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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING MINUTES

DATE: February 12, 2013

LOCATION: Department of Consumer Affairs
Headquarter Building Two
1747 N. Market Boulevard, Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Deborah Veale, RPh, Chair
Lavanza Butler, PharmD
Victor Law, RPh
Gregory Murphy, Public Member
Albert C.M. Wong, PharmD

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Staff Manager II
Debbie Damoth, Administration and Regulation Manager
Laura Hendricks, Associate Analyst
Joyia Emard, Public Information Officer

Call to Order

Chair Veale called the meeting to order at 9:10 a.m.

Executive Officer Virginia Herold announced the WIFI password and indicated the meeting materials can be found online and a copy is in the back of the room.

Chair Veale provided instructions for meeting attendees interested in receiving continuing education credit to sign in at the sign in sheet at the back of the room.

Chair Veale conducted a roll call. Committee Members Lavanza Butler, Victor Law, Gregory Murphy, and Albert Wong were present. Board President Stan Weisser and Board Member Allen Schaad attended the meeting in the audience.

Chair Veale announced the entire Licensing Committee is present to discuss the implementation of Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013).

1. Overview of the Advanced Practice Pharmacist Requirements Contained in SB 493 (Hernandez, Chapter 469, Statutes of 2013)

Background

Among a number of provisions contained in SB 493 that the committee discussed, SB 493 establishes an "advanced practice pharmacist" category of pharmacist licensure, which allows such licensed pharmacists to perform physical assessments; order and interpret medication-related tests; refer patients to other providers; initiate, adjust, and discontinue medications under physician protocol or as part of an integrated system such as an ACO; and participate in the evaluation and management of health conditions in collaboration with other providers.

The specific provisions in SB 493 relating to this new licensure category are presented below. The focus of the discussion under this topic will be on section 4210.

4016.5.

"Advanced practice pharmacist" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized advanced practice pharmacist is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

4052.6.

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
  (1) Perform patient assessments.
  (2) Order and interpret drug therapy-related tests.
  (3) Refer patients to other health care providers.
  (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
  (5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.

(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

4210.

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:
  (1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.
  (2) Satisfy any two of the following criteria:
    (A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
    (B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
    (C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.
  (3) File an application with the board for recognition as an advanced practice pharmacist.
  (4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

Also provided in meeting materials is background information on the Council on Credentialing in Pharmacy and its "Guiding Principles for Post-licensure Credentialing of Pharmacists." This document describes "credentials," "credentialing" and "privileging." This is a key document to review as the committee begins to establish parameters for qualifications for advance practice pharmacists. Additional background documents include: "Credentialing and Privileging of Pharmacists," "Credentialing in Pharmacy: A Resource Paper" and "National Commission for Certifying Agencies, Standards for the Accreditation of Certification Programs."

Discussion

Chair Veale stated section 4016.5 indicates what the Advanced Practice Pharmacist (APP) can do as an APP while section 4210 is the section the committee will be discussing how this APP implemented.

Chair Veale asked for comments from the committee and the public. There were no comments from the board or public.

2. Presentation by Brian Lawson, PharmD, Director of Professional Affairs, Board of Pharmacy Specialties, and Andrea Iannucci, PharmD, Board of Directors, Board of Pharmacy Specialties, Regarding Development of Certification Programs and Existing Certification Programs for Pharmacists

Background

The Board of Pharmacy Specialties (BPS), as its name implies, has developed eight pharmacy practice areas for which it has developed certification programs. The BPS literature provides that certification of pharmacists promotes the recognition and value of specialized training, knowledge, and skills in pharmacy. The eight specialties are:

- Ambulatory care pharmacy
- Critical care pharmacy
- Nuclear pharmacy
- Nutrition support pharmacy
- Pediatric pharmacy
- Pharmacotherapy
- Psychiatric pharmacy
- Oncology pharmacy

At the February 12, 2014, Licensing Committee meeting, Dr. Brian Lawson provided information about the certification programs BPS developed for pharmacists. Dr. Lawson also provided information about development of certification programs. Meeting materials included an overview of their processes, and then the content outlines for each of the specialties. These specialties are specifically listed in the new law (as section 4210) as qualifying routes for the advanced practice pharmacist licensure.

Dr. Lawson's presentation provides background for the committee as it moves forward with establishing qualifying components for advanced practice pharmacists.

Whereas the specific specialties listed in SB 493 are the programs certified by the BPS, this agency itself is not mentioned in the bill -- see "from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board" in section 4210(a)(2)(A). As such, the board will need to recognize this agency if this is the direction the board chooses to go.

Presentation

Chair Veale introduced and welcomed Brian Lawson, PharmD, and Andrea Iannucci, PharmD, from Board of Pharmacy Specialties (BPS) regarding the development of a certification program and the existing certification program for pharmacists.

Brian Lawson, PharmD, introduced himself as the Director of Professional Affairs for BPS and Andrea Iannucci, PharmD as a local specialist in oncology and serves on the Board of Directors for BPS.

Dr. Lawson congratulated the board on the accomplishment of establishing APP in California and thanked the committee for the opportunity to talk about pharmacist credentialing to the committee.

Dr. Lawson discussed the Council on Credentialing in Pharmacy (CCP) as a national coalition of about ten organizations as a forum to discuss credentialing activities in pharmacy. CCP directs the process to establish standards of quality, to improve patient care and overall public health. CCP meets on a quarterly basis to direct leadership guidance to provide public information and coordinate the pharmacy profession's credentialing activities. CCP is the only forum to set a framework for how that process works from graduation through to when someone becomes a practitioner.

Dr. Lawson continued to explain that CCP is comprised of 10 national pharmacy organizations including: American Association of Colleges of Pharmacy; American College of Clinical Pharmacy; Accreditation Council for Pharmacy Education; Academy of Managed Care Pharmacy; American Pharmacists Association; American Society of Consultant Pharmacists; American Society of Health-System Pharmacists; Board of Pharmacy Specialties; Commission for Certification in Geriatric Pharmacy; and Pharmacy Technician Educators Council.

Dr. Lawson explained one of the purposes of the group is to solidify the verbiage related to credentialing. BPS has a publication that frames the discussion between credentialing and privileging in pharmacy detailing there are three categories: prepare for practice, enter practice, and document voluntarily their specialized advanced knowledge and skills.

Chair Veale asked Dr. Lawson about the publication date of the paper being available March 2014. Dr. Lawson clarified there is a pre-publication draft available prior to publication.

Dr. Lawson continued that BPS did a paper in 2010 on credentialing in pharmacy to serve as a resource paper to give guidance and definition to the terms often used. Dr. Lawson clarified the terms "certificate program" and "certification" for the purposes of his presentation. Dr. Lawson defined a "certificate program" as a certificate provided upon completion awarded based on educational experience or continuing education gained. In most cases, a minimum of 15 hours of continuing education is awarded by an educational institution or pharmacy institution. A provider for these types of programs includes Accreditation Council for Pharmacy Education (ACPE). Certificate programs out in the market include the immunization and MTM certificate that are completed over the course of a weekend.

Dr. Lawson defined "certification" as a certification in an in area of practice that is recognizing an area of practice at a higher level of knowledge, skill set, and experience. Certifications focus on an area of practice such as cardiology, nutritional support, or pharmacotherapy. These certifications are currently awarded by BPS and Commission for Certification in Geriatric Pharmacy (CCGP) who administers the geriatric program. Dr. Lawson continued these certification programs are accredited by the National Commission for Certifying Agencies (NCCA).

Chair Veale asked Dr. Lawson if BPS is the only certification issuer in pharmacy. Dr. Lawson stated that there are two organizations that do pharmacy certifications. BPS offers eight certifications and CCGP offers one certification. Ms. Herold added that there is also a program for insulin in diabetics. Dr. Lawson indicated often times people with get additional certified as a diabetes educator or board certified and explained those are not specific to pharmacy but are multi-disciplinary credentials. Dr. Lawson provided the Web site to CCP of http://www.pharmacycredentialing.org/ for resource documents.

Dr. Iannucci reported to the committee that she is an oncology pharmacist working at UC Davis Medical Center. Dr. Iannucci has been an oncology pharmacist for about 20 years and has been on for over 20 years as well as been a clinical professor with UCSF School of Pharmacy. Dr. Iannucci directs the PGY2 oncology residency training program at UC Davis Medical Center. Dr. Iannucci stated she has been involved with BPS in the past serving as the Chair for the Oncology Specialty Council and is rejoining BPS this year as a member of the Board of Directors.

Dr. Iannucci stated she would explain the services and BPS process. BPS was established in 1976 as a way to recognize specialty practice areas in pharmacy and define standards for recognized specialties as well as evaluating the knowledge and skills of pharmacy specialists. Dr. Iannucci reported to the committee that the vision and mission of BPS are aligned with the goals of SB 483. BPS' mission is to be the premier post-licensure certification agency that will ensure board certified pharmacists are recognized within health care delivery systems while serving the needs of the public and the pharmacy profession. BPS' vision is to improve patient care by promoting recognition and value of specialized training, knowledge and skills in pharmacy and specialty board certification of pharmacists.

Dr. Iannucci provided to the committee that BPS is represented by the Board of Directors which oversees the specialty councils. Currently, there are eight recognized specialty councils. Each council is represented by a panel of experts in the area of practice and they put the examinations together for each of the certifications.

Chair Veale inquired if there is a process for the future to add a new specialty if needed. Dr. Iannucci indicated there is a process. Just recently, groups were successful in petitioning BPS for recognizing critical care pharmacy and pediatric pharmacy as specialties. BPS has specialty councils developed now for these two newer specialties and will be launching examinations in 2015. The councils have been created now to develop the role delineation and examinations. Dr. Iannucci indicated that is generally how the process is done. An organization sponsors a specialty group and petitions BPS.

Dr. Iannucci stated that in order for BPS to achieve the position of the premier post-licensure certification agency, BPS recognizes the importance of maintaining a validated and quality process. BPS maintains this by achieving accreditation of the BPS programs through the NCCA.

Dr. Iannucci shared with the Licensing Committee that NCCA was created in 1987 to ensure the health, welfare, and safety of the public through a variety of certification programs that assess professional competence. NCCA certifies a wide variety of programs including other health professionals, automotive professionals, and emergency technicians. NCCA has accredited more than 300 programs for approximately 120 organizations. In California, the Department of Drug Programs does require NCCA accreditation for qualified certification programs for alcohol and other drug program counselors.

Dr. Iannucci indicated NCCA standards require demonstration of a valid and reliable process for development, implementation, maintenance, and governance of certification programs. NCCA employs a rigorous peer review process to establish the accreditation standards, evaluate the plans for the standards, recognize organizations that demonstrate compliance, and serve as a resource for quality certification. The standards are comprehensive and cover all aspects of the certification process including administration, assessment development, and recertification. Dr. Iannucci reported currently 6 of the BPS certification programs are accredited by NCCA. BPS will be eligible for accreditation with the new programs in 2018.

Committee Member Law inquired as to the requirements for BPS to be certified by NCCA. Dr. Lawson provided there is a lot of documentation of standards required by NCCA provided in the handouts to the committee. New programs such as critical care and pediatrics cannot be added until 2018 because the process is a three-year cycle.

Chair Veale inquired if a pharmacist whose specialty is critical care/pediatrics but those haven't been approved yet, where would the pharmacist fall. Dr. Lawson indicated typically pharmacotherapy specialist, and can apply for the critical care/pediatrics if eligibility is met once the exam is rolled out in 2015.

Dr. Iannucci continued to explain the eligibility criteria for BPS examinations. Requirements include graduating from an accredited pharmacy program, and maintaining an active license to practice pharmacy. In addition to those requirements and similar to advanced practice requirements for California, BPS does require practice experience. Chair Veale inquired if BPS verifies good standing for the pharmacist license. Dr. Iannucci indicated yes. Dr. Iannucci explained experience requirements for the pharmacotherapy certification exam include 2-4 years experience with at least 50% of time spent in the specialty area or completion of PGY 1 residency program. Dr. Iannucci continued to explain the eligibility for the more advanced specialties such as oncology require additional years of practice experience and specialty PGY 2 residency training.

Dr. Iannucci reported BPS examination eligibility requirements are listed on the BPS Web site as well as an outline of the examination test content. BPS examinations are internet based and offered at over 650 national and international testing sites during two 17-day windows each year. An examination consists of 200 questions in a four option multiple choice format. The examination is administered 100 questions at a time over the course of two and one half hours for each 100 question set.

Chair Veale inquired if the BPS examinations are psychometrically sound as the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). Dr. Lawson responded NCCA accreditation requires BPS has a psychometrically sound legally defensible process. Dr. Lawson stated BPS also worked with a test consultant who works with the specialty councils and content experts to ensure the defensibility of the exams. Dr. Lawson stated BPS uses a criterion reference approach using the Agnoff method to determine the passing point for each exam. A threshold is set. Those who meet or exceed the threshold pass the exam; those who don't meet the threshold do not pass the exam. Passing the exam is not a guarantee.

Dr. Iannucci continued BPS recertification is required every seven years to document a specialist's current knowledge and skills. There are two options for recertification in most specialties (except nutritional support) to recertify by means of passing a 100 question recertification examination or completing 70-120 hours of BPS approved continuing education (CE). Currently for the nutritional support specialty, certification is only available by examination.

Chair Veale inquired how BPS determined seven years was the requirement for recertification. Dr. Lawson indicated the trend for recertification is 5-10 years. BPS selected the middle of the two trends. Dr. Lawson indicated this will be reevaluated.

Dr. Lawson continued that the CE option through BPS requires taking CE from BPS approved CE providers. Each BPS approved provider is required to administer an examination based on the BPS content outline for the specialty. The assessment questions must be passed the first attempts and aren't provided additional attempts if failed.

Chair Veale inquired to Executive Officer Herold if recertification every seven years would pose a problem given that the pharmacist license expires every two years. Ms. Herold indicated this would pose a bit of a problem and the board would have to decide how to handle this issue. Ms. Herold also indicated the board would have to determine if the APP was a one time certification for licensure or if it would have to be renewed in addition to renewal of the pharmacist license. Ms. Herold explained that the APP license will sync up with the RPH license which expires every two years. This could allow for a licensee to be renewed as an APP during the time in which the certification expires. Ms. Herold continued the committee and board will have to decide if APP is licensure once as long as the pharmacist license is maintained or if competence will have to be reestablished as some point in time. Dr. Lawson provided that since there are CE options, and the CE can be used toward their licensure. Ms. Herold explained there is an additional CE requirement.

Dr. Iannucci provided an overview of the international board certification growth process. From 2002 to 2013, BPS' number of certified pharmacists tripled and almost quadrupled. Chair Veale inquired if there were pharmacists with specialty certifications in the United States versus international. Dr. Iannucci provided and Dr. Lawson confirmed a majority of those are within the United States. Chair Veale inquired as to what percent of the pharmacists in the United States are certified. Dr. Lawson provided the percentage was small but would further explain how this fits into the landscape of the pharmacy profession in the United States.

Dr. Iannucci provided international candidates who sit for BPS specialty illustrates the merit of the examination process because the candidates have to take this examination in English and are subject to all questions that are subject to United States regulatory domain. International candidates are committed to the process and furthering their career. Dr. Lawson indicated BPS has had inquiries from Hong Kong and Saudi Arabia to assist the countries in the development of creating a similar framework.

Committee Member Law inquired who selects the 200 questions required for a specialty examination and the selection process for the specialty council experts. Dr. Iannucci explained each specialty council maintains its own items bank based on domain specified content outline. As part of the review process, the specialty council ensures the question is still valid, and there is evidence to still support the validity of each question. Periodically, the item bank must be purged to allow for variety, accuracy, and currency. Committee Member Law further inquired how often the specialty councils meet. Dr. Iannucci provided specialty councils meets annually to assemble the examination as well as periodically via conference calls to finalize examination content. Dr. Lawson clarified specialty councils use remote item banking system to develop items to allow specialty council members to develop items remotely. Dr. Lawson indicated specialty councils are working year round to develop examinations. Dr. Lawson further provided a role review to determine the tasks performed by each specialty as well as a test analysis every five years to reassess the content outline and update questions in the item banks. Ms. Herold commented this is identical to the process used by the board for the CPJE as well as the process used by the National Association of Boards of Pharmacy (NABP) for the North American Pharmacist Licensure Examination (NAPLEX). Ms. Herold stated the board uses

a criteria referenced based scoring but she was unsure if NABP used criteria referenced based scoring for the NAPLEX. The board conducts a job analysis every five years and adjusts the content outline based on the frequency and importance of the skill. Ms. Herold stated any examination selected by the board will have to meet the requirements of a job related examination.

Dr. Lawson continued in 2011, BPS conducted a group of stakeholders to determine the next steps in moving forward. BPS developed their strategic plan and white paper focusing on the growth of current specialties; the addition of new specialties; marketing the value of specialties; and assessing the model for recertification. BPS continues to meet with stakeholders to look at the landscape of what other health care professions do in terms of assessing, certifying specialties, and re-certifying specialties. BPS will continue to have this discussion as the environment continues to change.

Chair Veale inquired if a pharmacist who was not actively practicing a specialty but kept abreast of the specialty could pass the re-certification examination and be re-certified with a specialty. Dr. Lawson responded that yes this is possible but there are certain thresholds of experience that have to be met. It is possible to have pharmacists certified who are not practicing their specialty but are nearing retirement or entering administration. BPS checked with the American Boards of Medical Specialties (ABMS) who only requires their certified to only see one patient a year in order to recertify. Dr. Lawson stated BPS meets that minimum threshold.

Dr. Lawson summarized BPS' white paper in that BPS mission/vision is that board certification will be an expectation pharmacists engaged in patient care. BPS wants to ensure that board certification is understood by other health care professionals. Growth in BPS should align with training opportunities for pharmacists. Dr. Lawson reviewed BPS approved certification programs: ambulatory care pharmacy, nuclear pharmacy, nutrition support, oncology, pharmacotherapy, and psychiatric. Both critical care and pediatrics are in process and looking to administer the first exam in the fall of 2015. BPS is currently conducting role delineation studies for cardiology, infections disease and pain/palliative care. Potential areas for future certification may include HIV, patient safety, sterile compounding, pharmacoinformatics, and transplantation.

Ms. Herold indicated the main issues the board is dealing with right now are pain management and sterile compounding. Dr. Lawson indicated pain management could fit under pediatric, ambulatory care, or oncology specialties. BPS also wants to look into sub-specialties where pain may be a sub-specialty of another specialty.

Dr. Lawson provided BPS believes board certification is critical to ensure stakeholders of the level of knowledge of practitioners. Dr. Lawson indicated he was available for questions.

Chair Veale inquired if there were any other states that have similar APP laws. Dr. Lawson indicated he believed North Carolina and New Mexico had similar requirements and Iowa was in the development stages. Chair Veale inquired if the other states embraced BPS certification.

Dr. Lawson indicated BPS certification was not required in statute but BPS remains open to discuss.

Committee Member Law inquired as to the cost to participate in BPS certification. Dr. Lawson indicated the cost to sit for the examination is $600 and $100 annually to maintain the certification. If a candidate fails the examination, the cost is $300 each time up to a year until the exam is passed. Dr. Lawson indicated if a candidate doesn't pass within the first few attempts, the candidate understands they may not be up to the level required for certification and stops taking the exam.

Committee Member Wong indicated his concern of a seven year certification process being too long and would like to see it at five years because of the changes in industry. Chair Veale requested even number year renewal to align with California. Dr. Lawson indicated it was difficult to find the number that would meet each states' requirements but BPS does reevaluate.

Assistant Executive Officer Anne Sodergren inquired what other types of professions does NCCA accredit and what are the passing rates of those examinations and if they vary on area of specialty. Dr. Lawson responded NCCA accredits over 300 organizations with over 120 programs. Dr. Lawson indicated they accredit oncology nurses and pharmacy technicians in addition to the many others. Ms. Sodergren inquired about the medical profession. Dr. Lawson indicated the medical profession allows for a grandfathering clause that didn't need recertification and does not meet the NCCA standards. Dr. Lawson indicated the pass rate varies based on specialty and pool of candidates as standards and not bell curves are used.

Chair Veale indicated the requirements seem very rigorous with the years of practice or completion of a residency program. Dr. Lawson provided that the purpose of the credential is to demonstrate over time a body of experience in a specialized area of practice. Dr. Iannucci indicated she didn't believe she could recertify by either examination or continuing education without practicing in the specialty area.

Chair Veale asked Dr. Iannucci if she tried to teach to the examination. Dr. Iannucci provided she doesn't try to teach to the examination. Dr. Iannucci provided that she develops her residency to the ASHP structure and standards. Chair Veale inquired about the affiliation with APHA. Dr. Lawson clarified that BPS is an autonomous division of APHA. Additionally, APHA has a non-voting board member on the BPS board. NCCA wouldn't allow BPS to operate without the distinction.

Ms. Herold inquired as to why effective 1/1/13 BPS is only accepting ASHP approved residency as experience. Dr. Lawson provided BPS is relying on ASHP to validate the residency programs to be of high quality and standards for the training program. Ms. Herold inquired if the belief is that there will be higher passing scores. Dr. Lawson responded in concept this should be the case but this has not been tracked. If a candidate has attended a non-ASHP residency program, this can be counted as one year of experience of practice.

Ms. Herold inquired to the percentage of people who recertify with examination versus continuing education. Dr. Iannucci indicated she believed this number to vary but the majority recertify by non-examination route. Ms. Herold inquired to the continuing education programs accepted for recertification. Dr. Iannucci provided there are designated programs that meet the qualifications for recertification. Dr. Lawson added that BPS approves providers who submit a curriculum or blueprint that is evaluated. It must provide a parallel to the certification content outline. Dr. Iannucci added the specialty councils provide feedback to the continuing education provider programs. This is done on an annual basis.

Dr. Lawson provided contact information to the committee and thanked them for their time.

Chair Veale asked if there were questions from the public.

CSHP Board Member Ryan Gates addressed the committee. Dr. Gates worked as the co-chair between CSHP and CPHA to draft the legislation for the APP. Dr. Gates indicated the task force looked at New Mexico and North Carolina laws. Specifically, North Carolina recognized in statute as certification from BPS.

Chair Veale thanked Dr. Gates for his comments and asked staff to look at the other states. Specifically, Chair Veale requested a comparison of states' statutes/regulations with regard to specific accreditation requirements.

Chair Veale asked for public comment. Hearing none Chair Veale continued with the agenda.

3. FOR DISCUSSION: <u>Development of Other Certification Programs or Qualifying Methods for Licensure as Advanced Practice Pharmacists</u>

<u>Background</u>
The committee must discuss what elements it seeks to establish as components for advanced practice pharmacists. Specifically to qualify for licensure as contained in section 4210(a):

> (2) Satisfy any two of the following criteria:
>
> (A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
>
> (B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the

experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

Discussion

Chair Veale indicated agenda item #3 addressed other accreditation programs for the APP. Chair Veale asked if there were representatives from other credentialing programs interested in presenting on other certification programs or qualifying methods for licensure as an APP.

Chief Executive Officer John Roth for the California Pharmacist Association congratulated Board Member Gregory Murphy on his appointment to the board. Mr. Roth encourages and appreciates BPS' work. Mr. Roth stated BPS was contemplated as legislation for APP was being drafted but also understood there may be other pathways to licensure. CPHA is developing an institute that would be psychometrically sound and broader for the community pharmacist rather than a particular specialty. CPHA encourages the board to allow for more generalist certifications as pathways to licensure as APP.

Chair Veale asked CEO Roth if it was CPHA's intention to obtain NCCA accreditation. Mr. Roth indicated that was CPHA's intent. Mr. Roth indicated BPS was very open in sharing their process to allow CPHA to learn from BPS' experience in developing their accreditation program. Chair Veale inquired on CPHA's thoughts for recertification. Mr. Roth indicated the thought was to develop the recertification requirements to align with the statutory requirements of 10 hours of continuing education every two years, thus syncing up with the pharmacist license renewal. Ms. Herold pointed out this was half of the BPS recertification requirement.

Dr. Steve Gray representing the CSHP Board of Directors reiterated SB 493 was a collaboration between CPHA, CSHP, and others in the industry participants. Dr. Gray pointed out the difference between certificate and certification. Dr. Gray stated certificate means a person attends but is not tested for retention versus certification where there is a test for retention on the subject matter. Dr. Gray reminded the committee this concept is not new for California. Under Business and Professions Code section 4052.1 and 4052.2, approximately 1,000 pharmacists including 500 at Kaiser Permanente have been very successful in managing based on referral from a physician high risk patients on high risk drugs in virtually ever disease state with few problems. Dr. Gray indicated to the board that one of the reasons for SB 493 was to allow for pharmacists to assist with the increase in patients as a result of the Affordable Health Care Act. SB 493 provided for an alternative pathway outside of an ASHP residency in order to keep up with the demand of patients. Dr. Gray reminded the committee if only ASHP residency programs are allowed, this will not meet the intent of SB 493. Dr. Gray stated that he hoped the board was impressed with BPS and NCCA but keeps the doors open to other programs.

Chair Veale asked Dr. Gray what percentage of residency programs are ASHP. Dr. Gray responded the vast major are ASHP/AFCP accredited. There are also residency programs not hospital based. With regard to APP residency requirements, Dr. Gray warned to be careful to define clinical residency. Additionally, various employers have started non-ASHP residency programs. At the same time, there may be places for good experience such as veteran administration, Indian health service, or military. These were all factored in when the parameters for the statute were developed.

Dr. Gray was inquired by the committee as to how many of the 500 pharmacists at Kaiser operating under the auspices of Business and Professions Code sections 4052.1 and 4052.2 obtained certification. Dr. Gray indicated it was not a requirement for Kaiser and did not have that information. However, they are vigorously evaluated and reevaluated every two years. Ms. Herold asked if it was a written evaluation at the skill level or performance. Dr. Gray indicated the evaluation was at the knowledge and skill level of current disease treatment and management standards.

Dr. Gray advised the committee that many states use a similar practice to Business and Professions Code sections 4052.1 and 4052.2 known as a collaborative practice agreement with a physician. Because of the variety from state to state, this may make it difficult for staff to identify a uniform requirement.

Western University Dean Dan Robinson addressed the committee with regard to the recertification and relicensing process. Dean Robinson didn't believe there should be a problem to demonstrate BPS certification/renewal at the time the pharmacist license is renewed. Dean Robinson indicated if a pharmacist failed to maintain the BPS certification, they would be required to report this to the board. Ms. Herold indicated the APP would probably have to be surrendered as well.

Dean Robinson wanted to ensure everyone is on the same page in pharmacy school education trends. Dean Robinson indicated standards from 2007 and 2016 indicated pharmacists are involved in direct patient care and should be practice ready in an area of direct patient care. This is an outcome coming out of pharmacy school.

Dean Robinson indicated he was concerned that the California model is being scrutinized for future models and variations. Dean Robinson wants to ensure that the California model meets national levels and is valuable in terms of transferability. Additionally, this will require a higher level of patient assessment skills and physical assessment skills. This could be done through institutes across the states through certificate programs. There may be a series of certificates to achieve to provide skills needed to practice in a community environment and provide a high level of patient care, rather than a single certification. Chair Veale inquired if this was currently available today. Dean Robinson indicated this would be something to be developed in the future and how future programs are developed.

Ms. Herold indicated she reviewed the content outline at ambulatory care specialty that seems to be aligned with community pharmacy and requested what would need to be added. Dean Robinson responded the outcomes are well done and overlap perfectly. The only difference is the process: residency plus two years' experience.

Chief Executive Officer John Roth for the California Pharmacist Association indicated his concern is the requirement to qualify is two years where the statutory requirement is one year and/or residency. Mr. Roth hoped there would be another way to enter with less experience. Ms. Herold summarized that the entry to practice is too long and another route may be faster with the same outcome. Mr. Roth concurred with Ms. Herold's assessment and extrapolated that multiple ways to licensure as an APP was important to the intent of the legislation.

CSHP Board Member and ASHP Residency Director for eight years, Ryan Gates commented over 70% of his residency graduates are BPS certified within 15 months of leaving his program. All of his clinical pharmacists are either single or triple board certified through BPS or other accrediting bodies. Unfortunately, the requirements provide for competing requirements: If all residency programs could be filled, only 12% of graduates would be accommodated. This represents a serious bandwidth issues restricting the entry of APPs. Many states are looking to California. Requirements to take the BPS examination demonstrate advance practice pharmacist by the definition to qualify prior to taking the examination. Dr. Gates' experience with BPS pharmacists is that they are far and above non-BPS in that they are required to take over 70-120 hours of BPS approved continuing education to recertify.

CSHP Board of Directors Dr. Steve Gray pointed out to the committee there were three bills about the APP. The only reason SB 493 was successful was that pharmacists acknowledged they are not diagnosticians. Patients are referred from a diagnostic physician.

Committee Member Albert Wong queried Dr. Gray to see if Kaiser's APPs are properly compensated. Dr. Gray stated Dr. Gates addressed this issue in that there will be recognition of pharmacists as health care providers. Dr. Gray indicated all pharmacists are employees of Kaiser are well compensated through salary and benefits.

Sarah McVeigh from UCSD posed the question to the committee if the criteria for residency and one year experience could be coterminous. Chair Veale indicated the intent is that the two are done together. Ms. Herold indicated this opened a whole series of questions determine. Ms. Herold indicated the requirements are two of the three.

Dr. Gates readdressed the committee and provided that Sarah McVeigh was part of the committee for drafting the bill language for SB 493. Dr. Gates explained the option was to allow the grandfathering clause because there were not enough residency spots for all pharmacy graduates thereby addressing the bandwidth issue. Dr. Gates added the original language stated one of the three requirements. CMA indicated more experience was needed and that two of the three requirements should be met. In turn, this helped assure patient safety to CMA.

Committee Member Law inquired if PGY 1 residency would qualify. Dr. Gates indicated no, an applicant would need PGY 1 and one year experience. Ms. Herold stated the committee must look at the intent but also the approved language. Ms. Herold further explained, if a candidate is interested, they could get their experience after their residency through a collaborative practice agreement to get your experience while the board implements the application process for APP.

Dr. Gates provided to the committee the reasons why he became involved in the APP. Dr. Gates is a clinical pharmacist at a Safety Net Hospital in Kern County where pharmacists are used to expand access of care. Kern County is the: second worst county in death due to diabetes and cardiovascular health; second worst county in access to cardiology; and worst county in access to critical care. There are three endocrinologists in the county none of which take Medi-Cal in a county consisting of over 60% Medi-Cal patients. For the past four years, pharmacists have been the only providers for diabetes services which have been paid by Safety Net but there are no funds any more. In order for Kern Medical Center to offer diabetes services, the pharmacists need to be able to bill Medi-Cal. Chair Veale explained the goals of the committee are to implement SB 493 correctly and to protect the consumer. Dr. Gates indicated he is speaking for his patients who are consumers.

USCF Faculty Marilyn Stebbins addressed the committee. Dr. Stebbins indicated after 10-15 years from the effective date, less than 0.9% of the pharmacists in North Carolina are registered as the equivalent of an advanced practice pharmacists. Dr. Stebbins advised looking at the certification process for North Carolina to learn from it. North Carolina licenses through their medical board so that is one area. If the hurdle is so high, no one will be able to become licensed as an advanced practice pharmacist. Ms. Herold commented the practitioners will need to sell their services so they can be reimbursable and the incentive to become licensed as an APP will be there.

The committee took a break at 10:55 a.m. and resumed at 11:12 a.m.

Chair Veale reconvened the meeting and summarized a lot of comments have been received regarding the implementation of Business and Professions Code section 4210. Chair Veale indicated her thought was to receive and absorb the information and start trying to make changes at the Licensing Committee Meeting on March 19, 2014. The committee members agreed and there was no public comment.

4. FOR DISCUSSION: Application and Renewal Requirements of the Advanced Practice Pharmacist License

Background

The board's staff developed a draft application form for the advanced practice pharmacist license. This document, which is clearly a draft, is provided in meeting materials.

Under section 4210, the board will need to establish regulations to describe the elements applicants must submit to demonstrate they qualify for APP licensure. Specifically, the mandate is:

> 4210(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

Additionally, before the board can issue any license, the board will need to establish an application fee (and also a renewal fee) through regulations. The fee of approximately $300 which appears in the bill was an amount estimated by expected worked as SB 493 was moving through the Legislature. However, the language in SB 493 requires the board to establish the fees in regulation.

The committee needs to identify what it wishes to do. Does the committee want to encourage the board to move forward with the regulations now/in the near future with what we can implement at this time, or wait until we have evaluated possible other options for eligibility as an APP?

Discussion

Chair Veale asked Executive Officer Virginia Herold for her comments. Ms. Herold reported the intent of the application is to retrieve the information from the applicant so that a licensing decision can be made upon receipt without deficiencies. The application requests basic information for the pharmacist. A fingerprint background check will not be required again. There are three qualification methods as listed below:

> *Qualification Types:*
> Qualification (a): Certification in a relevant area of practice as specified in B&PC 4210 (a)(2)(A) – Question to the Committee: What type of documentation?
> Qualification (b): Completion of postgraduate residency program – Question to the Committee: What type of documentation?
> Qualification (c): Worked under a collaborative practice agreement or protocol for one year- Question to the Committee: What type of documentation?

Chair Veale indicated the board will probably have to require a signed form with a copy of the protocol. Ms. Herold indicated it may need to indicate the type of patients, how long the protocol was in place, etc. If too specific, the form will get too long. Ms. Herold indicated the board could look at examples from other states in addition to the BPS applications.

Chair Veale posed the question, is a certificate provided upon completion of a residency program? Dr. Steve Gray addressed the committee. Dr. Gray explained the requirements for ASHP residency represent substantial documentation. Dr. Gray suggested the committee be familiar with the requirements for the ASHP residency but not request the documentation in its entirety.

Chair Veale indicated the she is familiar with the ASHP residency but not non-ASHP residency. Chair Veale asked if it was too far to add an ASHP requirement. Dr. Gray addressed the committee and explained there are not enough ASHP residencies for all pharmacy graduates. Chair Veale asked Dr. Gray if he had suggestions of non-ASHP credible residency programs. Dr. Gray indicated he couldn't identify them personally. Chair Veale asked staff to research this. Ms. Herold suggested that the board outline the requirements for the non-ASHP residency and the requirements are verified by the providers.

Chair Veale posed the question if all residency programs are accredited. Dr. Ryan Gates reported to the committee that most residency programs are ASHP are accredited. ASHP does site visits as part of the residency program. A residency program with ASHP has to be 50% patient care with the exception of management care residency programs as he is not familiar with those types of residency. Ms. Herold requested Dr. Gates to provide a copy of the redacted documentation for a residency.

Dr. Robinson reported to the committee that PGY 1 and PGY 2 residency programs. In some cases, a pharmacy graduate may participate in a PGY 2 residency without completing a PGY 1 residency. Often times, PGY 2 residencies are specialty residencies not accredited by ASHP. Committee Member Law queried Dr. Robinson to see if PGY 2 still has 50% patient contact. Dr. Robinson responded yes.

Dr. Gates also indicated there are pre-candidate statuses or are missing one component and don't meet BPS' requirements. Dr. Gates encouraged the committee to allow for non-accredited residency programs. Dr. McVeigh indicated a residency may not be able to accredited because the actual site is not accredited making it ineligible for accreditation.

Chair Veale indicated the committee needs to determine the following information for each Qualification methods:

- Qualification A – verify all residency programs have 50% direction patient care.
- Qualification B – verify this information.
- Qualification C – identify what documentation is needed.

Committee Member Law indicated clarification for Qualification C is required for year and time. Chair Veale indicated Qualifications A, B, and C may all overlap.

Chair Veale asked why the form needed to request the type of service required. Ms. Sodergren indicated at the staff level the board is determining what information is required at time of licensure so that when an inspector goes out into the field for a site inspection, they have sufficient information. Historically, pharmacists had been working in pharmacies. With the implementation of SB 493, pharmacists may now being working in other settings. Additionally, the board is interested in identifying pharmacists' DEA registration numbers. Dr. Butler agreed this made sense.

Dr. Gray commented the application will need further development. Dr. Gray observed that the ordering and interpreting tests portion of SB 493 applies to all pharmacists. Would the board want to collect this information for all pharmacists? Additionally, the DEA license is not able to be obtained until the APP license is secured. Ms. Herold indicated the board will work with the DEA on this part.

Chair Veale indicated board inspectors will need to know where APPs work so that they can be monitored. Chair Veale queried if that would require an APP to notify the board of a change in location of work. Ms. Herold indicated the board is interested in where the APP will be storing records. Chair Veale indicated this may be part of the renewal. Ms. Sodergren confirmed this is the intent.

Mr. Roth from CPHA addressed the committee. He understood the reason to collect information for enforcement purposes. His concern is that it may appear to be an attestation by the licensee that their APP work is limited to what is identified on the application and only at this location. Mr. Roth suggested adding this as additional information not as part of the application but for board information only.

Chair Veale asked the committee if they had any public comment to add. Executive Officer Herold indicated a second version will be forthcoming.

5. FOR DISCUSSION: <u>Requirements for Pharmacists Who Furnish Self-Administered Hormonal Contraceptives and the Development of Draft Protocols</u>

<u>Background</u>

The Board of Pharmacy and the Medical Board of California will again have an opportunity to work together on two protocols for pharmacist activities under provisions enacted in SB 493. One of these protocols is for self-administered hormonal contraception. This provision will apply to all pharmacists who possess the training, not only advanced practice pharmacists. The specific mandate for this provision is:

> **4052.3.**
>
> (a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and

Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

And

(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical follow-up, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

Board meeting materials contain materials on hormonal contraception. The California Pharmacists Association has developed materials that they have submitted to the board; these are at the front this section. Behind these are materials downloaded from the CDC's Web site and several other locations.

The committee needs to review these materials, and determine if it wishes to develop its own draft materials. It then needs to convene a meeting with the designated parties listed in the statute (see above) to develop the protocol and patient-self-screening document. Thereafter, both this board and the Medical Board will need to approve the protocol which will be adopted as a regulation by this board.

Discussion

Chair Veale provided that the board does not have a fact sheet for each type of birth control. Ms. Herold thanks CPhA for their work in developing the draft as a basic component for the requirement. In addition to the general fact sheets are a series of questions to ask a woman before contraception is provided. Ms. Herold indicated the board will need to work with the Medical Board.

Chair Veale inquired as to how emergency contraception was handled by the board. Ms. Herold indicated a bill was secured and adopted by the board and the Medical Board. Medical Board Chief of Legislation Jennifer Simoes indicated she was present to listen and observe. At the next meeting she would like have at least one board member present to be involved so that the board and the Medical Board can work together. Chair Veale indicated a panel of experts is needed. Ms. Herold indicated she would coordinate with Chair Veale and Board President Wiesser. Ms. Herold asked the Medical Board if they had an Obstetrician/Gynecologist on the board. The Medical Board indicated no. Ms. Herold wondered if the previous board member might be interested.

Chair Veale indicated she would like to work with the Medical Board before this comes up again. She indicated her preference would be to use experts in the field while in development stages.

Dr. Gray from CSHP commented that the pharmacist board members explain to the non-pharmacist board members that the category of drugs have been recommended by the FDA to be OTC. Dr. Gray hoped that the instructions to the working group would be to not be too detailed and to refer to a fact sheet but not include it in the regulation. Ms. Herold indicated if the fact sheet is put into regulation, the minute there is a change, the fact sheet can only be changed a rulemaking.

Dr. Gray indicated SB 493 indicates the pharmacist may furnish these prescription drugs. The law allows the pharmacist to provide the prescription drugs to a woman who walks in and requests the prescription drugs; however, this does not allow the pharmacist to write a prescription for the woman to fill elsewhere. This doesn't authorize pharmacists not working in a pharmacy to buy and sell these prescription drugs. The prescription drugs can only be purchased by a licensed facility allowed to purchase prescription drugs.

Chair Veale asked for additional public. Committee Member law asked if there was a specific certification a pharmacist would be required to possess. Ms. Herold thought there might need to be one hour of continuing education but was unsure. Ms. Herold stated she was thankful for the draft provided by CPhA.

Amy Moy from California Family Health Care (CFHC) addressed the committee. In the spirit of SB 493, CFHC would be happy to provide an expert on developing protocols and hope the protocols can be as standardized as possible. Ms. Moy stated birth control is one of the safest and widely used medications but there are certain contra-indications and items that should be flagged. Additionally, CFHC would like to put out for consideration a recommendation that once a woman completes the questionnaire that doesn't stand in perpetuity. Some items such as items such as weight and blood pressure change over time that could impact contra-indications CFHC would like to see these items reassessed every two years. Chair Veale posed the question to the committee that this should be part of the standard of practice. Ms. Herold agreed this should be part of the protocol.

Brian Warren from CPhA submitted the document from a panel of experts completed relatively quickly and realized this is a draft. Dr. Besinque from USC was a main expert but unable to join us today. Dr. Besinque asked that Mr. Warren express her concern to work with the board. Chair Veale asked that Mr. Warren convey the board's appreciation for her work.

Dr. Gray from CSHP commented on the expectation that a new prescription is needed every year. Dr. Gray indicated this is not California law but company policy. Dr. Gray hoped that those who develop the protocol determine what the health care officials prescribing these medications determine what the expectation to be. Chair Veale added that could be part of the protocol.

Chair Veale asked the committee about the continuing education required. Ms. Herold indicated this would be part of the purview of the sub-committee developing the protocol.

Chair Veale asked for board and public. In the absence of either, Chair Veale continued with the agenda.

The committee broke for lunch at 12:05 p.m. and resumed at 1:18 p.m.

6. FOR DISCUSSION: Requirements for Pharmacists Who Initiate and Administer Immunizations Pursuant to Recommended Immunization Schedules by the Federal Advisory Committee of Immunization Practices of the CDC

Background

Senate Bill 493 allows all pharmacists who possess the designated training to provide immunizations pursuant to the CDC's guidelines.

The bill provides the following:

> **4052.8.**
>
> (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.
>
> (b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:
>
> (1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that,

at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

Meeting materials contain the CDC's materials on immunizations. The committee discussed and reviewed these components. The board's inspectors will check pharmacists administering immunizations for adherence to the CDC's requirements.

Discussion

Ms. Herold indicated there is no protocol in place. Chair Veale inquired as to what the committee needs to do. Ms. Herold stated this is for information and is self executing. The committee reviews this and ensures a regulation isn't needed. Pharmacists are able to do this without approval from the board.

Chair Veale opened the discussion to committee members to deviate from what is in place or recommend changes. There was no committee comment. Chair Veale asked for public comment. There no public comment.

7. FOR DISCUSSION: Requirements for Pharmacists Who Furnish Nicotine Replacement Products and Development of Draft Protocols

Senate Bill 493 directs the board to work on development of a joint protocol with the Medical Board to permit pharmacists to furnish nicotine replacement products.

The statutory requirements for this are:

4052.9.

(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate

entities and provide smoking cessation services if all of the following conditions are met:

(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.

(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.

(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.

(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.

(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.

Meeting materials contain a sample protocol developed by CSHP. The committee needs to determine how it wishes to proceed with the development of this protocol in conformance with the statute.

Chair Veale asked the committee if the protocol developed by CSHP is sufficient or does the committee want to modify. Chair Veale indicated the committee needs to look at training as the law appears to require one hour of continuing education. Chair Veale inquired if the board is aware of training currently available.

Sarah McVeigh with UCSD commented to the board that she was part of the group developing these materials. There is extensive free robust continuing education through University of California San Francisco RX for Change Program being used in most of the schools of pharmacy. This is an evidence based source designed for pharmacists. Chair Veale asked if Dr. McVeigh believed these were one hour or more and comprehensive. Dr. McVeigh indicated d this was what her committee reviewed when providing this information.

Chair Veale asked if the committee believes this meets the requirements, does the committee bring this to the Medical Board. Ms. Herold indicated this would be approved at the board level

prior to going to the Medical Board. Ms. Herold assumed the intent is to include the chart in the materials provided.

Dr. McVeigh indicated the intent is to make this document made available for the board for pharmacists but not necessarily needing to be part of the protocol. Ms. Herold asked who created this document. Dr. McVeigh indicated the document provided for the board's consideration was paraphrased from documents from UCSF's RX for Change. The intent is to use this fact sheet in conjunction with the protocol without being part of the protocol so as not to impede updating the document as needed. Dr. McVeigh provided there is a fact sheet.

Chair Veale asked Ms. Herold if there is a reason to have this in regulation. Ms. Herold indicated the board is complete to cover all materials but the Medical Board will also need to provide input. Dr. McVeigh identified three nicotine replacement therapy are available OTC: gum, lozenge, and patch without the protocol. The addition of the protocol includes the nasal spray and inhaler. Dr. McVeigh reiterated the board may not want to include the table as part of the protocol should more products be added. Ms. Herold believes the document is too light for a protocol as well as mentions "writing a prescription" on the fact sheet that would need to be removed. Dr. McVeigh indicated the prescription is documented in the profile to allow for reimbursement by insurance for payments.

Dr. Gray commented this can only be done in pharmacy and there has to be documentation of the furnishing of the prescription product that is labeled like a prescription. Dr. Gray indicated the word "prescription" may be misleading. Ms. Herold indicated the protocol would be approved by our board and then the Medical Board.

Dr. Gray indicated a clarifying statement about recordkeeping and inventory would be helpful. Dr. Gray indicated the statute didn't mention a specific age but the protocol indicated age 18. Dr. McVeigh indicated this referenced the FDA labeling and if it is used for someone under 18, the use is off label. Dr. Gray indicated this may need to be rethought as assistance to those under 18. Ms. Herold indicated Legal Office would need to review to determine what needs to be specified. Ms. Herold indicated she would strike the age reference.

Chair Veale asked for committee and public comment. Committee Member Law thanked Dr. McVeigh.

Chair Veale asked if there are any public comments for items not on the agenda or future agenda items.

Dr. Gray commented there is also the protocol for travel medication within SB 493 but CSHP was not ready to submit anything. Ms. Herold indicated the board has an expert lined up.

Chair Veale adjourned the meeting at 1:41 p.m.