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: July 19, 2022

LOCATION: Public Participation Via WebEx
NOTE: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Ricardo Sanchez, Public 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 with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa welcomed Board Member Renee Barker to the Board and Committee.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

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.

Alan Kim, nuclear pharmacists for Cardinal Health, requested that the Enforcement and Compounding Committee discuss Cardinal Health's request to increase the ratio given the unique operations. Dr. Kim was advised to contact the Executive Officer.

III. Approval of April 20, 2022, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes. Chairperson Serpa requested nonsubstantive changes be made and requested the following substantive change to be made was reflected on the screen:

Agenda Item V. Discussion and Consideration of Compounding by Board Licensees Outside a Pharmacy – Last paragraph edited to reflect:

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

Motion: Approve the April 20, 2022, Committee Meeting minutes as amended as well as discussed and reflected on the screen with corrections.

M/S: Oh/Patel

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

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

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

The Committee took a break from 9:12 a.m. to 9:18 a.m. Roll call was taken after break. Members present included Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; Indira Cameron-Banks, Public Member; and Maria Serpa, Licensee Member. A quorum was established.

IV. Discussion, Consideration, and Possible Recommendation to the Board to Approve Draft Changes to CCR Section 1715.1 related to Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge of Unlicensed AUDS

Chairperson Serpa advised relevant sections of Pharmacy Law were detailed in the meeting materials and established requirements for the use of automated unit-dose delivery systems, referred to as AUDS, under specified conditions. Related to this agenda item, are those AUDSs that are exempt from licensure by the Board but must otherwise comply with all other requirements for an automated drug delivery system.

Chairperson Serpa advised one such requirement is the completion of a self-assessment form for AUDS. Although the relevant regulation currently provides that a self-assessment must be completed annually, subsequently enacted statutory changes modified the frequency for completion of a self-assessment to every odd year, which is consistent with the required frequency to complete self-assessment form for other licensees. Dr. Serpa added the Board has previously considered and voted to update regulation section to be consistent with statute.

Chairperson Serpa advised the Committee has the opportunity to consider the policy goal of the self-assessment requirement specifically related to unlicensed AUDSs used in hospitals and determine if the Board should provide clarification of the requirement when a hospital is using the same device, with the same policies and procedures on the same computer platform, and if completion of a single self-assessment would be more appropriate. Dr. Serpa added such devices operated in

the same manner and under the conditions just outlined, would yield the same results related to compliance with provisions of pharmacy law, whether one self-assessment was completed or several of the forms would be the same. Dr. Serpa clarified the policy question for the Committee is whether there is value-added for the PIC to be required to complete a self-assessment for each AUDS or if a single self-assessment is sufficient.

Chairperson Serpa advised with a background was in hospital pharmacy, she knew that a large hospital could use over 100 AUDSs in a single building. Dr. Serpa believed a single self-assessment was appropriate because the manufacturer, policies and procedures, and staff are the same and coupled with the fact that programming managing the devices' operations is on a single platform. Dr. Serpa added there was no need for the PIC to complete over 100 forms containing the same information.

Dr. Serpa referenced the meeting materials that included draft language to further amend CCR Section 1715.1 that could be used to clarify the Board's expectations specifically related to the self-assessment requirement for unlicensed AUDS used in a hospital. Dr. Serpa noted the Board had previously taken action to amend this section which is currently pending. The language presented at the meeting has the additional changes recommended reflected in double underline and double strike-through. Dr. Serpa reviewed the specific changes related to the discussion:

- 1715.1(b)(2) – suggested change to simplify the language.
- 1715.1(c)(5) & (c)(6) – updated language to be gender neutral.
- 1715.1(f) – added new language that would clarify the Board's expectation related to completing the self-assessment form for the unlicensed AUDSs used in a hospital. Specified conditions include that to qualify for this modified self-assessment requirement, the mechanical devices used to store, dispense, or distribute dangerous drugs must be from the same vendor and controlled by the same software on a single system and must operate under the same policies and procedures.

Chairperson Serpa recommend replacing the term "vendor" with "manufacturer" and encouraged discussion and feedback on the suggested word change and policy decision.

Members were provided the opportunity to provide comment.

Member Oh inquire if BPC 4427.2 would allow the Board to add an additional layer that would allow an exemption for hospitals to not have to do the same self-assessment as BPC 4427.2 states for unlicensed everything else shall be the same.

Dr. Oh also inquired if the current proposed regulation would be pulled back to make the changes.

Ms. Sodergren confirmed with the Department of Consumer Affairs (DCA) Regulation and Legal Counsel that the Board has the authority to do what is in the language presented. The statue provides general authority and the regulation further clarifies the statutory authority. The current proposed regulation change to CCR section 1715.1 was under review by DCA and has not been publicly noticed so staff recommendation is if the Committee and Board agree appropriate, the current regulations undergoing review will be modified to incorporate additional changes.

Member Barker commented in agreement to change "vendor" to "manufacturer" as those types of equipment are discussed in terms of manufacturers.

Motion: Recommend incorporation of the additional proposed changes to CCR Section 1715.1 as proposed into the Board's current regulation proposal with the change of "vendor" to "manufacturer" in CCR Section 1715.1 (f)(1) giving the Chairperson and Executive Officer the authority to make nonsubstantive changes for the regulation to be approved.

M/S: Oh/Patel

Proposed Amendment to § 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge. Changes in ~~double strike~~ through and <u>double underline</u> are possible changes for the Committee's consideration.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code <u>(BPC)</u> shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every <u>odd-numbered</u> year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new automated drug delivery system license has been issued.

(2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~ 22) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
(C) DEA registration number, expiration date, and date of most recent DEA inventory;
(D) Hours of operation of the pharmacy; and
(E) ADDS license number, address, and hours of operation.
(2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
(3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that they have ~~he or she has~~ completed the self-assessment of the automated drug delivery system of which they are ~~he or she is~~ the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally

signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that they have ~~he or she has~~ read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:

(1) The mechanical devices used as part of the ADDS to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and

(2) The same policies and procedures required by Section 4427.2 of BPC are used.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4 and 4427.5, Business and Professions Code; and Section 16.5, Government Code.

The Committee heard a comment from a Kaiser representative indicating continued belief that the changes are inconsistent with BPC 4427.2 (i) and 4427.7 (a). The commenter appreciated the Committee's recognition that one self-

assessment should be required for all of the exempt AUDS operated by a hospital that will minimize the administrative burden and the direction taken.

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

Committee Member	**Vote**
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

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

Chairperson Serpa recalled as part of the July 2021 Board meeting, the Board approved draft FAQs related to ADDS. To ensure that Board FAQs remain relevant, updates are necessary when changes in the law occur. Dr. Serpa referenced the meeting materials that include draft updated FAQs. Dr. Serpa thanked Supervising Inspector Janice Dang and DCA Legal Counsel Eileen Smiley for their work to update these FAQs.

Members were provided the opportunity to comment. Member Patel commented the FAQs were excellent.

Motion: Recommend approval of the proposed revisions to the frequently asked questions related to automated drug delivery systems.

M/S: Patel/Oh

Members of the public were provided the opportunity to comment. No public comments were made.

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

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

VI. Discussion and Consideration of Committee's Strategic Objectives

Chairperson Serpa advised on an annual basis the Board receives recommendations from the various strategic committees. Dr. Serpa referenced the meeting materials include the strategic objectives for the Committee. Dr. Serpa noted later in the meeting, the Committee will receive presentations on the Board's inspection program and citation program, which is in part how the Committee monitors some of the Committee's strategic objectives.

- 2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.
  Status: Medication Error Reduction and Task Force Ad Hoc Committee established and has begun convening public meetings.
- 2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.
  Status: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided and top violations published in the Board's newsletter.
- 2.3 Complete routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees.
  Status: In FY 2021/22, Board staff conducted 1,598 routine inspections.
- 2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.
- 2.5 Assess, and pursue where appropriate, further use of a Standard of Care Enforcement Model to protect consumers.
  Status: Standard of Care Ad Hoc Committee established and has begun convening public meetings.
- 2.6 Establish greater consistency in how inspectors interpret the law and carry

our inspections to improve compliance, support licensees, and further patient care.

- 2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.
  Status: New inspector position received to perform inspections and related investigations stemming from new legislative mandates.
- 2.8 Educate licensees about enforcement responsibilities to improve compliance and build relationships.
- 2.9 Assess pharmacist involved in medication handling at locations not regulated by the Board of Pharmacy to increase patient safety and standardize care.
- 2.10 Evaluate if regulations align with federal regulations and standard governing the practice of compounding and pursue changes, if appropriate, to ensure patient safety and assist licensees with education about standards.

Chairperson Serpa stated she believed the established strategic objectives are appropriate and did not believe any changes are required. Dr. Serpa anticipated there will be significant Committee activity related to strategic objective 2.10 as USP completes its work to revise and release chapters related to compounding.

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

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

VII. Presentation and Discussion on Board's Inspection Program

Chairperson Serpa welcomed Chief of Enforcement Julie Ansel to provide a presentation on the Board's Inspection program.

Ms. Ansel reviewed the Board's mandate of consumer protection and policy goals to inspect locations every four years. Ms. Ansel reviewed the inspection process including observations of the Inspector when on an inspection including consultation procedure; notice to consumer poster, language sign, pharmacy permit; security features; nametags; audio and visual privacy; staffing ratio and duties being performed; and professional interactions. She referenced the Board's video on the Board's website entitled "How to Prepare for an Inspection." Ms. Ansel reviewed the items reviewed by the Inspector including self-assessment forms; transmissions to CURES; enrollment in the Board's subscriber alert system; quality assurance policy and medication error reports; and policies and procedures.

Ms. Ansel reviewed items inspected during an inspection to include the physical facility; security; cleanliness and orderliness; and expiration dates on labels. Ms. Ansel provided an overview of the educational opportunities an Inspector might discuss with a licensee to include questions from licensees and providing reminders of the Board's continuing education requirements, newsletter, website, pamphlets, written notice of right to consultation and self-assessments as a tool for compliance. She added Inspectors also discuss staffing at community pharmacies, keeping a log and signed policies and procedures, requirements for email address, and vaccine requirements. The education is to allow for dialogue with the Inspector and licensees.

Ms. Ansel reviewed the total inspections completed for the past five years highlighting in FY 21/22 2,938 inspections were completed consisting of 2,862 in person inspections and 76 desk audits. Ms. Ansel reviewed the types of inspections to include 1,099 routine pharmacy inspections for PHY/PHE; 313 compliance inspections; 331 pharmacist recovery program/probation; and 935 compounding inspections consisting of 64 new inspections, 799 renewal in person inspections and 72 renewal desk audit inspections. Ms. Ansel reviewed the inspections by type for FY 21/22.

Ms. Ansel provided a breakdown of outcomes by routine inspection outcomes for FY 21/22 including types (routine, complaint, probation) of inspections and outcomes including no violations, corrections and violation notices issued. Ms. Ansel reviewed the top corrections and violations for routine pharmacy inspections. She advised of the 66 routine inspections completed in FY 21/22, an Inspector observed that consultation was not provided to the patient in 9 inspections and in 57 inspections, the Inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions. Ms. Ansel provided an update on the policy goal of inspecting licensed facilities every four years. Ms. Ansel advised the Board has inspected 92 percent of the current pharmacy population since January 2013.

Chairperson Serpa thanked Ms. Ansel and the staff's efforts towards meeting the Board's strategic objective related to routine inspections. Dr. Serpa was pleased to see the data shows that pharmacies with no inspection or no inspection since 2013 has dropped from 2080 pharmacies 2 years ago to 463 this year. Dr. Serpa noted it appears this issue may be completely addressed within this fiscal year. Dr. Serpa advised this goal was established without additional resources noting these inspections were completed in addition to the current workload of the Board's inspections. Dr. Serpa expressed gratefulness to staff's efforts. Dr. Serpa expressed concern with pharmacist consultation not being provided to patients.

Members were provided the opportunity to provide comments.

Member Oh thanked Ms. Ansel, Ms. Sodergren, and staff for the amazing job of working on the policy goal. Dr. Oh stated the Board will have to continue to communicate the importance of consultation.

Member Patel commented consultation is key to medication error reduction and the safety of the consumers. With new electronic prescriptions and changes in how prescriptions are being filled, patients and pharmacy staff view prescriptions as refills. Member Patel stated the Board needs to communicate using email notification and statistics to help reduce medication error reduction.

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

VIII. Presentation and Discussion on Board's Citation and Fine program

Chairperson Serpa welcomed the Board's Executive Officer Anne Sodergren to provide a presentation on the Board's Citation and Fine Program.

Ms. Sodergren explained the citation is one type of outcome from an investigation. She provided a review of the citation program relevant law and citation program overview. Ms. Sodergren stated the Board uses its authority to issue citations and fines to address significant violations but not those that warrant removal or restriction of a license to ensure consumer protection. The Board's fine authority is typically $5,000 with few exceptions including internet prescriptions which is $25,000 per prescription; purchasing from unlicensed source is $5,000 per invoice; up to a fine of $100,000 for violations found in three or more community pharmacies that are similar and up to $150,000 for violations that result from a written policy of community chain policy that resulted in the violations of pharmacy law.

Ms. Sodergren reviewed the factors to consider in assessing administration fines. She further explained the citation process: investigation is completed; supervising inspector review; second level review; citation issued without fine and with/without abatement; citation completed with fine or abatement accepted; and appeal informally by office conference and/or formal appeal through the Office of Attorney General's (AG) office.

Ms. Sodergren reviewed the citations and fines collected over the past seven years. She reviewed the average process time from receipt to issuance in FY 21/22 is less than a year.

Ms. Sodergren advised in 2018 the Board provided direction to the staff to fully realize the order of abatement tool. The Board has been using the order of abatement tool more frequently since 2018. Ms. Sodergren reviewed the abatement types including requested/required continuing education to be completed by the licensee; internal policy training/in service training; updated self-

assessment; and updated policies and procedures. Ms. Sodergren advised 168 of 269 abatements were satisfied in FY 21/22. She noted not all abatements are required and some take a longer time to complete.

Ms. Sodergren reviewed violations that lend themselves to abatements such as pharmacy shall be clean and orderly; pharmacy security; medication error; vaccine/immunization; and compounding violations. She reviewed the appeal process through the office conference or formally appeal through the AG.

Ms. Sodergren reviewed the past seven years of citations completed or contested as well as the outcomes after office conference or AG. She reviewed the 10 violations for pharmacies and pharmacist with medication error being the most prevalent. The list of top violations is used for education in the Board's newsletter. Ms. Sodergren reviewed the top 10 violations for pharmacy technician with self-administer drugs/alcohol and conviction of a crime substantially related to pharmacy were the most prevalent. She reviewed the outcomes for the duty to consult for the past three fiscal years and outcomes as well as noted there were two citations issued to community pharmacies under common ownership or management.

Chairperson Serpa thanked Ms. Sodergren and noted consistent with the Board's strategic objective the common violations will be used as educational materials.

Members were provided the opportunity to provide comments. Member Oh thanked Ms. Sodergren.

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

IX. Discussion and Consideration of Community Pharmacy Staff Requirements including Business and Professions Code Section 4113.5 and Title 16, California Code of Regulations Section 1714.3

Chairperson Serpa referenced the meeting materials that detailed out the relevant sections of pharmacy law specifically BPC 4113.5 that provides a pharmacist shall not be required to engage in the practice of pharmacy unless another employee of the pharmacy or an employee of the establishment is made available to assist the pharmacist at all times. She noted the Board's regulation details out the requirements pharmacies must meet to satisfy the requirements of the statute.

Chairperson Serpa advised as there are investigations pending in this area, she requested members, staff, and the public keep comments general in nature to ensure members avoid any inadvertent exposure to information that would then preclude members from involvement in our role as a decision maker in an enforcement matter.

Chairperson Serpa advised the materials detailed out the implementation strategy used by staff, where staff initially focused efforts on education of the requirements. Staff efforts transitioned to issuing orders of correction to gain compliance. However, after a significant period of time to allow pharmacies to comply with the provisions, depending on the egregiousness of the violation staff determine the appropriate outcomes. To date the Board has issued two citations for violations of these provisions.

Chairperson Serpa noted there appears to be a misunderstanding by some about the requirements of the statute as well as frustration by some pharmacists who are not requesting assistance because such assistance would not be made available even if such a request was made. Dr. Serpa thanked the staff for the review of the implementation efforts.

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

Members of the public were provided the opportunity to provide comment.

The Committee heard comments from a representative from UFCW who expressed appreciation for agendizing the item and implementing the statute. The commenter underscored the importance of education in addition to three observations: confusion about the requirements; ongoing need to continue public education; and recognition of the Board that at the core a true health and safety issue if a licensee is unable to do their job if the pharmacy is not properly staffed.

Chairperson Serpa noted a recent alert sent to licensees via subscriber alert. Ms. Sodergren indicated an alert was sent about SB 362 but noted the information about retaliation, whistleblowing protections and filing complaints would apply to this as well.

X. Review and Discussion of Enforcement Statistics

Chairperson Serpa provided the year end and three-year comparison on the enforcement statistics were included in meeting materials.

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

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

XI. Future Committee Meeting Dates

Chairperson Serpa advised there are several meetings planned through the end of the year due in part to ensure sufficient time to consider revised USP compounding chapters. Dr. Serpa noted unfortunately, there is no timing on when the revised chapters will be released. Depending on the release, the Committee may need to adjust its meeting schedule. Dr. Serpa advised as part of its May 14, 2022, announcement, USP indicated that it did not have an anticipated date for final publication. Updates will continue to be monitored and may impact to the meeting schedule.

XII. Adjournment

The meeting adjourned at 10:45 a.m.