg/kg of AUGMENTIN ES-600 Every 12 Hours to Pediatric Patients

PARAMETER	AMOXICILLIN	CLAVULANATE
C_{max} (mcg/mL)	15.7 ± 7.7	1.7 ± 0.9
T_{max} (hr)	2.0 (1.0 to 4.0)	1.1 (1.0 to 4.0)
AUC_{0-T} (mcg*hr/mL)	59.8 ± 20.0	4.0 ± 1.9
T½ (hr)	1.4 ± 0.3	1.1 ± 0.3
CL/F (L/hr/kg)	0.9 ± 0.4	1.1 ± 1.1

* Arithmetic mean ± standard deviation, except T_{max} values which are medians (ranges).

The effect of food on the oral absorption of AUGMENTIN ES-600 has not been studied.

Approximately 50% to 70% of the amoxicillin and approximately 25% to 40% of the clavulanic acid are excreted unchanged in urine during the first 6 hours after administration of 10 mL of 250 mg/5 mL suspension of AUGMENTIN.

Concurrent administration of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid.

Neither component in AUGMENTIN ES-600 is highly protein-bound; clavulanic acid has been found to be approximately 25% bound to human serum and amoxicillin approximately 18% bound.

Oral administration of a single dose of AUGMENTIN ES-600 at 45 mg/kg (based on the amoxicillin component) to pediatric patients, 9 months to 8 years, yielded the following pharmacokinetic data for amoxicillin in plasma and middle ear fluid (MEF):

Table 2. Amoxicillin Concentrations in Plasma and Middle Ear Fluid Following Administration of 45 mg/kg of AUGMENTIN ES-600 to Pediatric Patients

Timepoint		Amoxicillin concentration in plasma (mcg/mL)	Amoxicillin concentration in MEF (mcg/mL)
1 hour	mean median range	7.7 9.3 1.5 to 14.0 (n equals 5)	3.2 3.5 0.2 to 5.5 (n equals 4)
2 hour	mean median range	15.7 13.0 11.0 to 25.0 (n equals 7)	3.3 2.4 1.9 to 6 (n equals 5)
3 hour	mean median range	13.0 12.0 5.5 to 21.0 (n equals 5)	5.8 6.5 3.9 to 7.4 (n equals 5)

Dose administered immediately prior to eating.

Amoxicillin diffuses readily into most body tissues and fluids, with the exception of the brain and spinal fluid. The results of experiments involving the administration of clavulanic acid to animals suggest that this compound, like amoxicillin, is well distributed in body tissues.

12.4 Microbiology

Amoxicillin is a semisynthetic antibacterial with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin is, however, susceptible to degradation by β-lactamases, and therefore, its spectrum of activity does not include organisms which produce these enzymes. Clavulanic acid is a β-lactam, structurally related to penicillin, which possesses the ability to inactivate a wide range of β-lactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. In particular, it has good activity against the clinically important plasmid-mediated β-lactamases frequently found responsible for transferred drug resistance.

The clavulanic acid component of AUGMENTIN ES-600 protects amoxicillin from degradation by β-lactamase enzymes and effectively extends the antibacterial spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other β-lactam antibacterials. Thus, AUGMENTIN ES-600 possesses the distinctive properties of a broad spectrum antibacterial and a β-lactamase inhibitor.

Amoxicillin/clavulanic acid has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections *[see Indications and Usage (1)]*.

Gram-Positive bacteria:

Streptococcus pneumoniae (including isolates with penicillin MICs less than or equal to 2 mcg/mL)

Gram-Negative bacteria:
Haemophilus influenzae (including β-lactamase-producing isolates)

Moraxella catarrhalis (including β-lactamase-producing isolates)

The following in vitro data are available, but their clinical significance is unknown. At least 90% of the following microorganisms exhibit in vitro minimum inhibitory concentrations (MICs) less than or equal to the susceptible breakpoint for amoxicillin/clavulanic acid. However, the safety and efficacy of amoxicillin/clavulanic acid in treating infections due to these microorganisms have not been established in adequate and well-controlled trials.

Gram-Positive bacteria:
Staphylococcus aureus (including β-lactamase-producing isolates)

Staphylococci which are resistant to methicillin/oxacillin must be considered resistant to amoxicillin/clavulanic acid.

Streptococcus pyogenes

S. pyogenes do not produce β-lactamase, and therefore, are susceptible to amoxicillin alone. Adequate and well-controlled clinical trials have established the effectiveness of amoxicillin alone in treating certain clinical infections due to *S. pyogenes.*

Susceptibility Test Methods:

For specific information regarding susceptibility test interpretive criteria and associated test methods and quality control standards recognized by FDA for this drug, please see: *https://www.fda.gov/STIC*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. AUGMENTIN (4:1 ratio formulation of amoxicillin:clavulanate) was non-mutagenic in the Ames bacterial mutation assay, and the yeast gene conversion assay. AUGMENTIN was weakly positive in the mouse lymphoma assay, but the trend toward increased mutation frequencies in this assay occurred at concentrations that were also associated with decreased cell survival. AUGMENTIN was negative in the mouse micronucleus test, and in the dominant

lethal assay in mice. Potassium clavulanate alone was tested in the Ames bacterial mutation assay and in the mouse micronucleus test and was negative in each of these assays.

AUGMENTIN (2:1 ratio formulation of amoxicillin:clavulanate) at oral doses of up to 1,200 mg/kg/day was found to have no effect on fertility and reproductive performance in rats. Based on body surface area (assuming a 20 kg child), this dose of amoxicillin is approximately 2 times the recommended clinical AUGMENTIN ES-600 dose of 90/6.4 mg/kg/day. For clavulanate, the dose multiple is approximately 15 times higher than the recommended clinical daily dose, also based on body surface area.

14 CLINICAL STUDIES

Two clinical studies were conducted in pediatric patients with acute otitis media. A non-comparative, open-label study assessed the bacteriologic and clinical efficacy of AUGMENTIN ES-600 (90/6.4 mg/kg/day, divided every 12 hours) for 10 days in 521 pediatric patients (3 to 50 months) with acute otitis media. The primary objective was to assess bacteriological response in children with acute otitis media due to *S. pneumoniae* with amoxicillin/clavulanic acid MICs of 4 mcg/mL. The study sought the enrollment of patients with the following risk factors: Failure of antibacterial therapy for acute otitis media in the previous 3 months, history of recurrent episodes of acute otitis media, 2 years or younger, or daycare attendance. Prior to receiving AUGMENTIN ES-600, all patients had tympanocentesis to obtain middle ear fluid for bacteriological evaluation. Patients from whom *S. pneumoniae* (alone or in combination with other bacteria) was isolated had a second tympanocentesis 4 to 6 days after the start of therapy. Clinical assessments were planned for all patients during treatment (4 to 6 days after starting therapy), as well as 2 to 4 days post-treatment and 15 to 18 days post-treatment. Bacteriological success was defined as the absence of the pretreatment pathogen from the on-therapy tympanocentesis specimen. Clinical success was defined as improvement or resolution of signs and symptoms. Clinical failure was defined as lack of improvement or worsening of signs and/or symptoms at any time following at least 72 hours of AUGMENTIN ES-600; patients who received an additional systemic antibacterial drug for otitis media after 3 days of therapy were considered clinical failures. Bacteriological eradication on therapy (day 4 to 6 visit) in the per protocol population is summarized in the following table:

Table 3. Bacteriologic Eradication Rates in the Per Protocol Population

	Bacteriologic Eradication on Therapy		
Pathogen	**n/N**	**%**	**95% CI***
All *S. pneumoniae*	121/123	98	(94.3, 99.8)
S. pneumoniae with penicillin MIC equal to 2 mcg/mL	19/19	100	(82.4, 100.0)
S. pneumoniae with penicillin MIC equal to 4 mcg/mL	12/14	86	(57.2, 98.2)
H. influenzae	75/81	93	(84.6, 97.2)
M. catarrhalis	11/11	100	(71.5, 100.0)

* CI equals confidence intervals; 95% CIs are not adjusted for multiple comparisons.

Clinical assessments were made in the per protocol population 2 to 4 days post-therapy and 15 to 18 days post-therapy. Patients who responded to therapy 2 to 4 days post-therapy were

followed for 15 to 18 days post-therapy to assess them for acute otitis media. Non-responders at 2 to 4 days post-therapy were considered failures at the latter timepoint.

Table 4. Clinical Assessments in the Per Protocol Population (Includes *S. pneumoniae* Patients with Penicillin MICs equal to 2 or 4 mcg/mL*)

	2 to 4 Days Post-Therapy (Primary Endpoint)		
Pathogen	**n/N**	**%**	**95% CI†**
All *S. pneumoniae*	122/137	89	(82.6, 93.7)
S. pneumoniae with penicillin MIC equal to 2 mcg/mL	17/20	85	(62.1, 96.8)
S. pneumoniae with penicillin MIC equal to 4 mcg/mL	11/14	79	(49.2, 95.3)
H. influenzae	141/162	87	(80.9, 91.8)
M. catarrhalis	22/26	85	(65.1, 95.6)

	15 to 18 Days Post-Therapy‡ (Secondary Endpoint)		
Pathogen	**n/N**	**%**	**95% CI†**
All *S. pneumoniae*	95/136	70	(61.4, 77.4)
S. pneumoniae with penicillin MIC equal to 2 mcg/mL	11/20	55	(31.5, 76.9)
S. pneumoniae with penicillin MIC equal to 4 mcg/mL	5/14	36	(12.8, 64.9)
H. influenzae	106/156	68	(60.0, 75.2)
M. catarrhalis	14/25	56	(34.9, 75.6)

* *S. pneumoniae* strains with penicillin MICs of 2 or 4 mcg/mL are considered resistant to penicillin.
† CI equals confidence intervals; 95% CIs are not adjusted for multiple comparisons.
‡ Clinical assessments at 15 to 18 days post-therapy may have been confounded by viral infections and new episodes of acute otitis media with time elapsed post-treatment.

In the intent-to-treat analysis, overall clinical outcomes at 2 to 4 days and 15 to 18 days post-treatment in patients with *S. pneumoniae* with penicillin MIC equal to 2 mcg/mL and 4 mcg/mL were 29/41 (71%) and 17/41 (42%), respectively.

15 REFERENCES

1. Swanson-Biearman B, Dean BS, Lopez G, Krenzelok EP. The effects of penicillin and cephalosporin ingestions in children less than six years of age. Vet Hum Toxicol. 1988; 30:66-67.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

AUGMENTIN ES-600®
amoxicillin and clavulanate potassium for oral suspension, USP:

600 mg/42.9 mg per 5 mL: Strawberry cream-flavored powder for oral suspension. Following constitution, each 5 mL of oral suspension contains 600 mg of amoxicillin as the trihydrate and 42.9 mg of clavulanic acid as the potassium salt (equivalent to 51.1 mg of clavulanate potassium).

NDC 81964-003-51	75 mL bottle
NDC 81964-003-69	125 mL bottle
NDC 81964-003-54	200 mL bottle

Storage
Store dry powder for oral suspension at or below 25°C (77°F). Dispense in original container. Store reconstituted suspension under refrigeration. Discard unused suspension after 10 days.

17 PATIENT COUNSELING INFORMATION

Administration Instructions
Inform patients to take AUGMENTIN ES-600 every 12 hours with a meal or snack to reduce the possibility of gastrointestinal upset. If diarrhea develops and is severe or lasts more than 2 or 3 days, call your doctor.

Allergic Reactions
Counsel patients that AUGMENTIN ES-600 contains a penicillin class drug product that can cause allergic reactions in some individuals.

Severe Cutaneous Adverse Reactions (SCAR)
Advise patients about the signs and symptoms of serious skin manifestations. Instruct patients to stop taking AUGMENTIN ES-600 immediately and promptly report the first signs or symptoms of skin rash, mucosal lesions, or any other sign of hypersensitivity *[see Warnings and Precautions (5.2)]*.

Diarrhea
Counsel patients that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial is discontinued. Sometimes after starting treatment with antibacterial drugs, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as 2 or more months after having taken the last dose of the antibacterial drug. If this occurs, patients should contact their physician as soon as possible.

Antibacterial Resistance

Patients should be counseled that antibacterial drugs, including AUGMENTIN ES-600, should only be used to treat bacterial infections. Antibacterial drugs do not treat viral infections (e.g., the common cold). When AUGMENTIN ES-600 is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by AUGMENTIN ES-600 or other antibacterial drugs in the future.

Storage Instructions

Keep suspension refrigerated. Shake well before using. When dosing a child with the suspension (liquid) of AUGMENTIN ES-600, use a dosing spoon or medicine dropper. Be sure to rinse the spoon or dropper after each use. Bottles of suspension of AUGMENTIN ES-600 may contain more liquid than required. Follow your doctor's instructions about the amount to use and the days of treatment your child requires. Discard any unused medicine.

Phenylketonuria

Counsel patients with phenylketonuria: Each 5 mL of suspension of AUGMENTIN ES-600 contains 7 mg phenylalanine.

Manufactured by:
USAntibiotics, LLC
Bristol, TN 37620 (USA)

Attachment 4

From: General Board of Pharmacy Subscriber List on behalf of California State Board of Pharmacy
To: PHARM-GENERAL@SUBSCRIBE.DCALISTS.CA.GOV
Subject: Information on Rights to Contraceptive Care
Date: Thursday, February 22, 2024 1:36:37 PM

During the November 1-2, 2023, Board Meeting, the Board received a presentation on research findings relating to implementation of pharmacist sexual and reproductive health services in California, including emergency contraception. Recent research findings suggest there may be a lack of awareness about certain provisions of pharmacy law and FDA actions relating to emergency contraception drugs levonorgestrel (also known as "Plan B One-Step") and ulipristal acetate (also known as "ella"), and the Board seeks to remind pharmacists of the following:

- **Legal Requirements to Provide Access to Contraception to Minors:** There is no age restriction to purchase over-the-counter levonorgestrel emergency contraception, and California law permits minors to consent to hormonal contraception to prevent pregnancy without the consent of a parent or guardian. (Cal. Family Code, §§ 6925, 6927.) More information about levonorgestrel is available here.
- **Independent Pharmacist Furnishing of Hormonal and Emergency Contraception:** Pharmacists may independently furnish hormonal and emergency contraception pursuant to the protocols established in California Code of Regulations, Title 16, Sections 1746 and 1746.1, after completing training on emergency or hormonal contraception. As required in the protocols, a pharmacist must provide patients with the emergency or hormonal contraception fact sheet. Information on the protocols and fact sheets are available here and here. As a reminder, a range of emergency contraception options are available, with varying efficacies for different populations.
- **12-Month Supply of Hormonal Contraception:** Business and Professions Code Section 4064.5(f) permits pharmacists who independently furnish self- administered hormonal contraception pursuant to the state protocol to furnish up to a 12-month supply at one time, at the patient's request if allowed by the patient's health plan.
- **Timely Access to Emergency Contraception:** As required by Business and Professions Code Section 733(b)(3) and (d), an employer is required to establish protocols that ensure that a patient has timely access to a prescribed emergency contraception drug if a pharmacist refuses to dispense the medication based on ethical, moral or religious grounds.

More information about the research and findings is available here and here.

https://pharmacy.ca.gov/webapplications/apps/subscribe/index.shtml

Attachment 5

Board of Pharmacy

Enforcement Workload Statistics FY 2024/25

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	706	0	0	0	706
Closed	764	0	0	0	764
					Quarter Ending
Pending	1,918	0	0	0	1,918
Average Days for Investigation	237	0	0	0	237

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	830	0	0	0	830
Drug Diversion / Fraud	242	0	0	0	242
Prescription Drug Abuse	178	0	0	0	178
Compounding	56	0	0	0	56
Outsourcing	7	0	0	0	7
Probation / PRP	36	0	0	0	36
Enforcement	59	0	0	0	59
Criminal Conviction	510	0	0	0	510

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	41	0	0	0	41
Closed					
Approved	29	0	0	0	29
Denied	17	0	0	0	17
Total Closed (includes withdrawn)	***49***	***0***	***0***	***0***	***49***
Pending	90	0	0	0	90

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	356	0	0	0	356
Non-Jurisdictional	86	0	0	0	86
No Violation	37	0	0	0	37
No Further Action	47	0	0	0	47
Other / Non-Substantiated	40	0	0	0	40
Subject Educated	19	0	0	0	19

Letter of Admonishments / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	0	0	0	44
Citations Issued	156	0	0	0	156
Proof of Abatement Requested	12	0	0	0	12
Appeals Referred to AG's Office	63	0	0	0	63
Dismissed	7	0	0	0	7
Total Fines Collected	***$612,872***	***$0***	***$0***	***$0***	***$612,872***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	43	0	0	0	43
Pleadings Filed	65	0	0	0	65
Total Closed	68	0	0	0	68
Pending					Quarter Ending
Pre-Accusation	123	0	0	0	123
Post-Accusation	181	0	0	0	181
Total Pending	**304**	**0**	**0**	**0**	**304**

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	4	0	0	0	4
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	20	0	0	0	20
Designated Representative	1	0	0	0	1
Wholesaler	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	***25***	***0***	***0***	***0***	***25***

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	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	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***	***0***	***0***	***0***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation, stayed, probation					
Pharmacist	11	0	0	0	11
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	3	0	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	5	0	0	0	5
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***20***	***0***	***0***	***0***	***20***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	5	0	0	0	5
Designated Representative	0	0	0	0	0
Wholesaler	2	0	0	0	2
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***8***	***0***	***0***	***0***	***8***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	7	0	0	0	7
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	1	0	0	0	1
Designated Representative	1	0	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	3	0	0	0	3
Sterile Compounding	1	0	0	0	1
Outsourcing	0	0	0	0	0
Total	***14***	***0***	***0***	***0***	***14***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted (with or w/o conditions)					
Pharmacist	0	0	0	0	0
Intern Pharmacist	2	0	0	0	2
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	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	***2***	***0***	***0***	***0***	***2***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	2	0	0	0	2
Designated Representative	0	0	0	0	0
Wholesaler	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	***2***	***0***	***0***	***0***	***2***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$281,598***	***$0***	***$0***	***$0***	***$281,598***
Cost Recovery Collected	***$198,145***	***$0***	***$0***	***$0***	***$198,145***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	0	0	0	5
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	1	0	0	0	1
Cease and Desist - Outsourcing	0	0	0	0	0
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	166	0	0	0	166
Intern Pharmacist	4	0	0	0	4
Pharmacy Technician	29	0	0	0	29
Designated Representative	1	0	0	0	1
Wholesaler / 3PL	3	0	0	0	3
Pharmacy	54	0	0	0	54
Sterile Compounding	9	0	0	0	9
Outsourcing	0	0	0	0	0
Total	***266***	***0***	***0***	***0***	***266***
Probation Compliance Measures					Total
Probation Office Conferences	21	0	0	0	21
Probation Interviews / Site Inspections	183	0	0	0	183
Probation Terminated / Completed	16	0	0	0	16
Referred to AG for Non-Compliance	0	0	0	0	0

As of 9/30/2024

Board of Pharmacy

Citation and Fine Statistics FY 2024/25

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	15	0	0	0	15
Pharmacist-in-Charge with Fine*	9	0	0	0	9
Pharmacist no Fine	24	0	0	0	24
Pharmacist-in-Charge no Fine*	24	0	0	0	24
Pharmacy with Fine	56	0	0	0	56
Pharmacy no Fine	29	0	0	0	29
Pharmacy Technician with Fine	9	0	0	0	9
Pharmacy Technician no Fine	11	0	0	0	11
Wholesalers	0	0	0	0	0
Designated Representative	1	0	0	0	1
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	2	0	0	0	2
Miscellaneous**	20	0	0	0	20
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	0	0	0	0	0

*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	%
1761(a)/4306.5(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Acts or omissions that involve, in whole or in part, the inappropriate	13%	1716 - Variation from prescription	38%	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	17%
4059(a) - Furnishing dangerous drugs without a prescription	13%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	18%	4059(a) - Furnishing dangerous drugs without a prescription	13%
11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	13%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	11%	4126.5(a)(5)(c) - A Pharmacy may furnish dangerous drugs only to the following: (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law. (c) Nothwithstanding any other law…	13%
4126.5(a)(5)(c) - A Pharmacy may furnish dangerous drugs only to the following: (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law. (c) Nothwithstanding any other law…	13%	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	7%	11153(a) - Responsibility for legitimacy of prescription; a prescription for a controlled substance shall only be issued for a legitimate medical purpose...	13%
4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	10%	1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	5%	1715(b)(2) - Self-Assessment of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment within 30 days whenever: there is a change in pharmacist-in-charge	8%
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	10%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	5%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	8%
1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	7%	1714(c) - Operational Standards and Security; pharmacy, fixtures and equipment shall be maintained in a sanitary and orderly condition	5%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	8%
1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	7%	1717.5(a) - (a) A pharmacy may offer a program to automatically refill prescriptions provided the pharmacy complies with this section….	4%	733(a) - Dispensing prescription drugs and devices- No licentiate shall obstruct a patient in obtaining a prescription	8%
1716 - Variation from prescription	7%	1714(b)(d) - Operational Standards and Security; pharmacy responsible for pharmacy security/Each pharmacist when on duty is responsible for security	4%	1776.1(a)(g) - (a) Pharmacies may provide Take-back services to the public. Retail pharmacies and hospital/clinics with onsite pharmacies may maintain collection receptacles in their facilities….(g)	8%
1707.2(a) - Duty to consult: A pharmacist shall provide oral consultation to his or her patient or the agent of patient in all care settings	7%	4078(a)(1) - False or Misleading Label on Prescription; No person shall place a false or misleading label on a prescription	4%	1714(d) - Operational Standards and Security; Pharmacist responsible for pharmacy security	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. This data includes July 2024 through September 2024.

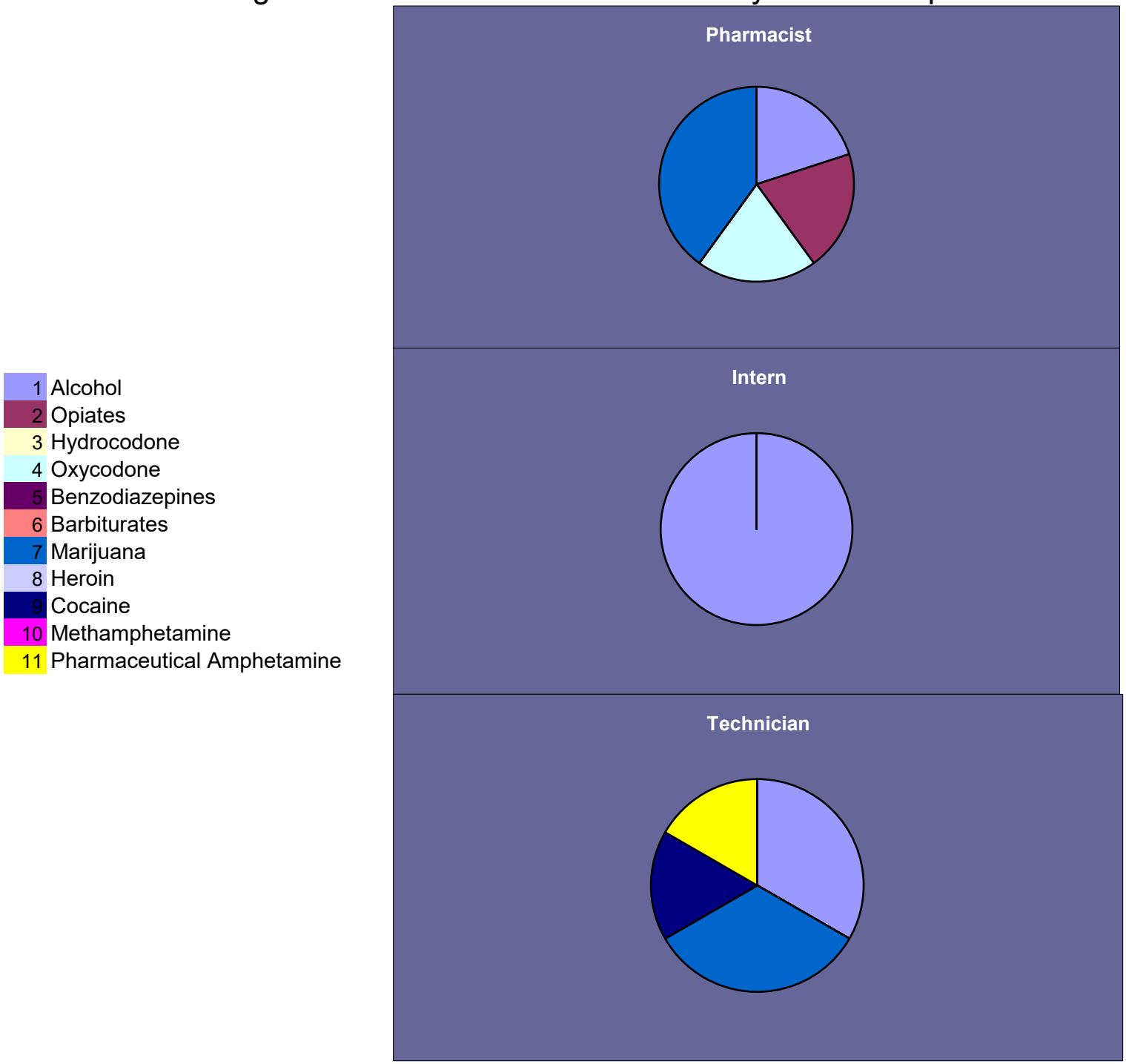
PRP Self-Referrals					
PRP Probation Referrals	3				
PRP Under Investigation	1				
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	4				
Pharmacists	5				
Intern Pharmacists					
Pharmacy Technicians	4				
Total New Probationers	9				
Total PRP Participants	29				
Recovery Agreements Reviewed	26				
Total Probationers	54				
Inspections Completed	28				
Referrals to Treatment (PRP and Probationers)	1				
Drug Test Ordered (PRP and Probationers)	433				
Drug Tests Conducted (PRP and Probationers)	421				
Relapsed (PRP and Probationers)					
Cease Practice/Suspension (PRP and Probationer	6				
Termination from PRP	1				
Probationers Referred for Discipline					
Successful Completion (PRP and Probationers)	1				
Termination (Probation)					
Voluntary Surrender (Probation)					
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)	1				1
Non-compliance in PRP or Probation	19				19
Other (PRP)					
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. This data includes July 2024 through September 2024.

Board of Pharmacy	July -Sep	Oct Dec	Jan Mar	Apr Jun	24/25
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 24/25**
Alcohol	1				1
Ambien	1				1
Opiates					
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines	2				2
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 24/25**
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 24/25**
Alcohol	2				2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana	2				2
Heroin					
Cocaine	1				1
Methamphetamine					
Pharmaceutical Amphetamine	1				1
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2024 to September 2024



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