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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: September 5, 2007

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Ruth Conroy, PharmD, Chairperson
Clarence Hiura, PharmD
Susan L. Ravnan, PharmD
Henry Hough, Public Member
Robert Graul, RPh

STAFF PRESENT:
Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Robert Ratcliff, Supervising Inspector
Anne Sodergren, Legislation and Regulation Manager
Christine Soto, Licensing Manager
Karen Abbe, Public and Licensee Education Analyst

CALL TO ORDER

Chairperson Conroy called the meeting to order on September 5, 2007 at 9:34 a.m.

1. Proposed Regulation Requirements for Pharmacies that Compound Medication – Amendments to 16 CCR Sections 1716.1 and 1716.2 and Adoption of Sections 1735 - 1735.8 – Self-Assessment Form

Dr. Conroy advised that at the July 2007 Board Meeting, the board voted to initiate the rulemaking process for the compounding regulations. To finalize the regulations, the self-assessment form needed to be developed.

She stated that the revised language and the draft self-assessment form were provided in the meeting materials for committee review and comment.

Deputy Attorney General Joshua Room stated that in addition to the self-assessment form, staff meshed the proposed compounding requirements with the existing sterile injectable compounding regulation. Compounding requirements as a general category are promulgated in proposed Article 4.5 and sterile injectable compounding in Article 7.

Article 7 is layered on top of Article 4.5, and provides the additional requirements for sterile injectible compounding.

Mr. Room noted key changes in section 1735(d). That subdivision makes explicit that the parameters and requirements stated by Article 4.5 (Section 1735 et seq) apply to all compounding practices; additional parameters and requirements applicable solely to sterile injectable compounding are stated in Article 7 (Section 1751 et seq).

Mr. Room said that revisions to Section 1735.1(c) addressed the presence of decomposed substances and other harmful contaminants to be excluded from quality compounded products.

Steven Gray, from Kaiser, commented that wording in section 1735.1(c) should reflect "quantitative" and "qualitative" and he suggested that "harmful amounts" be used in the language.

Mr. Room added that in Section 1735.3(a)(6), the word "supplier" was replaced by "manufacturer or supplier" because of the inability in some circumstances to get the name of a manufacturer. Some suppliers are unable or unwilling to get the name of a manufacturer.

Supervising Inspector Bob Ratcliff asked how e-pedigree would affect compounding.

Mr. Room responded that e-pedigree only deals with finished products.

Mr. Room said that most revisions to Article 7 reflect renumbering; for example, numbering of .01 and .02 was confusing, so these sections were renumbered to .1 and .2. The general idea of the revisions to Article 7 was to make it a subset for specialty compounding exceeding requirements of Article 4.5. Mr. Room added that all duplications should have been removed, and he welcomed comments if any items are still duplicative.

Mr. Hough noted the requirement to maintain records for at least three years had been deleted from Article 7 section 1751.1. He said that from an administrative standpoint, there should be some kind of time limit.

Mr. Room stated that the three-year retention would apply to all sterile compounding records as well. He added that section 1751.1 hadn't changed much, other than the numbering.

Mr. Graul asked about Article 4.5 section 1735.2(c) as listed on the self-assessment form. He stated that he believed the intent under subsection (c) is that (1), (2), and (3) are all to be followed.

Mr. Room responded that yes, all three criteria must be satisfied.

Mr. Room responded that it wouldn't hurt to put another "and" in the language. It's general statutory process to put it in only before the last item in a series.

Mr. Graul said he wants to ensure that everyone knows that all three must be satisfied.

Ms. Herold added that the boxes would be deleted from that portion of the self-assessment form.

Dr. Ravnan noted that federal requirements break it down into sterile compounding and non-sterile compounding.

Mr. Room responded that Article 7 is an additional step of sterile compounding, lying on top of Article 4.5.

Dr. Ravnan asked whether a pharmacy that is doing sterile compounding still needs to fill out the self-assessment form for nonsterile compounding.

Mr. Room responded, yes.

Dr. Gray added that there are three categories – compounding, sterile injectible compounding, and nonsterile injectible compounding. There may need to be more regulatory sections. When the regulations were first developed, stakeholders were not ready to take on all aspects of compounding.

Mr. Room responded that another option would be to have entirely duplicative regulations having all the same baseline. We want to set a baseline for all compounding, and set additional requirements for sterile injectible compounding. Any ideas about the best way to do that are welcomed.

Mr. Room also noted that variation in pharmacy practice is another reason to have this layered system. Individual pharmacists must have an additional license to do sterile injectable compounding or have specified accreditation and still comply with California's requirements.

Ms. Herold added that if the board wants to add another subsection, they could do so by adding regulatory language. She said she appreciated the time that Mr. Room spent developing this new language.

Phillip Swanger, Director of Governmental Affairs for the California Society of Health-System Pharmacists, said they sent a letter to Ms. Herold on the issue of sterile and non-sterile compounding. They believe Mr. Room's revised language resolves issues, but they suggest requiring just one self-assessment form.

Ms. Herold responded that for pharmacy operations, the self-assessment form should be completed. For sterile injectible compounding, there is a separate self-assessment form to be completed.

Mr. Room added that we can have one self-assessment form with an appendix for sterile injectable compounding, rather than two separate forms, which will have duplication.

Ms. Herold emphasized that she wanted to thank Mr. Room again for working on this regulatory language.

Ms. Herold added that the committee could decide whether to further refine the language, and then bring it to the full board for consideration. She suggested bringing the regulation to the board in October to hear additional comments at that point. Then the proposed language could go out to public notice, and the board could take action in January 2008.

MOTION: That the proposed language and self-assessment form regarding Pharmacies that Compound Medication (amendments to 16 CCR Sections 1716.1 and 1716.2, adoption of Sections 1735-1735.8, and amendments to sections 1751-1751.8) be presented at the October 2007 Board Meeting with the recommendation to release for the formal rulemaking process.

M/S: HIURA/RAVNAN

SUPPORT: 5 OPPOSE: 0

2. Update: Request to add the Exam for the Certification of Pharmacy Technicians (ExCPT) developed by the Institute for the Certification of Pharmacy Technicians as a qualification method for Pharmacy Technician Registration

Dr. Conroy summarized the background information in the meeting materials. In California, individuals may become qualified for registration as pharmacy technicians by one of four means:

- Possessing an associate's degree in pharmacy technology
- Completing a course of training specified by the board in regulations (accredited by ASHP, provided by the armed forces, or at least 240 hours of instruction covering specific topics)
- Graduating from a school of pharmacy recognized by the board
- Being certified by the Pharmacy Technician Certification Board (PTCB)

At the October 2006 Board Meeting, the board directed a review of a new exam, the ExCPT, to determine if it is job-related. The ExCPT is a relatively new computer-based test used to assess the knowledge of pharmacy technicians. The Institute for the Certification of Pharmacy Technicians developed the ExCPT, and made a presentation to the board in October 2006.

Section 139 of the Business and Professions Code requires a periodic assessment of all licensure examinations used by a regulatory agency for job-relatedness. Initially, board staff had hoped to use professional staff in the Department of Consumer Affairs Office of Examination Resources (OER) to conduct this assessment. However, the Department of Consumer Affairs was having a difficult time with recruitment of a PhD-level expert to oversee the office.

As a result, board staff met with the department to identify the appropriate means by which to contract with a consultant to provide a review of the documentation for both the PTCB and ExCPT exams to ensure they are job-related and meet California's requirements.

Ms. Herold added that in order to do an adequate assessment of both exams, we need someone specifically trained to do it. This type of specialized staff is in very short supply. The DCA no longer has a PhD to perform this task, and state agencies cannot contract it out until everyone in state service is exhausted. Ms. Herold asked whether the committee wished to continue with this effort.

Dr. Ravnan added that California's pharmacist associations are looking at qualifications of pharmacy technicians, and asked if the committee could table the matter until we get their recommendation.

MOTION: That the committee table the matter of reviewing the ExCPT exam pending the recommendation for changes in pharmacy technicians training currently underway.

M/S: GRAUL/RAVNAN

SUPPORT: 5 OPPOSE: 0

3. California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should Be Achieved by the End of Basic Internship Experiences

Chairperson Conroy summarized the background on this issue. The board participated in a project initiated by California's schools of pharmacy, who are working together with other stakeholders to evaluate the components of ACPE approved intern experience at both the basic (IPPE) and advanced (APPE) levels. The project is called the California Pharmacy IPPE/OSCE Initiative.

This initiative is in response to new ACPE accreditation standards that spell out how much time students must spend in IPPEs and APPEs rather than what they should learn (outcomes). Board Member Ravnan, Legislative Coordinator Anne Sodergren, and Ms. Herold attended three meetings, which resulted in a list of basic competencies that students should achieve by the end of the IPPE.

The second phase of this effort began in June 2007 and involves developing a reliable and valid performance-based exam. An objective structured clinical exam (OSCE) would assess student

achievement of these competencies. The timeline aims for incorporation of the standards during academic year 2007-08.

Dr. Conroy stated that the meeting materials included a copy of the competencies developed under this project, as well as a request from Mary Anne Koda-Kimble, who represents the UCSF School of Pharmacy. Dr. Koda-Kimble asks that the board affirm its agreement with this document.

Dr. Ravnan said that without clarification about the board's role, she is concerned that we do not have the authority to approve curriculum.

Dr. Conroy commented about Dr. Koda-Kimble's letter and whether she is asking for board approval.

Mr. Room clarified that this is the type of thing that is affirmed by silence. It would be more appropriate for individual board members to communicate their concerns about deficiencies, rather than the board to affirm the document.

Ms. Herold added that affirming the document has little effect unless the board makes a regulation. At the last meeting, it was suggested that the board look through the guidelines and if something rings untrue, we should call attention to it.

Dr. Gray commented that one of the original concepts of the OSCE program was concern by the school that the required number of hours would interfere with pharmacists' education. The 300-hour requirement was somewhat arbitrary. He suggested a list of competencies that must be obtained, and if they achieved the competencies in 100 hours, should satisfy the ACPE. The arbitrariness of 1500 hours or 500 hours or 2,000 hours doesn't serve the industry or the public safety well. Dr. Gray stressed that we still have students that come out that meet requirements for a license, but do not have these competencies.

Dr. Ravnan commented that we could consider changing the licensing requirements, and entertain the idea of offering a licensing exam similar to the Medical Board. We need to have control over the quality of the exams.

Dr. Conroy asked if there were any comments about the board existing requirements for 900 hours of the 1,500 intern hours be earned inside a pharmacy. She said that some board members felt that 900 hours inside a pharmacy was necessary.

Dr. Hiura stated that he has always had a problem with determining the level of competency of students practicing today. He would like to ask universities what they are lacking and how to correct those deficiencies.

Dr. Gray spoke about the objective of the project, which is that students will come out with experience. He asked whether Dr. Koda-Kimble's objective was that she just wanted

acknowledgement from the board without an official endorsement. He suggested taking it to the full board for discussion.

Mr. Graul stated that there are three issues at hand – basic versus advanced intern training as imposed by ACPE schools, whether or not the board's requirement for 1,500 hours is appropriate, and whether or not the 900 hours needs to be done as a subset.

Dr. Conroy stated that we tabled the discussion regarding the 900-hours about one year ago pending the ACPE project. She recommended that Dr. Koda-Kimble's letter be referred to the board in October for discussion.

4. Creighton University School of Pharmacy Program's Web-Based Pathway to PharmD Degrees

Chairperson Conroy stated that the American Council on Pharmacy Education (ACPE) has approved its first online PharmD program, which is being offered by Creighton University. They also offer a traditional PharmD program.

Ms. Herold added that this program has been accredited for a while, and it is innovative. She added that the item was provided to the committee only for information.

Ms. Sodergren added that this program began in 2000, and falls under the same accreditation standards as traditional schools.

Dr. Ravnan asked if any of their students had taken California's exam.

Ms. Herold responded that she did not know.

5. Update: Disaster Response/California Department of Health Services – Healthcare Surge Project

- Request from San Diego County to Exempt Prescription Container Labeling Requirements for First Responders and Their Families as Part of Emergency Preparedness

  The board received a request from San Diego County to provide up to 500,000 bottles of a 7-14 day dosing regiment of doxycycline or ciprofloxacin to first responders, that would be stored in their homes for their and their families' use, with the remainder being stored elsewhere. The county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers.

  Board staff was unaware under what authority the board could grant such an exemption in advance of a disaster unless the board promulgated a regulation or obtained statutory approval to authorize this.

Dr. Conroy advised that San Diego County withdrew their request, in order to gather more information.

- Request from Ralphs to Deploy Mobile Pharmacies After Declared State of Emergency

Chairperson Conroy advised that the board had received a request for guidance from Ralphs Grocery Co. about the appropriate use of mobile pharmacy trailers. Ralphs would like to use these trailers under emergency conditions or in the event an existing pharmacy is damaged or closed. A copy of the request was provided in the meeting materials packet for committee discussion and recommendation.

Dr. Conroy stated that there are two different situations – damage to a pharmacy, where you would put an RV in the parking lot, or 2) if an entire area is destroyed.

Ms. Herold added that she would defer to Supervising Inspector Ratcliff, and that the NABP recommended that pharmacies have mobile units available.

Mr. Room asked whether they meant a disaster to Ralphs was a disaster to an entire region.

Dr. Ratcliff responded that there are two examples. Example 1 would apply to an existing licensed Ralphs Pharmacy that is damaged and closed. Ralph's would deploy a mobile pharmacy to the parking lot of the closed store, activate the generator, and operate under the current license of the damaged pharmacy.

Mr. Ratcliff clarified that the law currently allows that practice for pharmacies. If there's a fire, or they want to do a remodel – they can operate out of a trailer. We tell them that the wheels must be removed from the trailer so it can't be towed away in the night.

Example 2 would apply to an existing licensed Ralph's Pharmacy that is completely destroyed, and the current license location is not available to park the mobile pharmacy.

Dr. Ratcliff clarified that the drugs ordered must be delivered to the address of record for the licensed entity under California Business and Professions Code section 4059.5. Example 2 creates problems for a supplier, and statutorily, they can't do it, unless a change of address has been approved.

Ms. Herold asked if there were any thoughts on whether we can promote this.

Mr. Graul said the concern is licensing. They can only use the license to replace that pharmacy. If there's a disaster in Sante Fe, from a bigger perspective, trailers could be deployed to bring them in to where the emergency is. Mr. Graul said he was not sure of what is the best way to handle this.

Dr. Conroy added that many chain stores have RVs for this purpose. She gave MEDCO as an example of a chain store that came in to the areas affected by Hurricane Katrina.

Mr. Room stated that the board could certainly issue a temporary license for some fixed location in that area, saying in the interest of an emergency, it has waived provisions. However, you do need to have fixed addresses or locations to issue a license.

Dr. Conroy asked how fast a temporary license could be provided. If it was provided in a matter of weeks or months, that would be of no use during an emergency.

Mr. Hough stated that, as a matter of principle and general policy, the board should be on record encouraging these kinds of trailers. Obviously, in terms of disaster preparedness, it is essential that this would be a matter of policy to encourage Walgreens and others to consider this kind of thing. Mr. Hough stressed that we have got to prepare, and that September 11th showed a need for preparedness.

Mr. Room responded that there are two possible ways to do this. There could be an amendment to the disaster preparedness statement on the Web site to specifically mention and encourage the use of trailers. Another way to do it would be to preload a temporary trailer license procedure that could be expedited in the event of an emergency.

Mr. Walker stated that a statutory or regulatory change could be made, and that the Board of Optometry addressed the matter in their regulations. The Board of Optometry specified how the trailers are to be used, and in what circumstance. Mr. Walker added that he did not think it would be wise to amend the board's emergency preparedness statement at this time prior to an investigation about whether it can be done without regulatory change.

Dr. Hiura added that he felt that during an emergency, anything goes as far as he's concerned. As far as regulations and paperwork, tons of people affected by Katrina got their medications. If you're a professional, you can do as much as possible to help people.

Mr. Graul said that trailers will exist ahead of time, and that having a regulation on the books that addresses those specific trailers makes sense.

Dr. Ravnan added that she liked the concept of trailers as well, but she would rather see one in person and consider the security issues and other factors.

Dr. Conroy added that during Hurricane Katrina, some pharmacies were wiped out and the National Guard was guarding them.

Ms. Herold asked how may trailers Walgreens has.

Dr. Conroy responded that she doesn't know how many trailers they have, but they have RVs ready to respond as needs arise, like in fires.

Ms. Herold said that it appears they drive an RV to a site, and take care of patients, but they are not necessarily licensed at that location. She agreed with Mr. Ratcliff that in the event of a disaster, we don't want to get in the way of doing the right thing. To plan for disaster, we can encourage the use of trailers and develop a regulatory framework for it. Possibly temporary permits may be a solution.

Dr. Conroy added that she served on the NABP committee.

Doug Hillblom, from Prescription Solutions, commented that there are a number of issues as we go into this. For example, what happens to the supplies in the pharmacies that are destroyed? How are pharmacies licensed? What about moving stock from semi-destroyed pharmacies to other pharmacies?

Dr. Gray asked that the board not stray too far. He said that Examples 1 and 2 are taken care of already because the board has recognized those situations in the past. For example, taking the wheels off a trailer. Another example being getting a temporary address change quickly, and the pharmacy is still under a local licensed entity. But there is an "Example 3" which would be an entity wanting to help, but not having a local address. Kaiser has a contingency contract with a mobile home/trailer company that promises, on 12 hours notice, to deliver a unit with security, air conditioning, inside toilets, and washing stations to meet health requirements. The units will be readily available, and they have the same contract with suppliers of generators that run on diesel oil.

Ms. Herold asked whether "immediate" meant within 24 hours.

Dr. Gray responded that he had experience during the Northridge earthquake. During a short period of time, just 48 hours, they had a mobile unit set up in a parking lot.

Mr. Graul asked whether the board has a subcommittee looking at the regulations.

Dr. Conroy responded, no.

Mr. Graul suggested that a subcommittee review the regulation and statutes, looking at disaster preparedness.

Ms. Herold added that the Office of Emergency Services (OES), and part of the Department of Health Services, understand that without medication during an emergency, patient care is compromised. In *The Script*, the board encouraged the flow of medicine so that people can be treated. The board got so far out in front on this issue, the DHS thought the board would waive all of its requirements. To be clear, the board would not waive all requirements – we just want pharmacists to be there taking care of patients. Ms. Herold emphasized that the board wants to be better prepared to perform its role during an emergency.

Dr. Conroy stated that she sat on the NABP panel. It has since disbanded, but in two days, they came up with guidelines. We should continue to look at licensure issues, and specifically mobile pharmacies that aren't tied to a specific pharmacy.

Dr. Gray added that, as we proceed, we should bring DHS in for discussion because there will be a problem for patients that need Medi-Cal and other indigent patients that can't pay. If medications can't be provided for free, our most disadvantaged patients cannot pay the money and be reimbursed later. He said that, especially in isolated areas, there would be problems because of transportation services. Dr. Gray encouraged the board to ask that DHS participate in this discussion.

Dr. Conroy added that in Hurricane Katrina, FEMA didn't require payment. FEMA later did pay, but you must have had a contract or agreement with FEMA to get that.

Dr. Gray responded that many pharmacies never got paid by FEMA.

Dr. Hiura stated that payments to pharmacies will not be an issue during an emergency.

- Rough and Ready 2007

Dr. Conroy stated that she recently attended "Rough and Ready 2007," a joint civilian-military disaster field training and demonstration. The scenario presented was a Southern California disaster causing mass casualties. She said it was quite interesting, and the event included participation by three mobile field hospitals. The field hospitals were set up, and a number of different organizations were also there. The California National Guard, among other agencies, participated. The California National Guard can put 82 gurneys on one plane.

Dr. Conroy emphasized that the different programs that participated talked about how they all linked together. Emergency personnel, from fire fighters to nurses, provided better understanding about how they all work together. The Governor has emphasized emergency preparedness during the last couple of years.

Dr. Conroy added that the communication capabilities are impressive, and a plan is in place outlining which entity comes in first second, second, and third, to provide care.

- California Medical Volunteers

Dr. Conroy advised that board staff recently participated in the evaluation of proposals for the implementation and operation of California's Emergency System for the Advanced Registration (ESAR) of Volunteer Health Professionals. This system, known as the California Medical Volunteers, will play in instrumental role in the deployment of registered health care professionals in response to disasters and terrorist events.

The board will continue to highlight this in upcoming newsletters to encourage pharmacist participation.

Ms. Herold added that it was an honor to be asked to participate in this, which is due to the board's efforts in disaster response. Anne Sodergren sat on the panel.

Ms. Herold said that the board would continue to promote it in *The Script*. She emphasized that the importance of training and drills. She said that pharmacists have not been well represented in the planning stages, until recently.

6. Legislative Proposal: Establishment of State Protocols for Immunizations

Dr. Conroy summarized the history of this issue. She stated that at the July 2007 Board Meeting, the board voted to adopt the proposed state protocols to allow pharmacists to administer immunizations. At the last Licensing Committee Meeting, Dr. Jeff Goad, a professor from USC, made a presentation to the committee about establishing state protocols for immunizations by pharmacists. Dr. Goad stated that pharmacists can administer immunizations in 44 states. California is one of these states.

Business and Professions Code Section 4052(a)(9) allows a pharmacist to administer immunizations pursuant to a protocol with a prescriber. According to testimony provided by Dr. Goad, physicians are reluctant to accept the liability for this action, even though it has wide support. Additionally, Health and Safety Code Section 1261.3 allows for a pharmacist to administer both the influenza and pneumococcal immunizations for a certain patient population in a skilled nursing facility pursuant to standing orders.

Since the July 2007 Board Meeting, the proposed language has been revised to detail more specific training requirements, continuing education requirements, as well as recordkeeping and reporting requirements.

The meeting materials contained a draft of the proposed language for committee consideration as follows:

Business and Professions Code Section 4052.8

(a) A pharmacist may order and administer immunizations pursuant to a protocol with a prescriber or pursuant to the current Recommended Adult and Adolescent Immunization Schedules provided by the Centers for Disease Control and Prevention consistent with the published recommendations of the Advisory Committee on Immunization Practices.
(b) Any pharmacist administering vaccines pursuant to this section may administer epinephrine by injection for severe allergic reactions.
(c) Prior to performing any procedure authorized by this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization

certificate program or another pharmacy-based immunization training program endorsed by Centers for Disease Control and Prevention within the last four years.

(d) A pharmacist administering immunizations pursuant to this section must complete 2.5 hours of immunization related continuing education coursework annually.

(e) Any pharmacist administering vaccines pursuant to this section shall maintain current Basic Life Support certification.

(f) Any adverse event must be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.

(g) The patient or patient's agent must receive the appropriate Vaccine Information Sheet for each vaccine administered.

(h) A pharmacist who administers vaccines pursuant to this section shall provide documentation of vaccine administration to a specified provider as directed by the patient or patient's agent.

(i) The pharmacist must maintain a vaccine administration record that includes the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, vaccine information statement date, and the name and title of the person administering the vaccine

Dr. Conroy asked whether item "c" relating to a pharmacist completing a certification program within the last four years was an additional requirement.

Ms. Herold responded, yes, that is an additional requirement.

Mr. Room said that vaccination records would be kept for three years, and medical records would be kept longer. He said that another possibility would be that vaccination records be transmitted to a patient's primary care physician.

Ms. Sodergren noted that subdivision "h" might not be clear. The language needs to be reworked if a pharmacist is to provide the records to a specific provider.

Orriette Quandt, Longs Drugs, said that pharmacists who do immunizations keep the records for four years.

Dr. Gray said the requirements may not be exactly applicable to community pharmacy programs because most vaccines are pediatric. They keep the medical records until the age of majority plus one year, because that's the law regarding minors. With new vaccines for pre-teens and teenage girls, they keep records often longer than the three or four years, the traditional period for record keeping. They keep records for a national fund set up to cover costs for patients harmed from the vaccine. They must have records to reference.

Dr. Gray added that the liability of providing these vaccines is so high, a fund was set up for kids harmed by a vaccine. He also added that people who come in saying "give me a shot," usually don't have a doctor.

Mr. Room responded that the best option is to have cascading requirements. If a patient's provider can be identified, then keep the records for three, four, or five years, or age of majority plus one year. That could be a possibility.

Dr. Gray responded that for vaccines covered under Medicare Part D, there's a ten-year record-keeping requirement.

Medical records are required to be kept for seven years. An immunization would qualify as treatment or service provided by a medical provider, so it would fall under that requirement.

Dr. Gray said that, here again, we need to engage DHS' campaign to provide vaccines to children. DHS has a program, which is trying to get indigents, American Indians, and everyone vaccinated. They are putting together a database to feed into. With those populations, patients themselves don't keep good records, or complete inoculations if a series of inoculations is needed. He suggested that the board ask DHS what they do. He offered to get the name of the DHS person who is interested in increasing their outreach program.

Dr. Conroy said that there's a lot of talk about a statewide registry for childhood vaccinations. If that was in existence, we would want pharmacists to report into it. She asked if there were any thoughts or comments on that.

Mr. Graul suggested that the board ask Dr. Goad because he's been running a travel clinic for many years. Dr. Goad may have insight into this issue. Mr. Graul said he agreed with Mr. Walker that seven years is the requirement for keeping records on adults. For minors, it is the age of majority, plus one year.

Dr. Gray suggested considering a requirement that a pharmacy give a patient a record of their vaccinations. He said that patients get confused on where they're at in a series.

Dr. Conroy responded that pharmacies are required to give patients a vaccine information sheet, but not a record of their vaccines.

Following a discussion about the age for adolescents, staff agreed to refine the regulation.

Dr. Gray added that immunizations are not necessarily an injection. For example, flu mists.

Dr. Ratcliffe noted that under subdivision "d" a pharmacist administering immunizations must complete 2.5 hours of immunization-related continuing education coursework annually. Other than emergency contraception, this is the only carve-out. He asked whether is 2.5 hour requirements was going to be maintained, other than being sent to the board.

Dr. Gray added, that as a practical matter, you don't receive continuing education for a half hour. It would be either two or three hours, and it should be from an accredited provider.

Ms. Sodergren noted that Dr. Goad said that information is contained in the CDC recommendations.

Ms. Herold said that this is a piece of legislation we want to sponsor next year. We should get the language in good shape, and we are seeking comments and legislative proposals so we can refine it. The board needs professionals to support this as a coalition.

Dr. Conroy asked if there were any additional comments on this issue. There were none.

7. **Competency Committee Report and Update on Transition to a New Test Administration Company for the California Pharmacist Jurisprudence Examination**

Conversion to New Examination Vendor

Dr. Conroy referred to the information in the meeting materials. On June 1, 2007, the board converted to a new vendor to administer the CPJE. The new firm is Psychological Services, Inc. (PSI). Board staff is working to resolve the issues that have arisen as a result of the transition to the new vendor.

Examination scores from tests administered at PSI were released on August 27. Part of the delay was due to the conversion, but also there was slow test taking since June 1, 2007 by the applicants. Another quality assurance check is scheduled to begin September 1, 2007.

Ms. Herold stated that the overall pass rate so far is 80 percent. Quality assurance reviews are built in, and they are important to ensure the integrity of the CPJE. Ms. Herold emphasized that the board's priority is to license those who have passed the exam.

Competency Committee

The Competency Committee held a two-day meeting in August to discuss exam-related issues and work on future questions. One issue discussed was the compromise of exam questions and cheating on the exam, which led the committee to request that the board seek higher penalties from those applicants who compromise the exam discussed below. There are two meetings scheduled this fall; one in September 2007 and one in October.

NAPLEX Compromised

Dr. Conroy stated that on August 6, 2007, the NABP issued a notice to all state boards of pharmacy that US Marshals seized materials and computers from the University of Georgia College of Pharmacy after allegations of breaches of the National Pharmacy Licensure Examination (NAPLEX). As such, the NABP was suspending administration of the NAPLEX until the matter could be investigated. A process that could take months.

Dr. Conroy noted that the meeting materials contained recent updates by the NABP, as well as the information posted on the board's Web site and news articles.

The board supports the efforts by the NABP to secure its examination from possible compromise and to fully investigate the matter before resuming administration of the examination. Failure on the part of NABP to take such action could result in compromised public safety.

Dr. Conroy added that applicants should continue to apply for the NAPLEX, so that once the exam is ready, they can take it.

Regulation Proposal to Strengthen Penalty for Dishonest Conduct by Applicants

Dr. Conroy referred to the meeting materials, which contained draft regulatory language for the committee's consideration. The language strengthens the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation is generated from the board's Competency Committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is $2,000 per test item (there are 90 test items on any test). Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

As recently as September 2005, the board disciplined two licensees for compromising the board examination and is currently working with the NABP to address allegations of a recent candidate who allegedly cheated on the NAPLEX while attempting to qualify for a pharmacist license in California.

Ms. Herold noted that the proposed language in the meeting materials was developed prior to the recent compromise of the exam. The recent compromise involved an applicant who was caught in her car while taking the exam. Dr. Hiura and Dr. Ravnan were prior members of the Competency Committee, and they were aware of the hard work of this committee because the integrity of the exam is important.

Dr. Ravnan asked whether penalties are in place for applicant found cheating, after they have already received a license.

Mr. Room responded, yes; however, it became a formal disciplinary process.

Dr. Gray stated that in Georgia, there was confusion among faculty about whether they could ask a licensed pharmacist about the exam experience. If faculty asked a pharmacist if this was on the exam or that was on the exam, would that be considered cheating? He added that it happens all the time.

Ms. Herold responded that, technically yes. And if you are specific about the questions and possible answers, you are reconstructing the exam. The agreement candidates must sign before taking the exam says they agree with this policy. This is a licensing exam, and the board spends a lot of money validating whether a person has the knowledge to perform safely. Generally helping students prepare is different than crossing the line by memorizing questions and answers. Ms. Herold recommended that applicants just don't talk about the exam.

Dr. Conroy suggested that there is a difference between confirming that there are questions about hypoglycemia on the exam, as opposed to memorizing a specific question and then sharing it.

Dr. Gray stated that he knows there are dinner meetings where faculty are general interested in whether they gave them the help and information they needed for the exam. They may ask if the exam went into a pharmacodynamic. Well meaning people may mislead a student down a wrong path. Education and outreach may be needed, so this issue should go to the Communication and Public Education Committee. Dr. Gray added that he's familiar with an exam prep course that went over the line, but there is ordinary faculty discussion that coursework is pertinent to what students need to know. He considers cheating as writing on a cup or going out to their car.

Mr. Room added that he was fine if we want to provide public education, but we shouldn't engage too much in hypotheticals as far as what would constitute a violation for fear of compromising future cases. It comes down to discretion – when it crosses the line into "teaching to the exam," it should be left in the hands of enforcement staff as to when that becomes an enforcement case. Don't be so specific as to say you can ask three questions about the exam, but not four questions. The general message is that the exam is confidential. Don't repeat items on the exam, and don't convey how many questions about this or that are on the exam. They may be innocent questions, but they endanger the confidentiality of those exam questions.

Ms. Herold added the members of the Competency Committee are sworn not to discuss the exam, and not to tell people that they're on the committee. Members of faculty sometimes put pressure on people to reveal what's on the exam.

MOTION: That the committee approve the proposed language to strengthen the penalty for dishonest conduct by applicants, amending Sections 1721 and 1723.1 of Division 17 of Title 16 of the California Code of Regulations from one year to three years.

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern ~~card~~ license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

M/S: GRAUL/HIURA

SUPPORT: 5 OPPOSE: 0

ADJOURNMENT

There being no additional business, Chairperson Conroy adjourned the meeting at 11:55 a.m.