**California State Board of Pharmacy**
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: April 20, 2022

LOCATION: Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833

Via WebEx

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at 9:02 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted as a hybrid meeting in person and with participation through WebEx and being webcast.

The meeting moderator provided updated WebEx instructions.

Chairperson Serpa welcomed Board Member Indira Cameron-Banks to the Board and Committee.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Indira Cameron-Banks, Seung Oh, Ricardo Sanchez, Debbie Veale, and Maria Serpa. A quorum was established.

Chairperson Serpa advised the public Agenda Item VI would not be discussed and would be deferred to another meeting.

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

Members of the public were provided the opportunity to provide comments for items not on the agenda.

No members of the public were present at the Sacramento location.

Members of public attending via WebEx were also provided with the opportunity to provide public comment.

The Committee heard public comment from a representative from Walgreens requesting reconsideration of the definition of compounding within or create an exception to the quality assurance requirements for items such as magic mouthwash. Public comment referenced action taken by Mississippi related to this issue.

Chairperson Serpa advised the Committee would be discussing compounding in depth about the implementation of USP standards.

## III. Approval of January 18, 2022, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes.

**Motion:** Approve the January 18, 2022, Committee Meeting minutes as presented.

**M/S**: Oh/Sanchez

Members of the public were provided with an opportunity to provide public comment at the Sacramento location and via WebEx; however, none were provided.

**Support: 6** **Oppose: 0** **Abstain: 0** **Not Present: 0**

| Committee Member | Vote |
|---|---|
| Cameron-Banks | Support |
| Oh | Support |
| Patel | Support |
| Sanchez | Support |
| Serpa | Support |
| Veale | Support |

**IV. Presentation, Discussion and Consideration of Hospital at Home Programs**

Member Serpa provided an overview of Hospital at Home (HaH) programs noting that these programs were established under a waiver program established by CMS that provides flexibility for certain health care services that can be provided outside of a traditional hospital setting and within a patient's home. As part of the program requirements, patient can only be admitted into a program from an emergency department or inpatient hospital bed and an in-person physician evaluation is required prior to starting the services. The meeting materials include the link to the CMS Hospital at Home Pharmacy FAQs.

Chairperson Serpa advised in December 2020, the California Department of Public Health released an all facilities letter (AFL) related to general acute care hospitals and its flexibility requirements for hospital at home programs. A link to the AFL was also included in the meeting materials. A review of the California Department of Health Care Services website reveals that a few hospitals within California have received approval to operate these programs.

Chairperson Serpa noted as part of the Committee's education on this topic, the Committee would receive two presentations today.

Chairperson Serpa introduced Pat Blaisdell, Vice President of Policy, with the California Hospital Association.

Ms. Blaisdell provided an over of the HaH program noting that it is a new and unique service and indicated that this is not the same as other services such as home health, case management, chronic care management, skilled nursing, remote patient monitoring or admission prevention.

Ms. Blaisdell reviewed during COVID-19, CMS noted hospital capacity was challenged by COVID surges and previous at-home hospital care models were successful. In May 2020, CMS issued a blanket Hospital Without Walls waiver and in November 2020 developed the Acute Hospital Care at Home (AHCaH) provider waiver.

Ms. Blaisdell reviewed the required services that must be provided as part of the AHCaH, including pharmacy services. Ms. Blaisdell indicated that seven hospitals have been approved by CMS. Members were advised that one hospital has received approval from CDPH to provide services and three are going through the process.

Ms. Blaisdell discussed some of the pharmacy related areas including patient self-administration of medication, bedside storage of medication, monitoring of medication temperature and the stocking and re-stocking of medication "kit."

Members were advised, that for the right patient, there is data that suggests the model is beneficial. CMS notes that the 7.14% of escalations trends lower than previously published results. CMS data suggests there is value in this type of program moving forward.

Members were advised that federal legislation has been introduced to extend the current CMS waiver, AHCaH program for an additional two years to allow for more additional data collection to evaluate the safety of the program. Legislation is also pending to allow for this at the state level.

Members were provided the opportunity to provide comments. However, no comments were provided.

Chairperson Serpa introduced Dr. Kyle Robb, American Society of Health System Pharmacists (ASHP) State Policy and Advocacy Associate. Dr. Robb provided history of the model at John Hopkins in 1995 and noted that initial trials were conducted between 1996 – 2002 that concluded HaH was feasible, safe, cost-effective, and met disease-specific quality standards at rates similar to acute hospital.

Dr. Robb provided an overview of the patient HaH experience which starts with the patient being identified in the emergency department, inpatient hospital bed or ambulatory clinic site. A patient must provide consent to transition to this program. Dr. Robb noted should tests be required that cannot be provided at home, a patient would be transported via medical transport. Members were advised that the most common acute conditions managed through HaH programs include heart failure, pneumonia, COPD exacerbation and soft tissue infections.

Dr. Robb advised ASHP released a report in November 2021 on HaH related to pharmacy services. Pharmacy considerations include medication handling, technology and patient information management, medication storage and waste disposal, workforce, and access to provisions of clinical services.

Dr. Robb reviewed medication storage and administration questions including ideal timing and quantify for delivery of medications; handling of missing medications; administration of medications; available emergency medications; securing and storing controlled substances; handling hazardous drug waste; and disposal of discontinued or unused medications.

Dr. Robb provided technology and information management issues include integration of information into the EHR, documentation of medication administration, and impact of patients with limited broadband internet access connecting to the care team.

Dr. Robb explained the provisions of clinical pharmacy services includes process to teach patients and validate medications were taken; completion of medication reconciliation; provision of medication management services; and 24/7 pharmacy coverage.

Dr. Rob provided ASHP HaH pharmacy future considerations included pharmacists involved in the planning, implementation and maintenance; legislative and regulatory framework to promote safe and effective medication use; education, training and resource to empower pharmacy workforce; and research additional HAH care models.

Member Veale asked about actions taken by other state jurisdictions. Dr. Robb provided the two states he spoke with about it were concerned with discouraging the practice by being too prescriptive and developing regulations too soon. They were making sure the hospitals participating were adhering to labeling requirements for outpatient prescriptions and being informed based on existing home infusion regulations. Dr. Robb reported none of the boards he spoke with felt is necessary to have comprehensive set of regulatory guidelines on currently regarding HaH, although it is early in the process.

Dr. Serpa noted that the program provides great opportunities, but there are concerns that may need to be addressed including some patient safety issues for medications in the first dose kits which would be administered prior to a pharmacist review; consideration of security of transportation and storage issues; controlled substances security; and documentation of administration as well as monitoring.

Member Veale agreed the concept could be a very positive idea and wanted to ensure the Board doesn't get in the way by overregulating.

Member Patel added closed door facilities currently provide prescription e-kits to skilled nursing facilities and this program mimics with the skilled nursing facilities. He noted there are current labeling and record keeping requirements for e-kits in place. If it is kept as is, they can operate within the current Medical Board requirements to operate a hospital.

Dr. Serpa noted these areas need to be reviewed and ensured they are there because it is a different license category. She noted there are differences in regulations between acute care and long-term care pharmacies. Dr. Serpa added there are opportunities to discuss to make sure the process is consistent and safe.

Members of the public were provided with an opportunity to provide public comment at the Sacramento location.

A representative of CVS Health commented in Idaho allow hospice e-kits listing the drugs that could be contained in it however it has now been removed from the regulations.

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

Dr. Serpa provided the Legislation and Regulation Committee was reviewing pending legislation in this area and the information learned today may help shape the Board's actions when considering this legislation. Dr. Serpa added at this time any further action may be premature until the Board's policy specific to these programs is understood. She added if these programs continue to operate, it will be very important to consider how pharmacy related care is provided in this type of patient care model to ensure patients receive appropriate care.

Member Veale inquired about a policy statement. Dr. Serpa indicated it might be premature as it is operating under a waiver. Ms. Sodergren indicated positions taken on pending legislation will indicate the Board's policy.

## V. Discussion and Consideration of Compounding by Board Licensees Outside of a Pharmacy

Chairperson Serpa referred to the meeting materials that provide some of the relevant sections of pharmacy law. Dr. Serpa noted Members have received comments about pharmacy personnel compounding outside of licensed pharmacies and Board staff have observed this practice as well. Dr. Serpa referred to the meeting materials where staff are familiar with some investigations and patient care issues that have been identified regarding some compounding practices in some locations.

Chairperson Serpa indicated her concern included:
• Board licensed technicians ordering drugs under a physician's license, compounding, and overseeing compounding in physician offices and/or licensed clinics with no pharmacist present.
• Board licensed technician working at an oncology medical practice, preparing cancer treatments for injection or infusion with no pharmacist present.
• Board licensed pharmacists compounding, overseeing compounding and providing additional pharmacy services in physician offices and/or licensed clinics following lower standards because they are not in a pharmacy.
• Board licensed pharmacists compounding and overseeing technicians at an unlicensed infusion center.

The Committee discussed managing the current jurisdiction and in the future additional jurisdictions as well as considering laws related to name tag requirements and licensees. The Committee agreed the Licensing Committee would be an appropriate avenue to discuss the issue about pharmacy technician licensure and name tags. The Committee agreed to add a new agenda item to discuss compounding in other practices outside of licensed pharmacies.

Chairperson Serpa continued for pharmacists compounding outside of a licensed pharmacy and not following compounding regulations, it was her understanding that as a pharmacist, the pharmacist is still required to follow all of the compounding regulations. Ms. Sodergren offered at the staff level to research the issue and see how other jurisdictions are addressing the issue as well as provide additional education on federal requirements. She reminded the Committee that the Standard of Care Ad Hoc Committee's work may impact how pharmacists are performing compounding.

Members of the public were provided with an opportunity to provide public comment at the Sacramento location.

A representative from CVS Health commented on consequences and suggested that going to a standard of care model may address issues.

Members of the public were provided with an opportunity to provide public comment through WebEx.

A representative from Kaiser encouraged the Board to remove statutory provisions that limit where a technician can work.

A representative from California Councill for the Advancement of Pharmacy agreed with the Kaiser representative and asked if pharmacy technicians can perform clerk duties.

Chairperson Serpa suggested that issues regarding pharmacy technicians be discussed under the Licensing Committee. The Committee agreed with the suggestion.

Chairperson Serpa summarized the Committee will continue to investigate with staff researching actions at the national level and compounding outside of pharmacy and request the Standard of Care Ad Hoc Committee address the issue.

Chairperson Serpa added the issue of unlicensed locations that do compounding by Board licensed personnel will be added to a future agenda regarding compounding.

**VI. Discussion and Consideration of the Proposed Revisions to Frequently Asked Questions Related to Automated Drug Delivery System (ADDS)**

This agenda item was deferred.

**VII. Review and Discussion of Enforcement Statistics**

Chairperson Serpa advised enforcement statistics were included in the meeting materials with a summary provided in the chair report. Dr. Serpa noted this fiscal year the Board has received 2,336 complaints and has closed 2,360 complaints. The Board has issued 230 Letters of Admonishment, 949 Citations and referred 120 cases to the Office of the Attorney General. The Board has revoked 44 licenses and accepted 67 disciplinary surrenders.

Members were provided the opportunity to provide comment; however, no comment was provided.

Members of the public were provided with an opportunity to provide public comment at the Sacramento location and through WebEx; however, no comment was provided.

**VIII. Future Committee Meeting Dates**

Chairperson Serpa advised the next Enforcement and Compounding Committee will be July 19, 2022. Dr. Serpa advised to watch for updates as the Enforcement and Compounding Committee was hoping to add an additional meeting date in August to discuss compounding.

**IX. Adjournment**

The meeting adjourned at 10:49 a.m.