



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: January 20 and 21, 2010

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

BOARD MEMBERS

PRESENT: Kenneth Schell, PharmD, President
Randy Kajioka, PharmD, Vice President
Stanley C. Weisser, RPh, Treasurer
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Greg Lippe, Public Member
Shirley Wheat, Public Member
Deborah Veale, RPh

BOARD MEMBERS

ABSENT: Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Fraga, Staff Analyst

Call to Order

President Schell called the meeting to order at 9:04 a.m.

General Announcements

President Schell provided that the board has recently received two appointments.

President Schell recognized new board member Deborah Veale and DCA Director Brian Stiger.

Mr. Stiger performed the swearing in of Ms. Veale as a board member.

President Schell recognized Kimberly Kirchmeyer, DCA Deputy Director of Board and Bureau Relations, and Carmen Catizone, Executive Director for the National Association of Boards of Pharmacy (NABP), who were present in the audience.

President Schell recognized former board members Darlene Fujimoto, Richard Mazzone, James Burgard, Robert Swart, and Susan Ravnan who were attending the meeting and in the audience. President Schell presented Mr. Burgard, Dr. Swart, and Dr. Ravnan with an acknowledgment for their recent service as board members.

I. Approval of the Full Board Minutes of October 21 and 22, 2009

MOTION: Approve the minutes of the October 21 and October 22, 2009 Board Meeting.

M/S: Weisser/Hackworth

Approve: 6 Oppose: 0 Abstain: 1

II. Communication and Public Education Committee Report and Action

a. Board of Pharmacy Video on Steps Consumers Can Take to Prevent Receiving Med Errors

Executive Officer Virginia Herold provided that throughout 2009, there have been a number of media inquiries about pharmacies making medication errors and the impact on patients.

Ms. Herold stated that 350 million prescriptions are filled each year in California and medication errors do occur. She stated that part of the board's mandate is to educate consumers so they can represent themselves in the marketplace.

Ms. Herold provided that very recently, the board partnered with DCA and contracted with a private firm to produce a three-minute video for consumers on how patients can prevent receiving a medication error in a community pharmacy.

She stated that the video is available on the board's Web site. Due to technical problems in the hearing room, the video could not be shown.

No public comment was provided.

b. Board of Pharmacy's Report to the Legislature on the Implementation of SB 472 Regarding Patient-Centered Regulations

Ms. Herold provided that when SB 472 (Corbett, Chapter 470, Statutes of 2007) was enacted, one provision required the board to submit two progress reports to the Legislature. She stated that one progress report was due January 1, 2010, the second is due January 1, 2013.

Ms. Herold stated that the board submitted the first report in December 2009. A copy of this report was provided in the board packet and on the board's Web site.

No public comment was provided.

c. Update Report on *The Script*

Ms. Herold provided that the January 2010 issue of *The Script* is undergoing layout by board staff. She stated that it should be released before the end of January. Ms. Herold explained that this is the first issue in nearly one year – budget and other workload priorities were the primary reasons for the delay.

Ms. Herold provided that this issue will be the last issue that is printed and mailed to board site licenses (wholesalers and pharmacies) as has been done in the past. She indicated that in the future, the newsletters will be released online to the board's licensee subscriber list. Ms. Herold advised that effective July 1, 2010, all sites licensed with the board must join our subscriber alert system. She provided that only a few issues will be printed for distribution at public outreach events and from the board's office.

No public comment was provided.

d. Update on Public Outreach Activities

Ms. Herold referenced the following public outreach activities performed by board members and staff:

- October 2, 2009 – Executive Officer Herold gave a presentation on new laws and regulations at the California Society of Health Systems Pharmacists (CSHP) Annual Meeting.
- October 2 - 3 – Board staffed an information booth at CSHP's annual meeting to advise licensees about pharmacy law and respond to questions.

- October 5, 2009 – Supervising Inspector Ratcliff gave a presentation “How to Survive an Inspection” to the California district managers for WalMart.
- October 17, 2007 – Board inspectors provided a presentation to the California Pharmacists Association (CPhA) as part of “Compounders Day” on “How to Survive an Inspection.”
- October 20 – 23, 2009 – Supervising Inspector Nurse provided information to national narcotics officers and officials at the National Association of Controlled Substances Authority Meeting.
- October 29, 2009 – Board President Schell presented information on intern hours requirements at the UCSD School of Pharmacy.
- November 1, 2009 – Board President Schell provided career insight to USC students.
- November 2, 2009 – Executive Officer Herold, Board Member Schell and Supervising Inspector Nurse attended the California Integrated Waste Management Board Conference and advocated for use of their guidelines for pharmacies and other sites establishing drug take back programs.
- November 3, 2009 – Board President Schell attended “Golden Opportunities: Building Bridges Between Federal, State, Corporate and Local Environmental Leadership”
- November 16, 2009 – Executive Officer Herold provided a presentation on medication errors and how the board enforces pharmacy law to pharmacists attending a CE presentation at California Northstate School of Pharmacy.
- November 16, 2009 – Executive Officer Herold attended a conference on e-prescribing for practitioners and regulators, hosted by the California Healthcare Foundation.
- November 30, 2009 – Executive Officer Herold met with the DEA’s Office of Diversion Control in Washington DC on enforcement issues involving controlled substances
- December 1: EO presented information on e-pedigree to the Healthcare Distribution Management Association’s Track and Trace national meeting
- December 2: EO and Board President provided information to subcommittee on drug distribution in hospital meeting hosted by the California Hospital Association.
- December 11: EO provided information to CPhA's Long-Term Care Association on prescription container labels.
- December 17: EO provided information about drug take back to Local 20 rural county government representatives
- Supervising Inspector Dang did a CE presentation to the Orange County Vietnamese Association.

No public comment was provided.

- e. Second Quarterly Report on Committee Goals for 2009/10

Ms. Herold referenced to the second quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

No public comment was provided.

III. Regulation Hearing and Possible Action on Proposed Regulations

- a. Proposal to Adopt New Section at Title 16 California Code of Regulations Section 1707.5 – Requirements For Patient-Centered Prescription Container Labels

President Schell called the hearing to order at 9:41 a.m.

Oral Testimony

Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy

On behalf of NABP and its member boards of pharmacy, I speak in support of the board's efforts in regard to the proposal to adopt or modify section 1707.5 relating to patient-centered prescription container labels. Our support is founded in the findings of the NABP taskforce on uniform prescription labeling requirements which conducted an extensive research and discussion of the critical issues facing patient care and medication errors and mirrored and replicated the exhaustive research and findings of the California Board of Pharmacy.

The results of our taskforce and the proposal today have only minor differences. Our taskforce maintained, again congruent with the findings of the California Board, that the patient label is a critical piece of information and there are no alternatives to helping the patient understand their medication and complying with their medication regiment. Current wavering requirements in place in California and across the country do not address critical elements of the prescription label such as what is necessary, what the font size should be, and what is understandable for the patient. The proposal and efforts of the California Board of Pharmacy as mandated by (the) senate bill address all these critical issues.

We also have reviewed the comments that were submitted by those groups that oppose the efforts of the California Board of Pharmacy and do not agree with those comments. NABP's taskforce analysis confirmed the findings of the California Board of Pharmacy that certain information need to be mandated, certain information on the label need to be at a different font size, and certain information needed to appear on the label but not needed to be highlighted,

again as found by the California Board of Pharmacy. We also don't agree with the contention that this would be overly burdensome for pharmacies to implement. There are a number of pharmacies that have already implemented this label. And, in fact, research that we conducted and participants in our taskforce helped us design the label based upon current systems that they have in place in their pharmacy and some of those pharmacies operate across the country in several states.

Again, we applaud the efforts of the California Board of Pharmacy. We have the confidence that the board would work with stakeholders to implement the proposal in a way that wouldn't be burdensome, but would benefit the patient and satisfy the mandates of the senate bill to ensure that the patient label is patient-centered and understandable. Thank you for this opportunity to present.

Greg Light, Pharmacy Advantage

I'm here on behalf of California Pharmacists Association's Long Term Care Management Counsel. We are here to address the proposed labeling regulations as it relates to the patients we serve which are residents of skilled nursing facilities, intermediate care facilities, assisted living facilities, and residential care facilities. Our major point of our proposal is that these regulations for patients in this setting be exempted from these regulations for the following reasons.

The major points of our request that these labeling requirements be exempted for these patients were outlined in a letter sent to Ms. Herold within the last 30 days. But, I am here to emphasize some of the major points. Primarily, for those patients, there are two separate issues here, for the patients in the skilled nursing facilities and the intermediate care facilities, I want to emphasize that the prescriptions dispensed for these patients are never in control of the resident, nor are they self administered. The information provided for the prescriptions dispensed in this setting are for the nurses in this setting. They control their storage and they control the administration. All of the information we provide is meant to be provided directly to the nurse so that they can safely administer these medications to these patients. Adhering to the regulations that have been proposed in this case would provide a fair amount of inconsistency to those nurses who administer and care for these patients in these facilities. In addition, as we progress with technology in these nursing homes we are increasingly putting automated dispensing machines in them to prevent waste and to provide more immediate access to medications. Requiring these new labeling requirements on machines that we have heavily invested in already would be technically and virtually, practically impossible.

The other setting of the patients I would like to address is community care licensed facilities, we refer to them as assisted living facilities in California, RCFs, and residential care facilities. Again, the vast majority of these cases of residents

in these facilities; the medications are not in control of the resident. There are caregivers, in most cases trained caregivers, that except these medications from the pharmacies, they store them, and they assist the patient with administration. It is very important from our standpoint to ensure public safety and safety for the resident to minimize medication errors that the labeling is consistent in regards to what we provide information wise to the caregiver, not to the patient.

Standardization of the information to ensure safe assistance with administering these medications is very important. And, having for example, the label in the language of the resident in my opinion would only create problems because who knows if the person assisting with the administration of those medications could actually speak the language of the patient. The intent for our pharmacy in providing medication is to make sure that the caregiver understands and is has a complete understanding of the directions and the instructions on those medication labels.

In addition, one last point, is that for these patients in the community care licensed facility, such as ALFs and RCFs, there are also unique packaging that we sometimes use for these facilities. An example is multi-dose packaging where in a single plastic bubble pack you might have four or five different medications to be administered at one time. Under the new labeling regulations it would be virtually impossible to accommodate labeling that we have already put in place to ensure the safe administration of these medications. Having to label multi-dose package medications would be virtually impossible to meet under the new proposed regulations. Thank you.

Doreena Wong, National Health Law Program

On behalf of the National Health Law Program, I wanted to just say that although we support the efforts of the board of pharmacy to provide and address the needs of the limited-English proficient (LEP) patients, we don't believe that the current regulations meet the intent or the statutory requirements or the needs of the LEP patients. There are seven specific requirements. I will not go through all of them, as they are outlined (in the handout provided). I have proposed changes to the language. I will highlight some of them and then if you have questions you can ask.

One of the issues that we have talked about repeatedly is that the proposed number of languages does not properly cover enough of the population given the large population of LEP patients in California. According to the American Community Survey, over 42% of Californians speak a language other than English. This is above the national average of 20%. And of that, 47% say that they do not speak English very well, which would be considered LEP. We believe that the number of languages that you should translate, the 17 directions, should follow the Medi-Cal managed care threshold requirements. This is a state defined

number of languages of 12. We know that this can be done because in one of the regulations on the Web site the emergency contraception factsheet is translated into 10. The factsheet is much larger and longer than the directions that you are proposing to translate.

The other issue that we feel needs to get strengthened, is in the prior proposed regulations there was a requirement that the pharmacist translate the items in (a)(1), which is the four items that are supposed to be standardized and put on all prescription drug container labels. Without having some kind of requirement for translation, it will be voluntary which it has been all this time and it will probably never be fully implemented. We understand that in New York there is an attorney general settlement where seven of the largest chain pharmacies are required to translate the drug container labels into six different languages. They are required to do this by May 2010. Many of those pharmacies including CVS, Rite Aid, Wal-Mart, Target, and Costco are actually doing it already. And, since they are already doing it, they will be doing it nation wide. So, they will be doing it in California as well. It can be done. We understand for some of the smaller pharmacists and the independent pharmacies there may need to be a phasing period. The board may consider a phasing period for that. But, we need to have a deadline for that. Otherwise, without any kind of requirement for translation of the labels, as you heard from all the testimony from time after time of different LEP patients who faced really serious consequences, their needs will never get addressed. Not only would we ask that the specific directions that you are going to have translated on the Web site be required to be used by pharmacists; but, that the entire label in section (a)(1) be translated. And, as I said, a phasing period is needed.

The other issue is that in the section where you provide for oral interpreters for LEP patients you have a condition where you say that it has to be requested by the patient. Under Title 6 and many state requirements, there is no requirement that the patient should ask for an interpreter. It is the responsibility of the provider or the pharmacist to offer an interpreter. The burden should not be on the patient. In order for the patient to even know that they have any rights to an interpreter, or to the translated labels, or even any other translated materials, they should be provided notice. There is no notice requirement in these regulations. We would recommend that the board come up with a standardized notice that should be posted like other consumer notices that the board requires and put it up in a clear visible place where patients could see it so that they would know that they had a right to an interpreter and that they would have a right to translated materials.

Finally, the other recommendation that we would make is that the primary oral and written language of the patient be recorded in the patient medication profiles. There is a requirement that pharmacists maintain a medication profile for each patient. Within this profile, the language can be recorded. We would recommend that the board require this so that when a patient comes in the pharmacist will know what kind of services the patient will need.

Generally, those are our requirements. We do applaud the board for trying to develop these regulations. Although, we don't think that they meet adequately the needs as proposed. We hope that if you adopt these recommended changes than we can whole heartedly support these regulations.

Stephen Rosati

I am representing my pharmacy and my customers. Some of the comments I have presented on a document to you and I just wanted to highlight a couple of them. I still believe that the form of the drug should be in 12-point. I think it is important for the consumer to realize whether they have got a capsule or a tablet. I'm afraid that if it is not required it could possibly disappear from the label. I think that would be a big mistake. Adding the form in I think is an easy task.

Last time I mentioned auxiliary or warning labels. I firmly believe that they need to be a minimum of 6-point sans serif typeface. The auxiliary labels, I believe, are part of the enabling legislation. If we are cleaning up the major directions, the auxiliary labels tell you how to utilize the tablet, or cream, or whatever that you are using two or three times a day. If they can't read the proper usage then we are back to where we started. I did provide an example in the vial that you have before you with 12-point directions (and) 6-point typeface for the warning labels. This is pretty small. This is only allowing 1 ¼ inch for that. You can see at 6-points you can get easily five warnings. If you have a couple of short warnings you can get six on there. Most of the computer vendors, I think, provide six maximum. Just as a comparison, I noticed that on your alternative language for consideration, item number 2 where you are suggesting that if any typeface used on the label is less than 12-point, such as 8-point (again I provided some 8-point there for your review), we are supposed to provide a separate document with 12-point print. Well, if we are making the effort to provide another document for 8-point print, you are allowing the auxiliary labels to be as small as 3-point or 4-point. It seems a little hypocritical to me personally to require us to provide number 2. I know we are not into tradeoffs here, but I kind of think that if we are not going to require 6-point for auxiliary labels then I do respectfully request that you strike number 2 and just stick to the alternative language which is (a)(1)(C)(1) and just use the upper portion. I think that's a fair analogy to the importance of the auxiliary labels.

I'm also requesting that on section (5)(A)(4) that you add the directions or phrases that I have included here. There are seven more. I think you would have an excellent package of common phrases to provide for the consumer. On my advertising, I think with the unique shape in bottles with nooks and crannies on the side and top, I do think that a simple sentence (should be added to the regulation that states) "There shall be no form of advertising on the prescription label, container or container top; only the information required by the Board of

Pharmacy and the name, address and phone number(s) of the pharmacy that filled the prescription.” I think that is all that should be on the label, and of course with the warnings. Any other form of advertising should not be allowed. I’m afraid there is a possibility that could creep up in the future to help offset our cost. The 12-point typeface being reduced to 8-point, I think you have covered it very well in (a)(1)(C)(1). Again, I have showed examples of a prednisone prescription. Keeping with the spirit of these improvements, you can see on the directions instead of saying “Take 6 tablets daily,” the customer really doesn’t know if it’s divided doses or not. So, in keeping with the spirit, you can see that you do need the smaller print to put in there “1 time daily” or “in divided doses.” You have to provide as much space as you can.

The board is requiring, if I’m not mistaken, if we are translating languages that we do it verbally and not on the label. We have to make sure that if ever it occurs where we have to start putting multiple languages on a label in order to properly identify the correct directions there has to be the English translation next to the other language on the same screen so at least it can be reviewed in some hope of making sure that the right directions are being (provided). Having (them both) present on the screen at the same time so that the technician, typist, and pharmacist can easily look back and forth to make sure it is correct. And, that still isn’t going to be a guarantee.

Cost, I just thought I would make a couple remarks about cost. Since the last meeting, I have talked with my vial container manufacturer. They are in the process of making some changes with the resins for plastics. It seemed that our minimum bottle was going to jump up one size which would have increased it about 3 cents a prescription just for the bottle. It looks like that might be negated or up to maybe 2 cents max for the bottle. I think the manufactures are waking up and they are making little shorter, wider bottles to compensate for increased width of the label. I am in compliance today, I believe, with what I have given you. That really didn’t cost me anything. I am going to have to get a new plate to add the little strip on the bottom so I can have more white space in there. That’s going to cost me about \$40 if I use that same label. So, I will have a one time charge of \$40. If you have a custom made plate, then that’s going to be a one time \$400 charge roughly.

Linda Okahars, Asian Health Services

I am the community services director at Asian Health Services or Community Health Center in Oakland, California and Oakland Chinatown. Before Mrs. Im and Mrs. Chen provide a testimony, I wanted to just introduce you a little bit to some of the challenges that we face at Asian Health Services and some thoughts in terms of how to overcome some of the language barriers for our patients.

We have about 20,000 patients that we serve at Asian Health Services and about 90% of them are limited English speaking. On any given day that we are providing service, we deliver languages in at least nine different languages, often more. One of the strategies that we use to really kind of make our services much more efficient in terms of being able to deliver services is to have language identification on the patient records. I know that's one of the proposals that has been brought before you. I would really encourage you to consider that and incorporate that in terms of patients' records for the pharmacies. It will just make the whole process a lot easier if you can get through and not have to worry about that language identification first step.

More than 60% of our patient's visits are actually dealing with chronic disease patient visits. They're managing multiple visits. Both Mrs. Im and Mrs. Chen will talk about some of the problems when trying to manage those different medications. Our community pharmacists, providers, and our patients work together to the best that they can in terms of trying to ensure that our patients are taking their medications accurately. Some pharmacies are able to provide written translations in maybe a few languages. Others are not able to or are not doing so at this point and we would really like to see that all pharmacies, no matter where our patients went, would be able to actually have access to translated instructions in terms of their medications. And, I think they will talk about some of the readability issues.

President Schell: I just want to refocus. The purpose of this particular hearing is to talk about the language of the regulation. We had an opportunity to accept public comment about issues and opportunities. Now we have language before us that we are trying to move forward. What we are looking for now as a board is public comment on the language itself that will help to address their issues.

Joshua Room: It might be helpful to have counsel explain the difference between a 45-day hearing and a 15-day hearing.

Kristy Schieldge: What we are looking for is whether you agree or disagree with the language that is before the board. If you agree, state why. If you disagree, indicate which sections of the language you would like to see changed. If you have a proposal for additional language that you would like them to change; that's what the board is looking for. You want to stick to the issue which is the prescription drug container label issues. Those are the issues that are before the board. If we add any additional issues we will have to go out for a 45-day comment period which is an additional period beyond what the scope of this particular proposal is. We want to stick to the scope of this proposal which is the drug container labels and the language that you have presented to the public for comment.

Ms. Okahars: The language we would like to support is the translation of the labels in having a standardized list of common translations and to have them

available in common threshold languages that are available through Medi-Cal Managed Care and also the Healthy Families. And, we would like to see it in a 12-point font and also that we would want to see that language identification be in the patient records.

Mrs. Im (translation provided)

First of all, I don't speak English and I have many problems. I have many medications and I got mixed-up about the long term and short term (instructions). I can not remember accurately the daily dose and when to take it ,before meal or after meal. I got confused many times and went to the emergency room many times. Secondly, most of the diabetic patients like me, my eyesight is bad and I can not see well. If the font would be 12 or larger I maybe can see. Thank you for listening.

Lee Myer, California Pharmacists Association Academy of Long-Term Care

I would like to speak to a couple of concerns that the academy and also the Long-Term Management Counsel have about the proposed regulation. I am speaking generally in support. However, the Long-Term Care Academy recognizes some issues with respect to residents of skilled nursing facilities that might not apply to patients out in the community. So, first of all, the effort to improve the safety of medication administration in the community in general is applauded. That's what we fully support. In the community-based senior population this particular regulation can do nothing but enhance the safety of medication administration in the home. In the skilled nursing facility, however, there are some issues that may come in conflict with some of the proposed requirements of the regulation. In the skilled nursing facility there are already a numbers of regulations that are in place that address medication safety. And, as has been said, in this environment medications are administered by care givers rather than taken by the residents themselves. The need for the resident to understand medication is really communicated through the licensed nursing staff.

Kristy Schieldge: You have seen the proposed language, correct?

Mr. Myer: Yes.

Ms. Schieldge: Is there anything in the proposed language that you do not agree with? What is your recommendation to the board to change that language?

Mr. Myer: Nothing specific in the regulation, with the exception of the language requirement or the translation request by the patient. Because there is a caregiver involved, that particular request should be clearly coming from the resident only and not from the caregiver. In the caregiver population, or the

caregiver setting, there is often turnover of caregiver staff. If this option is left to the caregiver, that could pose an issue for this “dispensing” pharmacy for multiple requests for different languages.

The other thing of concern to us about the regulation is that automated dispensing systems are becoming more and more popular in controlled environments such as skilled nursing facilities (and) even assisted living facilities. We would not want the progress in this area to be impeded by the requirements here of labeling which may not apply to medications packaged by automated dispensing machines.

President Schell: Are you opposed to this proposed regulation applying to your specific setting?

Mr. Myer: We would like to see the option of skilled nursing facility residents be exempted from this regulation while they are in the skilled nursing facility. There is also the issue of discharge of the residents out from the skilled nursing facility to the community. At that point, an option for them to except medications with the current labeling, which may not be in compliance with the community pharmacy requirements. They would be able to opt to except that medication on discharge. But, that medication would not be refilled with that same label by that pharmacy. This is in place already with the packaging requirement for child-resistant packaging. Medications in skilled facilities are not packaged in child-resistant containers and the resident has the option to take those home knowing that they are not child resistant.

Dr. Ramón Castellblanch: So, you want the patient to be able to take drugs home (and) that bottle will also be exempt?

Mr. Myer: Yes, that one bottle or container.

Stan Weisser: Are you the second speaker on behalf of the California Pharmacists Association?

Mr. Myer: Yes.

John Durham, PharMerica Inc.

I would like to reiterate what my colleague, Greg Light, said earlier. We are here to respectfully ask that for residents in facilities licensed by the Department of Health Services and facilities licensed by the Department of Social Services be exempt from this regulation. The settings are caregiver focused. These medications are stored centrally and the caregivers, be it licensed vocational nurse, registered nurse, or trained medication aid, then administer those medications to the resident. In addition, the facilities employ multiple caregivers (and) multiple nurses. All of these nurses would speak multiple different languages. (This could) actually lead to potentially more medication errors if we have a label in one language of the resident when we have caregivers that actually speak multiple different languages. So again, we respectfully request that those residents in those facilities be exempt from this regulation. Thank you.

Missy Johnson, California Retailers Association

Community pharmacies are more than places where people go to pickup their medication. Sure, we provide over the counter medication and first aid for people who have to deal with minor medical injuries and we certainly dispense medications to folks who need medication to manage their chronic illnesses as well as some of their more severe health issues. But, we also do much more. We have a dedicated staff of healthcare professionals who have invested a significant amount of their own resources to help serve the healthcare needs of our patients. Sure, we are national corporations; but, we operate on very slim margins. Despite that, we have been able to innovate and develop wellness initiatives designed not just to treat sick people, but also to help them from getting sick in the first place, to get them well, and to help them stay well. We offer a number of services either at no cost or very little cost in terms of screenings for cholesterol, hypertension, and diabetes. We offer smoking cessation tips and programs to folks who want them. More importantly, as the flu season demonstrates, we have been a very effective way of disseminating flu shots to folks, even more so than some would say the county health officials. We offer medication therapy management services to folks who need the service to manage their chronic illnesses and we do all this without government mandates or direction from our healthcare partners. And, we do it because we care. We see ourselves as the most convenient and cost effective way to access healthcare.

We support the board's goal of reducing medication errors and developing a standardized patient label. However, we have significant concerns with the language as it is currently drafted.

Mary Staples, National Association of Chain Drugstores

I want to detail the joint letter that the California Retailers Association (CRA), the California Pharmacists Association (CPhA), and the National Association of Chain Drugstores (NACDS) submitted to the board on January 4, 2010 that numerates our concerns with the proposed rule in that it is too overly prescriptive, its costly, and it stifles innovations. Many of our members have spent millions of dollars doing extensive research on labeling (including) surveying far more than 600 customers, running focus group studies, and voluntarily making improvements to enhance the readability and understandability of their labels.

Our members are fine with the label conforming to a standard format clustered together. However, we do have specific concerns with the language in the proposed rule section (a)(1) when it talks about that 50% of the label has to be dedicated to four particular elements: the patients name, drug name and strength, directions for use, and conditions or purpose. These requirements seem unreasonable in the limited amount of space. It's going to require increase label and vial sizes. Pharmacies are willing and able to provide patients on request this information on a separate sheet of paper in a larger font size. We are able to do that and it is appreciated by the patients right now.

Our industry is proposing that a 10-point font be recommended for the patient name, the drug, and the prescription refills that are left on the prescription. There is just too much verbiage to have the directions for use and the condition or purpose in that 12-point font size on the 50% side. You have to remember that California law does require many other things be listed on the label (including) the prescriber's name, the date, the name and address of the pharmacy, the prescription number, the quantity, the expiration date, the physical description of the medication which includes the color, the shape, and the id code, and now the condition or purpose which can be wordy. We also have to put the DEA number of the pharmacy on the label. The pharmacy often adds for the patient's convenience the number of refills remaining and the expiration date so that they can get those refills paid by their insurance company. So, that is a lot of information crammed on the less than 50% side of the label. We are hoping that the board highlights the important information that we talk about in our comment letter and leaves the rest to the discretion of the pharmacy and the ability of industry.

Dr. Ramón Castellblanch: What do you think should be in 12-point font?

Ms. Staples: In 10-point font size, we are recommending the three most important things: the patient's name, the drug name, and the prescription number. In 12-point font, we are not recommending that that be a mandate across the board.

Dr. Castellblanch: The directions would be any size at all?

Ms. Staples: We do not specify on the directions. We have already innovated many labels and our pharmacies have spent millions finding out what customers want, emphasizing that information, not necessarily the font size emphasizing, but by highlighting some information, by spacing it different, (and) by creative ways they put information on different sides of the prescription vial. We don't want to specify and limit that kind of technology and that innovation.

Ryan Brooks: The difference between 12-point and 10-point in your public research, was there a drop-off in readability for average patients?

Ms. Staples: We as an industry have not done that research. Individual companies have taken upon it in order to better promote services for their patients. I believe some are here to address that today with specifically what their company has chosen to do in their findings.

Mr. Castellblanch: So, you have no research on font size and readability to present.

Ms. Johnson: We don't as an industry; but, our individual member companies may. They are the ones who have taken the initiative to develop the labels in a way that best reflects and suits the needs of their patients.

Deborah Veale: Has your research shown that there is a problem on the size currently being used?

Kristy Schieldge: I'm sorry but we are getting into substantive issues. It is really just what are there comments and please tell the board whether you agree or disagree with the proposed language. We are not getting into the public policy arguments and things like that and whether they presented research and that sort of thing. It's do you think the proposed text as written is acceptable or do you not and what is your alternative suggested language.

Ms. Johnson: If that is what the board is looking to hear from us, the 12-point font we have severe issues with. We would prefer it to be a 10-point font and for the three items that Mary previously mentioned.

Lynn Rolston, California Pharmacists Association

We are generally in support. The California Pharmacists Association sponsored the original SCR 49 panel to look at medication errors in the community setting. That panel came up with a number of recommendations. The label was only one small piece of many others. While we would like to get this right and we think this is ultimately a valuable move, there are so many other things that we need to focus on. I hope the board continues this effort; but, (also) looks at these many other areas that could in fact net us a lot of reductions in errors than some of

these. I would like to mention that this is as you know an important effort and its being looked at all across the country. You have had some national organizations already commenting. The National Alliance for State Pharmacy Associations, which has all 50 member state associations involved, is also concerned and watching this and has asked if we wanted comments made. They are very concerned about being overly prescriptive in terms of mandating what the label looks like because so many pharmacies have already been working on this at both independent levels as well as in the chain setting. They would like as much latitude as possible to serve their customers in their local setting and with their local culture and language requirements as they can. So, I wanted to bring you there comments on this.

Cost is an issue and we are very concerned about that. I think that you went a long way to moving towards addressing a number of concerns with the alternative language throughout this. I will address a couple of points. We just got to see this. We ran through this very quickly. We only just saw this this morning. A number of us were either out of power or out of touch after 4:00 p.m. yesterday. So, this is new for us. But, we think you really went in the right direction and want to acknowledge the board for having heard previous comments. Across the nation, pharmacy is embattled in almost every state and reimbursements are dropping left and right. Many independents are on the verge of going out of business. We are very sensitive to extra cost here. So, even though we are maybe talking about two or three cents a vial or we are talking about some new label stock and having to discard old label stock, or we are talking about a \$400 strike plate, there are 2,000 independents and a number of different systems. So, this idea that was mentioned earlier of a phase-in would be a recommendation for us in regards perhaps to the entire issue. Do your best right away, but have this done within two years. Give a chance for everybody to move those costs across a longer timeframe.

Finally, directly to the language, in the alternative language (a)(1)(C)(i), we mentioned already the 12-point font issue. Below that, is the wording regarding an auxiliary label. That has a couple of different meanings and it would be important to specify what you are talking about. Some people call auxiliary labels those little tiny strips that have been referenced and some people call an auxiliary label the large printed sheet that the patient goes home with. We would appreciate if you could clarify that.

We again want to emphasize that the 12-point font be reduced to 10-point because a big concern in regards to patient safety is if the pharmacies have to continually go to larger vials the likelihood of patients taking the vial home and decanting the medication into a little cup or a little jar in their kitchen is higher every time you increase the vial size. We are very concerned that we maintain the smallest vial size possible for the medication that's contained within it.

While we applaud the idea of changing to a more general name called "pill." There is a little bit of a concern over the fact that pharmacists like to be a little more specific to be able to say "tablet," "capsule," etc. I know that has to do with your translation; but, if you could look at that one more time before you settle on the word "pill."

In (a)(4)(D), can we say "in the patients language if available." There are some dialects that are very rare that the translation services don't cover and it will be very difficult for pharmacies to be required to find (these services). This seems to indicate that no matter what language the person had, the pharmacist would be required to find a translation service to deal with that. So, if we could say "if available" or something along those lines.

Finally, in the alternative language, section (D) on the last page says that "pharmacies should have policies and procedures." If that is going to remain in there, can you be clear about what you have in mind. It did not exist earlier and we would be interested in knowing where that came from and why that was added in that particular section because that sort of expands a whole new area in what was put into the regulation.

Ms. Johnson: To expand on Lynn's point about the vial size, I had one of my members prepare a label that currently conforms to the regulation as it was drafted before 4:30 p.m. yesterday. This is the smallest size vial that would accommodate a label that would fit all of those required elements. This is a 30 dram vial. If the information required to be on the label were to go any larger, the bottle size would have to shift up. We would run the risk of people taking (medication) out of these and putting them into smaller containers, thereby not having access to the prescriber's information and directions for use.

Ms. Staples: On section (c), the alternative language for directions of use, in talking about the auxiliary label we interpret label to mean something that has to be affixed to the prescription vial. We are wanting you to allow us to increase the font size on a separate document, a consumer patient information piece of paper, to increase the font size. We would ask that you clean up or clarify that language.

Dr. Ramón Castellblanch: So the Pharmacy Association objects to any standard font size for directions, is that correct?

Ms. Rolston: No, we just want a little bit of latitude. We would prefer that instead of saying 12-point, it said 10-point. The pharmacies, generally speaking, do their best to make (the font) as large as possible. They understand the issues that their patients' have. It's always a trade off between vial size for patient convenience as well, which is another huge complaint by patients all the time. Most of them say "Why did you give it to me like this. You know I'm just going to have to take it out?" Many patients take 10, 12, or 20 of these and they need another suitcase when they get to the airport to take it in. We are just looking for the latitude. A lot of people need to get magnifying glasses at home. I'm not

looking for tiny; but, I'm just not looking for an over specification. I think there needs to be some belief in the pharmacist's good faith. They go to school, they setup a business, and they work all their lives to serve their patients. They are certainly not trying in anyway shape or form to confound the patient's ability to understand what they are taking. If it will fit, we would love it all in as big of font as possible. But, the concern is that it won't and it is no longer convenient. We should go to working more with the separate paper auxiliary labels and make it easier for patients to work with them.

Veronica Ramirez, California Medical Association

I am here representing the California Medical Association (CMA) and over 35,000 of our physician members. We are speaking generally in support of the regulations but do have one concern over a certain portion of the regulation that is a little unclear and maybe inconsistent with current California law. Currently, the proposed text states that the purpose or condition of the drug must be listed on the prescription label "if desired by the patient." We feel that it is impossible for a pharmacy or a prescriber to know whether or not the inclusion of the purpose or condition is desired by the patient if it wasn't stated. In general, we request that the word "desired" be changed to "requested" to protect from possible liability.

Tina Diep, Asian Health Services

I work for Asian Health Services in Alameda County in the city of Oakland. Asian Health Services and Ms. Chen are speaking in support of section (4)(D) and (E), regulation standard translation of common medication instructions.

Angela Chen (translation provided by Tina Diep)

My name is Angela Chen and I speak on behalf of my mother who did not understand the instructions for her blood pressure medications. My mother is a Cantonese speaking patient at Asian Health Services and emigrated from China to America 19 years ago. She has big challenges on following her daily medication instructions. She has diabetes, high cholesterol, and high blood pressure. About nine months ago, she took her refill high blood pressure medication from the pharmacies. A couple hours later she felt dizzy and had difficulty getting out of her bed for the next two days. After a doctor's visit, we found out that the drug company for her high blood pressure medication had been changed to a new drug company. Therefore, she had to take less pills per day. But, the pharmacist did not give her any explanation and the medication bottle was the same size and color.

Most immigrant seniors have difficulty following medication instructions because they cannot read English and the instructions are not written in their native language. In addition, seniors often do not remember oral instructions given by the pharmacist. Most seniors take a lot of medications daily because there are many types of medication for the same disease. Many patients get very confused. Translation instructions that a patient can understand will definitely make a huge impact on the patient's health. Therefore, we support the regulation that the pharmaceutical companies should have on the label instructions translated into the patient's native language in 12-point font. Thank you.

Don Gilbert and Bruce Wiswell, Rite Aid

Don Gilbert: I appreciate the opportunity to be here and provide some brief testimony. I am with Bruce Wiswell who is a pharmacy district manager for Rite Aid and a pharmacist. Our number one concern is going to be customer service and patient safety. There are very self evident reasons as to why. We appreciate many of the changes and amendments that the board made and the staff made to the translation provisions of the proposed regulations based on testimony last time. So, thank you very much for that. We oppose primarily one provision in the current proposal which is the 12-point font requirement. I'm going to let Bruce get into the details of that in a second as to why we oppose it. Just to be clear for the record, we support a 10-point font across the board requirement. We can do that without creating the problems for our self and for patients that we think will be created by the 12-point font requirement.

Bruce Wiswell: What we created to show you is the same label on four of the smallest vial sizes. (Mr. Wiswell displayed the vials to the board and explained that many would not support the new label requirements.) We took the board's regulation and created a paper copy of the labels in a 12-point font. We feel that a 10-point font works for us.

Ryan Brooks: Have you done the same exercise in 5 different languages?

Mr. Wiswell: When we print a language today we currently print it on a separate sheet with an English translation along with it so the pharmacist has a reasonable opportunity to do a legitimate quality assurance comparing the English to the (other language). We are doing 13 languages now. Quite honestly, I can read Spanish but I couldn't read those others. I need that English translation. Obviously, that isn't going to work here.

Mr. Brooks: If we adopt a 12-point font regulation, how would that look in Spanish, Chinese, and other languages?

Mr. Wiswell: It would be printed on a separate sheet still for us rather than on this label because the pharmacist (performs) quality assurance from this label.

Dr. Ramón Castellblanch: So, you do the translations and the way you do it is on the separate sheet that has both Spanish and English or whatever language and English.

Mr. Wiswell: Yes, that's correct.

Mr. Gilbert: We do the oral translations, which we testified to last time, over the phone in something like 150 languages. Our primary concern is the 12-point font. We think that the 10-point font across the board is clear, neat, (and) effective. We think the 12-point font will create some issues for us. We are not even talking about those issues; other than the fact that we can't use these vials. It will create patient issues as well. The fact is, based on our experience, we believe there is a very strong likelihood that many patients will not want to use these size bottles. They will get them with the requirements that you have in your proposed regulations, they will open them up, they will dump the pills into a smaller container, and they won't have any label to read. That is our concern. In addition, and it may not be the purview of this board, but it obviously is not a very smart use of resources to triple the size of the vial and also create the concern that we already mentioned.

Mr. Brooks: I have a question for counsel. I believe when I read the regulations that the translated language had to be off the label.

Joshua Room: No, currently we are talking about oral interpreter services. We used the words "oral translation" but that was confusing to people because "translation" usually refers to written print. The intent was always that what would be provided is oral services at the pharmacy counter. There was a previous version that had translation on the label. This is not in the current draft of the regulation.

Shirley Wheat: Just to clarify, you said that you currently do not fit the second language or the translation on the label and that you put it on a separate paper.

Mr. Wiswell: Yes.

Mr. Room: But, it is a translation of the label that you put on a separate sheet.

Mr. Wiswell: Yes.

Greg Lippe: Have you experienced problems where a patient gets several prescription bottles and several additional documents. Do they mix them up?

Mr. Wiswell: It's a consultation issue. We have to handle that at consultation and make sure we have matched them up.

Dr. Castellblanch: Are you sure this is 12-point font?

Mr. Wiswell: Yes.

Mr. Room: Different 12-points look different in different fonts. It looks like a large 12-point. Is it arial or sans serif?

Mr. Wiswell: It is sans serif. I don't know which of the sans serifs that it is.

Mr. Gilbert: It is our understanding of what the proposed regulations require. We don't think they are going to fit on these smaller vials and that's our concern. As someone testified to earlier, these people are trained their whole professional careers to serve the patients and on patient safety. Rite Aid has chosen to add some other information that I don't think is in the regulations which we think serve the patient very well. We can explain that in a second. The point is that people in the market place working may be able to innovate and find better ways to serve patients. That isn't being considered here today. One of the examples is something that Rite Aid does now.

Mr. Wiswell: In addition to the regulation, we print information that we were asked for by special services. For example, the ambulance driver that needs to call the patient's family and now has a phone number on the label. They don't have to make a second call and look it up. The nurse in the emergency room, they were part of our focus groups. As you master this label to get a 12-point font into place, sooner or later things have to go away. Those things were patient-centric. They were intended for an emergency use. Those are the things that are not required, so, what else could go away? I happen to have been the designer of this system and the label. I went through those focus groups and I have a great concern that I'm going to lose something that is really good for patients. I know that we are not the only chain that puts that on there.

President Schell: What are you recommending with regards to the language of the regulation?

Mr. Wiswell: I really think that we are trying to command to large of font. Dividing the label space up and calculating the label space is very difficult. I'm not sure how you can realistically do that.

President Schell: Are you speaking to opposition to the regulation in its entirety?

Mr. Gilbert: No, the 12-point font. We think it should be 10-point font. That's our position.

Dr. Castellblanch: You can't tell us the typeface you used here? We are comparing the 12-point font to other models and it looks larger.

Deborah Veale: Actually, I disagree. I think it's just a different type of sans serif.

Dr. Castellblanch: It's 12-point; but, you used wide font.

Mr. Gilbert: Our testimony is that, regardless of the category, we don't think it's going to fit on the other vials. It will fit on the 40 dram vial and all the problems we just described flow from that.

Mr. Room: One of the alternate things the board will be discussing is whether to allow for flexibility specifically as to the directions for use. It appears from the bottles that what's causing the greatest difficulty is that that's a particularly long directions for use. Is it the directions for use that you think being in 12-point font is causing the greatest difficulty? Everything else can be 12-point and directions for use can be something more flexible.

Mr. Wiswell: I would really need to mock that up to know for sure. Because, part of what you are doing with the directions is you have to leave enough space incase you have a longer font. I'm not speaking to the prednisone directions. On a standard font, when you start getting into the third or forth lines, you really have to go out and put it on a label to see what it looks like and see what you lose.

Mr. Room: Have you had the chance to review the alternate language?

Mr. Gilbert: I heard that it existed. I went online last night at 10:30 p.m. to your Web site and didn't see it posted there. Basically, someone put it in front of me this morning for one minute. We really haven't reviewed it.

Elizabeth Abbott, Health Access

Good morning. My name is Beth Abbott. I am the project director for Health Access California. I was formerly the regional administrator for the Centers for Medicare and Medicaid Services so I do have considerable sympathy and understanding for the task before you in writing regulations that protect consumers and are reasonable for the industry. Generally, Health Access supports the regulation that you have written. We were much fonder of the earlier version. But, we do support this version generally.

I have a couple of requests for relatively small changes to this. We believe that the translation into five languages is not sufficient. We work extensively with the Department of Insurance, the Department of Managed Healthcare, the Healthy Families program, (and) the Managed Risk Medical Insurance Board. We are collectively moving toward what I would describe as a California standard on language issues that started with the Escutia law that you reference in your material. There are 144 languages spoken in the Los Angeles school system. We don't think it would be reasonable and we don't argue for that in front of boards to have everything translated into 144 languages. That is burdensome. That is difficult. But, what the California standard is becoming is the threshold languages as outlined by the state of California's Medi-Cal program. There are 13 of them. We have argued successfully in front of boards such as yourselves for those languages. It is determined to be a reasonable way to deal with the language issue in a multicultural and multilingual society such as California where people can read in languages and they have partners, friends, and family that can read in those languages. That is becoming more or less the standard. I urge you to consider that in the language that you are adopting.

I also would argue that there needs to be a notice that is required. There is lots of notices required in healthcare in terms of you should be aware that you can get x in another language and you should be aware that you have the right to appeal. (These notices can be found in) hospital emergency rooms and doctor's offices. I would urge you to put a stipulation in your regulation that calls for a notice to be placed in pharmacies saying you are entitled to have these services in a language that you can read or you can have an oral interpretation of what you need. People have talked about using the AT&T language line and other ways to get interpretation services. I am taking it at face value, your statement in your regulation, that the language that you would translate would deal with at least 90% of the issues on the language on labels. Several of the chains have spoken to the effect that they are already doing these kinds of requirements for their customers. I would urge you to include a requirement. You are getting this translation done so that it be included in labels. It sounds almost like it is an optional thing for the small pharmacies to do. So I would change your language slightly to make it a requirement that they either use their own language that they have devised, as many chains have been quite forthcoming that they regularly do, or that they adopt the language that will be available on your Web site based

on the translation that you are getting. It should actually be a requirement that somebody uses that language in the pharmacy rather than make it an optional provision.

The last comment that I would make is I urge you to use the 12-point font requirement as you have written in your language. I think it is essential. All of us should be sympathetic to the seniors amongst us. We all hope that we will be seniors some day (and want to be able to) read the language. This is critical for medical interventions so family, friends, and the people can look at this and read the instructions. I applaud you for including that requirement and I urge you not to reconsider that. I think it's very critical. I appreciate the fact that you have had a very open process on this. It is a very difficult, but very important law and regulations. I applaud all of your consciences approach to it. Thank you.

Dr. Ramón Castellblanch: You say the Medi-Cal standard is 13 languages. Do you know anything about the development of that standard or how they got to 13?

Ms. Abbott: I don't know. It didn't always use to be that. It used to be like 9, it then became 11, and then 13. They use a standard I believe that exceeds 5% of the spoken language in our populace. But, I would hate to have you rely on that because I do not know.

Dr. Castellblanch: It was a result of a regulatory process also?

Ms. Abbott: It was absolutely a result of a regulatory process and the intent to make it such that the Medi-Cal population could in fact respond to requirements and understand what their rights and responsibilities were.

Marty Martinez, California Pan-Ethnic Health Network

We generally support the regulations as written today. We support the 12-point font issue and support the standardization issue. We just saw the new language related to part d on interpretive services. We do like the newly proposed alternate language better. We support both versions; but, we would particularly support the alternate version. As you know, and as a few of us expressed, we did have concern about moving away from the more stringent requirement in the prior draft that required pharmacies to translate labels if they weren't one of the ones put on the board's Web site. I'm a little bit concerned that the regulation doesn't fully meet the statutory requirement and that the label itself addresses the needs of people who don't speak English. I'm also concerned about the clarity issue. I'm concerned that there is a lack clarity in terms of the sample labels that are going to appear on the board's Web site. I think those two issues work hand in hand. The way I read the current (regulation), there is actually no requirement at all that a pharmacy put anything in writing that is in another language. The regulation

states that the board is going to put some translated labels onto the Web site. But, it is not clear to me that if a pharmacy never looks at the Web site that there is anything wrong with that. It doesn't appear to encourage necessarily. It just says that these will be there to facilitate use if you want.

President Schell: Are you making a recommendation?

Mr. Martinez: I do think that if at a minimum we could require pharmacies to use (these labels that the board puts on its Web site) unless there was a compelling reason not to. I understand from prior conversations you want to allow some flexibility for the pharmacists to make determinations for the safety of their patient. Where everything is applicable, it seems to me there is no reason you couldn't require the use at a minimum of the label you are providing. If you go that route I would also maybe ask to change the language to say that the board will put at a minimum the five languages so that at the board's discretion they could go further with putting additional languages on.

The Medi-Cal standards were developed over a long period of time and they are in the contract with health plans.

Joshua Room: It does say at least five languages.

Mr. Martinez: Does it? Ok, sorry, it does say at least five languages. That is helpful. If there was a way to ensure that they were used. I also want to maybe give an option if the board didn't feel comfortable requiring their use if they are on the Web site. If you adopted the new alternate language for d that basically says that a pharmacy has to have a policy in place to address people that don't speak English, there could be a way perhaps to incorporate this in there. If you adopt this piece, you are basically spelling out elements that a pharmacy's policies have to take into account. You could include in there ways to identify the patient's language, how interpretive services will be provided, how the label is provided on the board's Web site will be utilized where appropriate. Those are just some suggestions that we have. Thank you.

Phillip Swanger, California System of Health-System Pharmacists

I am the director of government affairs for the California System of Health-System Pharmacists. We represent approximately 4,000 pharmacists, pharmacy technicians, and associates that practice in varied settings including hospitals, ambulatory care, and long-term care. We shared this information with our membership directly after the board released the rulemaking file. I want to share with the board that from that information we have received no opposition or objection to the proposed rulemaking file. Our board is meeting this Friday to discuss the issue further. Nonetheless, we thought it was important to tell you that we have no opposition to the language as stated right now. Also, we were strong supporters of SB 472.

Dr. Ramón Castellblanch: Can you just please tell us a little more about who you represent; is it pharmacists?

Mr. Swanger: That's correct.

Nan Brasmer, California Alliance for Retired Americans

Good morning. My name is Nan Brasmer and I am the president of the California Alliance for Retired Americans (CARA). We have within our membership of CARA 850,000 members in California and we are the largest grass routes senior organizing organization in the state. I came today. I was here at the hearings in October. I was concerned about some of the things that took place and I came today to express CARA's point of view on what the decisions are that you have to make.

President Schell: The purpose of today is for the board to look at the language that was presented so that in our deliberations we are able to focus on particular support and concerns that the public has.

Ms. Brasmer: I have concerns.

President Schell: If you could, please summarize your concerns.

Ms. Brasmer: As seniors, we are concerned about the size of the type. Eight-point font is way too small for most of us to read safely, if not effectively. We do prefer the 12-point font. My pharmacy currently gives me that big bottle you were passing around for 60 little tiny pills. At first I thought it was kind of strange; but, now I think it makes a whole lot of sense because they can write a whole lot more on that label than "take as directed," which I found terribly confusing. The World Health Organization uses 12-point font. It would keep it more uniform, I think, throughout the profession if we also did that and required 12-point font. The size of the bottle is a concern because there have been reference made

today about using smaller sized containers. I just would like to remind you that most of us who are older and have arthritic fingers don't handle those little containers very well. The larger bottles are not that big of deal to put in our purse or our suitcase.

The translation issue is of concern to CARA because we have a number of people within our membership who are not English speaking or English literate. It is very difficult to be sure that what's being proposed or prescribed to them is given to them safely. We know through the Medi-Cal requirements that the languages that are required are also available through services that are free for the consumer to use to get the translations. So, it is not up to the pharmacist or the pharmacy to do that translation themselves if they are not comfortable doing that if they are not literate in whatever language it is those seniors or those customers require. We are interested in keeping the translations very broad so that as many people as possible can be protected by having proper instructions both orally and in writing. We like some of the changes that were in the proposal today. Thank you.

Jan Howe, California Alliance of Retired Americans

I am a retired registered nurse. I belong to the California Alliance of Retired Americans and the California Nurses Association. I am very much in favor of the regulation changes and I am thoroughly in support of the points brought forward by Liz Abbot and Nan Brasmer. As a senior who has worked in peoples homes, has done instruction on medication, and has worked for Kaiser for 25 years, I think that it is time that we do make these changes on the labels. The 12-point font is much easier to read. I am sorry that the bottle problem size may be of concern to certain commercial interests. I understand that; but, I agree with Nan when she says that it is easier to open a large bottle than a small bottle if you have MS, Parkinson's, arthritis, neuropathies with diabetes, etc. It's much easier to open up a large bottle. I will get you the research material if you request that. I do believe that translating into all the languages that exist, especially here in our state over time, if we are going in parallel with the federal government for Medi-Cal that's a good idea. We had many opportunities at Kaiser as an advice nurse and a home care nurse for hospice. I could use the phone to get a translator anytime I wanted it. Any time that the state or feds changed labeling requirements, those regulations, Kaiser made those changes and as you notice they are still in business. They have not gone out of business. They were not bankrupted by the changes. So, I would like to see this particular body go forward with their very good wording on changing the labeling in the state of California to be safer. Thank you.

Dr. Michael Wolf, North Western University

I am Michael Wolf, Associate Professor of Medicine and Learning Sciences, North Western University and also director of the Center for Communication in Healthcare. We have done a great amount of work on this and I just want to make specific comments about certain aspects of the bill and I will be very brief. I am very enthusiastic about the bill that you have proposed in its current condition with just some very specific points to make.

With regards to the font size, we have about 3 decades worth of research that supports the font that you have talked about. The evidence in the past 5 years has also supported the pieces of information that you are targeting with the 12-point font in particular. I would be very cautionary about reducing the 12-point font to the 10-point font. Also, evidence clearly supports sans serif fonts which can be everything from what the NIH, National Institutes of Health, currently identify as being either Arial or Helvetica. But, there is many other fonts that support comprehension is improved and a systematic review which you have already cited as clearly listed them in the work. As for point four, the instructions that actually we provided to the state board in putting this bill together and are currently being tested in actual use. I am the principle investigator of this study, examining their ability to improve patients' understanding as well as use of medicines.

One small minor change that I would propose to the bill is that with these instructions, we actually change the term based on patient report that "pill" was an easier standard versus the word "tablet," despite the fact that pill may not mean much to a pharmacist or someone with technical expertise in this background of pharmacology or medicine. But, it does mean something to (the) patient. In keeping with the patient-centered labeling instructions, "pill" is a universal term that patients, whether it's a caplet, tablet, or capsule, patients understand. So, if you could change the language to "pill" instead of "tablet."

Also, we have an instruction change for what we are building on evidence, and especially if these are being as applicable in the language, for the instructions that are as needed specifically for pain, which in our review around 350,000 medicines which supports the number that these fit in for solid pill-form drugs, 90% of all prescriptions, this information was also backed up by data in talking with Kaiser as well in a much, much larger data set. For the next larger chunk, beyond the 90%, are the PRN instructions at the bottom. It is very important to dissect a few different elements. One, reason for taking, which would be "if you have pain," should be first. Second, "take one or two pills at a time," to specify dose. "Wait at least four hours before taking again." The last component would be making sure that a maximum daily instruction is added at the very bottom, especially for these pain medications which would be to say specifically "do not take more than ___ pills in one single day." I can actually provide that instruction directly to the board as this is what's decided in our actual use assessment.

Joshua Room: Can I just clarify that what is in current language (q), the new version of (q), you would change that to say “if you have pain.”

Dr. Wolf: “If you have pain, take one or two pills at one time.” And, actually the “one” or “two” is obviously whatever, based on the dose. Instead of saying “you should not take more than,” the language which actually better follows appropriate comprehension standards would be to say “wait at least four hours before taking again.” And then a final sentence, again, I know it seems like its more, but this is the way it breaks down. We have actually shown we can fit this on some standard dram vial sizes. We are actually doing this within a central fill pharmacy at this time. And then to say “do not take more than ___ pills in one day.” These are important patient safety components. It is something that we are talking right now with the nonprescription world to work on and that they are trying to adapt. So, especially when people think of nonprescription analgesics, how they are taking those medicines they apply in a similar fashion.

Kristy Schieldge: With the proposed (q) language, it should read “if you have pain, take one or two pills.”

Dr. Wolf: (It should say,) “take ___ pills at a time. Wait at least four hours.” This is better compared to the current standard which we see in our own healthcare system in Chicago which would say something like “take one or two pill tablets every four to six hours as needed for pain.” (This) convolutes all of the important elements in what we see right now in current studies with patients at multiple sites. What ends up happening is you lose something like patients not knowing that they have to stop at a point which is often not included in perhaps one of the most important pieces of information, especially for with what you are seeing right now with acute liver failure and information for acetaminophen.

For point B, very quickly, we are the principle investigator leading the California Endowment Study to get those five language translations. So, we support. Working towards a Medi-Cal standard of 13 or if its 14 languages, I’ve heard both, but right now I think the language actually does hold very well to say at least five languages. The message that I’m reading into it is that it’s not saying only five, but it’s saying at least five. We will have that provided to the state board for this bill in the time that’s required because of the California Endowment support.

Ms. Schieldge: So, you are saying that currently there is only funding for five.

Dr. Wolf: That’s correct. We are using the most state of the art process for ensuring adequate translations of each of these languages individually, recognizing cultural differences might require some differences across languages. Not everything is directly translatable. So, we are using a community translation approach to make sure that we have the most accurate language in each of these different five languages and that they are tested with patients.

Dr. Ramón Castellblanch: Are you looking at all to do the other eight languages?

Dr. Wolf : We would love to be able to do the other languages. But, it is a very intensive process so we are in very strong support that we even have the five languages starting out. We would love to work with and will talk to the California Endowment about seeking support for the additional languages. We will have these vetted for the state board in time. Again, I think the language holds though as at least five. You are not putting a cap on it per say and if you want to add language to say that you are going to move towards being in unison with the Medi-Cal requirement that's fine. Again, this is a time intensive process. The next language that Ms. Bailey, who is the director of our health literacy and learning program who has been co-leading efforts on language translation, pointed out is that it should be that pharmacies should be required to post in all of the languages. There is no reason that they have the availability for oral translations services. That might want to be one addition to section (d) about the posting piece to make sure that patients across all languages that are using these pharmacies can recognize that they can ask for that service. I would like to again thank you for the great effort.

Ryan Brooks: Does your research show that comprehension dramatically goes down from 10-point or 9-point to 12-point?

Dr. Wolf : We have had this issue. I am on the U.S. Pharmacopeia Taskforce for the drug labeling. We are already going ahead and making recommendations. The recommendations follow the state board of pharmacy's current regulations isolating the certain pieces of information using 12-point font. Just to clarify, the issues with font size and text cues and formatting, that evidence base is very rich and longstanding to the point where a lot of us in the field of health literacy research are no longer trying to evaluate currently specific elements about font. To be honest, we recognize that there are limitations on the pill label. That's why we are trying to focus in on the most essential pieces of information because you wont get people to be able to see everything. The other issue of auxiliary warnings, which we just showed in a medicine paper last week that's being publicized now that talks about the fact that the more you put auxiliary warning information on it the less intended that information becomes. So, on the 12-point issue there are actually recommendations within NIH and different institutes at the NIH as well as throughout the other departments within the Department of Health and Human Services requiring 14-point font for older persons. I would say that yes, there is evidence available that supports decreased comprehension with font size. Whether that cut point can be specifically isolated between 12 and 11 and 11 and 10, I would argue that that evidence will probably never become immediately available outside of some eye tracking studies that have shown clearly that comprehension can be improved in 12-point, has been the standard that's been supported by multiple agencies within NIH. What I'm suggesting is that there is a precedent for 12-point font that has been longstanding and available for throughout Health and Human Services that people have been

working for. You can choose 10-point font, and I would actually argue one other thing too is that someone also argued that you request to say let's put everything in 10-point font. That I would completely disagree with because the other issue about having a larger font size for the five critical pieces of information that make this label patient-centered suggest that font size itself can be a cue to help people recognize that this information is more important and that it should stand out amongst other pieces of information such as the pharmacy logo. So, I think it is important to recognize that there needs to be a larger font size.

I would also argue that against other testimony that directions for use, sure you can give hypotheticals like tapered-down dose of prednisone or instructions that are not going to fit on the label, but that this is the single essential most important piece of information for a patient to be able to get off of a drug label which is tailored to them which often times is not found anywhere else. To not have a regulation for a standard minimum font size for that instruction I think is very problematic. The reality that we are facing is that some of these instructions that are overly complicated we appreciate but it's likely that you are going to have to use something other than a container label at some point to supplement how that person learns how to take a medicine such as an inhaler or something that requires something other than text messages on a small pill bottle. Or, it may require that you do have to bump up to a larger pill bottle. I personally don't carry them in my pocket. I think we do see some small evidence that patients do dose up medications in pill organizers with increasing age. Better instructions, a better bottle, it may be taken out of the bottle; but, that may not be a bad thing. Giving them clear information is going to help them then do the task of putting it in the pill organizer.

President Schell: At this point, I would like anybody who needs clarification of Dr. Wolf's comments on his changes to the proposed regulations please offer them now.

Dr. Castellblanch: I want to ask about the issue that has been raised all day about bottle sizes and whether or not there is any research as to the importance of pill bottles.

Dr. Wolf: There is no evidence to my knowledge. I completely appreciate from the industry side that many patients might want smaller bottles and I don't know of much literature that has talked about either patient preference or usability with one bottle size over another. I would say that with the U.S. Pharmacopeia, with multiple national pharmacy chain members on that board, they have actually shown that even when some of the smallest dram vials that they could implement. I didn't actually see any of the bottles that went around. But, we know somebody, and I don't want to specify specific national chains, but we do have multiple members that were able to in real time implement the bill that was presented to the board in a label type that would fit that small. I think that part of the issue is you have to recognize is what else is required on the bottle clearly.

We in actual use using PDX software as a common pharmacy base system, we worked with the pharmacy and the software designers to actually mockup this patient-centered label. This is what we are using in actual use and it has worked fine. We are using probably a larger than average dram vial. But, that's because the central fill pharmacy provides care to safety net clinics and gives them 90 day supplies so you do imagine that they are getting a larger pill count in there. But, again, I would probably get back to your question. I don't know if having a larger pill bottle necessitates that it's going to decrease adherence to the medication. That is the other thing to be considered.

Stan Weisser: In regards to the word "pills," do you find that to be universally acceptable for all ages?

Dr. Wolf : We studied in 395 patients across three cities, two Midwestern and one southern city. We have repeated the study again in actually New York, Shreveport, and Chicago and sampled 357 patients ranging from 18 to I think we had the oldest was around 85. We did both quantitative data where we actually had people dose out their medication and read and review medication bottles. We documented their verbatim responses. We also did some more thematic research. In our research in both of those studies across that diverse age range, we found patients naturally gravitated towards the term "pill." People actually offered up that language. Regardless of what we called it giving them different pills, they would actually see these things and refer to them as "pills," even if it was a capsule. That led to a report that we filed in which we suggested the use of the term "pill." That was also vetted in our Institute of Medicine report, *Standardizing Medication Labels*, which is cited in this report.

Mr. Brooks: I'm going to give you a little quick background because I think it's important. Along with the font size, I have read a lot of research trying to find if there is a correlation between font size and patient care. If font size increases, is there an adverse effect? The reason I ask the question, my grandma was taking six or seven different pills a day. She would go out and put them in her purse. My concern is if we are having larger font and she has to go to larger vials, is that going to have unattended consequences. I read a study from I think 2006 or 2007, I can't remember, that said that font size didn't really correlate to understanding. It was more about how the label read that was the main factor, not necessarily a 12-point or 10-point. Going back to my question earlier, you said that basically it has always been that way that 12-point was the standard. What I am trying to find out, what is that based on.

Dr. Wolf : The way I would probably respond is that in the cognition and aging literature, which has really driven a lot of that and that has involved some of my tracking work to look at how people navigate and look at not just a pill bottle. On pill bottles, you've got a different element going on with most containers which is the rap around text which also gets things out of the visual range. That makes it difficult. There is evidence that has been focused in on not just font. The problem

is that there are all times multi-component pieces that you are trying to factor in to. You are not isolating necessarily font size versus font. You are looking at different pieces. I would say the consensus, just in the same way our standardizing medication labels reports was dealing with consensus so much from exports of the field, the consensus that has been looking at developing print materials to optimize comprehension, the consensus has clearly been and has continued to be, and there is some very similar reports, that have kind of has built this. The most being around Doak, Doak, and Root in 1995 developing health literacy materials for patients with illiteracy that has clearly delineated that 12-point is a minimum, not even an optimal target. A lot of that is probably focused on the fact that a lot of aging patients who are addressing multiple concerns of both cognitive decline, limited literacy concerns, as well as issues with their visual field, is that you have to be able to, that they thought that 12-point, and in some cases they even referred to it as 12-14 point font with the sans serif font. So, again, I appreciate the concern that there is no evidence on it. I'm also a little bit concerned that if this part gets held up and you are waiting for the evidence, that most people have moved passed doing that kind of research and have accepted that as an issue, whether or not maybe your argument is that can you really say it's going to be a detriment if it goes longer.

Ms. Schieldge: I think that discussion is more appropriate for the discussion portion. I just want to remind the board members that is where we are going to have the substantive dialogue.

Diana Madoshi, California Alliance for Retired Americans

I am a member of CARA, but I am also a member of Phyllis C.U. Network in Placer, a small senior group. I am speaking on behalf of myself and no commercial interest. I want to thank the board for the work you have done already. I have read the language. I agree with it. I am strongly in support of it. I want to clarify a couple of things that I have heard about this. As a senior, I am not so much concerned about the size of the bottle. I am more concerned about the label. As a former nurse, do no harm. I've heard people talk and the first thing I keep hearing first comes cost, then comes patients. I am here to say patients come first, consumers, cost comes second. I have also heard that from some of the people that cost can be minimum. I also want to say that the word "pill" is common vernacular. My years as a nurse, I've always heard my patients use the word "pill." I have never had a pharmacist give me my medication, which are tablets or pills, however you want to say it, and say "Diana take the tablet." They always use pills. There shouldn't be any opposition to using the word "pill." I also want to say the changing on the proposed changes for pain medication, I think that is excellent. The day before yesterday, I heard one of the ladies in my exercise class say "my pain medication is not working, I took it but I'm going to take another one in two hours." I said but it doesn't say in two hours. It says every four hours. So, I think that would be an improved change to save lives. The

point size, I support the 12-point. I looked at this little flier here and this size looks like it is about 10-points. I only wear glasses simply for reading. I have pretty good vision. It's a struggle. You don't want to have your patients struggling. People don't like to own up when they don't see that well or hear that well so they sort of interpret. We have enough seniors. Lastly, I will say that, please, as far as the language is concerned I support that. We understand about the expense; but, please support this bill. I hope I don't have to come back here again.

Angela Blanchard, Target Corporation

I am here today on behalf of Target Corporation. Target shares your commitment to ensure that we have consumer friendly labels. As such, we have developed an entire system focused on the patient. It is called Clear Rx and I have distributed bottles on both the left and the right for board members to review.

Today, I want to address specifically the font size on our labels, both small and large, and also discuss our concerns with the auxiliary label language in the new draft. On the smaller bottles you will see the font size on the guest name measures 9.5. On the directions and the drug name, it's 11 or 11.5 on all of our smaller bottles. Eighty-five percent of our drugs end up in these smaller bottles. On the larger bottles, the font size does indeed go up. On the directions, it can be up to 13.5 and on the guest name it is 10-point font. In a letter to the board, Dr. Colenbrander noted specifically to Target that the font is up to size 14 for the name and up to size 12 for the instructions. While this is not untrue, this is the exception rather than the rule. Again, 85% of our drugs end up in this smaller bottle. And, in addition, should the instructions exceed five lines, the font is automatically shrunk down accordingly. I believe that there is a bottle with highlighted notes so that you can see the difference between the two sizes. I am encouraged by the language as drafted, produced yesterday. We support the direction you are moving to allow some flexibility. We specifically support readability of the language and not being overly prescriptive on the font size.

Specific to the new language about the auxiliary label accompanying the container, we have to talk internally amongst Target. But, currently what we do include a patient info card and that should also be floating along here. That includes all of the additional information that doesn't necessarily fit on the label. As a service to our guests, we provide free magnifiers should they need additional assistance reading the labels.

Clear Rx has been hailed across the country as a program that has been successful and consumer friendly. We ask that you take Target's concerns into consideration as you move forward with this important regulation.

Dr. Ramón Castellblanch: One of them says 11.5 the other I can't tell. I see you have the directions in the largest font size.

Ms. Blanchard: On our larger bottles, the patient's name is up to 10-point font. The maximum size for the drug name is 14-point font with the directions, the maximum size being 13.5 size font. Again, should the instructions exceed five lines, our program automatically adjusts the font to accommodate all of the pertinent information on the label. So, you will see two large bottles and two small bottles circulating and if you hold them side by side they will differ. Again, Target strives to make the font as accessible as possible for our customers. However, we do believe it is very important to ensure that all the information is included on the label and that is why we shrink accordingly should the information exceed five lines.

Dr. Castellblanch: So, what you prioritize are drug names, directions, and patient name.

Ms. Blanchard: The patient name is always smaller than the drug name and instructions. We prioritize instructions and drug name.

Joshua Room: You were supportive of the alternate language for (a)(1)(C), the language about the flexibility for the directions for use?

Ms. Blanchard: We are encouraged by the flexibility in the new language. However, we have only had 15 hours to review it. So, again we will have to take it back to our team. Moving in a direction that allows for some flexibility to ensure that Clear Rx can continue to function.

Steve Gray, Kaiser Permanente

There are people in the audience from out of state that might not be familiar with Kaiser Permanente so just let me describe. We have been providing high quality healthcare to Californians for over 60 years. We currently are responsible for the comprehensive healthcare of almost 7 million Californians and growing quite rapidly. The reason I make a point of that is because we have seen the effects of the complications in the emergency rooms, the hospitals, the doctor's offices, and etc when patients cannot read or understand, two different things, cannot read or understand their prescription instruction information. Approximately 20 to 25% of our membership turns over every year, people going in and out of the Kaiser Permanente system. Quite often, in fact the majority of the time, their first connection with our system when they come into it is through the pharmacy and we have to dedicate almost 50-60 pharmacists for outreach programs to clarify and correct their medication instructions and therapies because we find that they are often very confused about what they are supposed to be on in terms of medication. We strongly support and have strongly supported these statutes that required the standardized readable prescription patient-centered prescription label and we strongly support this regulation. But, I have some specific comments regarding the regulation's language.

First of all, we do support the concept of the alternative to the 12-point. But, we are concerned about the fact that it can be reduced to 8-point. We have heard a lot of testimony that 10-point would be satisfactory. We believe that the alternative if you can't do 12-point should be 10-point, not 8-point.

Second, we believe that the very first phrase in that alternative language, "where it is not possible," is ambiguous and will cause problems in enforcement. If you cannot come up with better language than "where it is not possible," whatever that means, then I think that the language should require that pharmacies have written policies and procedures to describe to their staff the criteria for determining when it is not possible. You can add that to that section.

The point being that for some of you that may not be familiar with initiation of this, this was a movement started by consumer groups who sponsored the initial legislation. The initial legislation with the Board of Pharmacy would not have had control over the prescription labels or the sigs. The initial legislation would have left this in a special commission controlled by consumers. It was the Board of Pharmacy and the industry that said let's trust the Board of Pharmacy and the industry to come up with things that meet their objectives which is patient-centered standardized labels. And, I emphasize the standardized. We have heard a lot of discussion here about innovation. If the innovation over time had worked well enough (and) fast enough we wouldn't be here today. There is plenty of room for innovation. In California law, any organization can come to the Board of Pharmacy and ask for a waiver of any regulation if they will collaborate with a school of pharmacy to do an evidence based study as to the effects of what waiver they want. We strongly support at Kaiser Permanente evidence based medicine and evidence based pharmacy practice and we believe that requiring such studies for waivers is the best way to go and so we support. I don't think you need to add that to the regulation because it is already part of California pharmacy law.

The next thing that specifically I am concerned about (is) we don't believe that there needs to be language added for an exception to the long-term care or the residential. But, I do think that there should be exercised some enforcement discretion in those areas. We are more sympathetic to the long-term care if it's a skilled nursing facility where the Department of Public Health requires certain qualifications of individuals. But, when you are talking about residential care or assisted living, which are regulated by the Department of Social Services, not the Department of Public Health, you are talking about a much lower level of minimum qualifications. And, in fact, our experience shows and we send pharmacists and physicians out to these facilities all the time to resolve problems, the care is often provided by minimally educated, sometimes limited English proficient personnel including their family members. So, the first level is usually family members come in to help and they are often the senior's spouses. Later, they get some help from the staff as the family member availability decreases. So, it is not the same when you say long-term care when you are

talking skilled nursing or you are talking assisted living or residential care. If you are going to make an exception you should split those two up. Second, we believe that the practice of letting patients in skilled nursing facilities or assisted living take their medications that were given to them and go home is real. But, they are essentially outpatient prescriptions. They are not hospital prescriptions. For that reason, when the patient goes home they need all of the assistance in understanding and readability that would be provided to any outpatient. That's one of the reasons we are concerned because we see readmissions and readmissions after they get out of a skilled nursing facility where they do have the help from someone and then they get confused and the next thing you know they are back into those facilities or a hospital.

We also believe and support the language that says "at least five languages" because we believe that that will evolve and the board's intent is to evolve. We were confused about the word "pill." We don't oppose the word "pill;" but, I remember when I was eight years old my teenage sister use to use that phrase to refer to me. So, it does have some negative connotations.

We also support strongly the alternative language for the interpreter services, especially the alternative language that requires the policies and procedures. I think that that alone will increase the ability of staff to understand how they are supposed to apply those services and require by definition, then require organizations to give substantial thought to the various situations that will come. So, we support that section (d) alternative language.

I think that pretty much covers our testimony. I just emphasize again that we are in strong support from both the medical group side, which sees these problems, and in the pharmacy operations side of both the statutes and those that were part of this including the one that is already in effect, January 1, about the purpose or condition being on the prescription and then on the label. We specifically support the language here which gives the pharmacist clear understanding that they have the ability to put that purpose or condition upon the label using their professional discretion if it is omitted by the prescriber. Thank you.

David Grant

I am speaking in favor of the regulations proposed today. As the director of Health Policy and the executive director of Senior Action Network, I was one of the organizational sponsors that Mr. Grey just mentioned of the original legislation that brought us to these regulations. We have heard a lot of comments today from retailers so I am here to speak on behalf of consumers who originally helped passed this legislation. Specifically, there are over 4 ½ million seniors in California. They take an average of 8 ½ prescriptions each. Medication errors, as was mentioned, is one of the leading causes of readmission to acute care hospitals. It is also, at home, one of the major healthcare problems that seniors

have. Like me, many of these people have kitchen cabinets loaded with medications that look like a pharmacy locker in a hospital. This morning I checked mine. I had several big bottles, several little brown bottles, several bottles with stickers from previous prescriptions that had expired that I don't take anymore, there were red ones, there were yellow ones, there was a green one that said no grapefruit, and my personal favorite was a tiny little blue sticker that had a loaf of bread on it.

President Schell: Mr. Grant, if I can focus you on the legislation.

Mr. Grant: As I said, I am in favor of it. As a result, as one of the sponsors of this original legislation, I don't see that the situation we faced when it was passed has changed. That brings us to the need for adopting the regulations that we are talking about today. I strongly urge the board to do that.

Margie Metzler, Gray Panthers and the Older Women's League

Gray Panthers and Older Women's League (OWL) are strongly in support of the legislation and keep fighting to make it just as strong as we possibly can because we represent the seniors who are most affected by this. What I want to point out (is) that the fastest growing segment of the population in this country and in the world as a whole is the senior population. I would think for those of you who represent drug companies, pharmaceutical companies, and pharmacies that you would use that as a selling point. It seems to me that it would have been wise to have increased the font size on your own and then advertise it as being a senior friendly pharmacy or a senior friendly organization. It just seems to me logical to appeal to those people that are going to be your largest customers. I have nothing wrong with me except that I wear glasses and I have slight hearing impairment and I have trouble with 10-point font. This obviously is just anecdotal information; it's not any study. But, if you talk to all of the CARA people here we all are in that position. Twelve-point font is about the bottom level of where I can comfortably read something. I'm not saying I can't strain and see it; but, when you get down to 8-point font it is impossible. Ten-point is a strain. I want to point out also, that when I first started using a computer, which is in the 70s or 80s, I guess in the 80s really when I really used one, the default font for Microsoft Word was 10-point. By the time they got to Office '97 the default font was 12-point font. I think that's not a coincidence. I think they recognized that that was a readable font for the largest group of people that was out there. The fact that the bottle is going to cost a penny or two more is really not a relevant point. As Dianna said, it's patients first, cost second. If we don't as consumers perceive that that's how you are thinking than we are not going to do business with you because that is really the way it needs to be in our society. Gray Panthers, OWL, and CARA feel very strongly about that. Thank you.

Ria De Groot, California Alliance for Retired Americans

I wanted to confirm and say that I agree exactly with the 12-point. At 12-point I need to get my glasses. Anything smaller than 12-point, I need to go find other kinds of methods but I cannot read it. Twelve-point would be exactly the bottom line. The other thing that I wanted to say; support passing this. And the other thing that I wanted to say is that there needs to be a written, not just oral, translation. I am for the translations being (what) the Medi-Cal requirements are to use that many translations. But, it needs to be written because as a senior memory is also an issue. You may understand it but go home question it again. You need to go home with a written version in the language of the patient; but, also perhaps a two sided page with the other side English incase they read only English, or they might read the language of the patient, maybe not, and the same if you are in a care giving facility. So, have a two sided page, one with the language of the patient and one with the other. Thank you.

The hearing was closed at 12:14 p.m.

The board suspended the discussion regarding Section 1707.5 in order to recognize pharmacists in service for 50 years.

IV. Recognition of Pharmacists Licensed with the Board for 50 Years

President Schell provided that the recognition of pharmacists in service for 50 years was a program initiated by former board member Stan Goldenberg several years ago. He noted that it is the board's honor to be able to continue the tradition.

President Schell recognized Dale Barker. Mr. Barker was licensed in 1959. He highlighted some of the changes he has seen throughout his career as a pharmacist and offered encouragement for young pharmacists. Randy Kajioka presented Mr. Barker with a 50-year pin.

President Schell recognized George Econome. Mr. Econome was licensed in 1957 after graduating from Idaho State University. He first worked in a pharmacy at the age of 14 when it became his dream to become a pharmacist. Mr. Econome highlighted some of the advantages of owning his own store. Greg Lippe presented Mr. Econome with a 50-year pin.

President Schell recognized Ernest Dokimos. Mr. Dokimos was licensed in 1959. He stated that choosing pharmacy was one of the best decisions he has made in his life. Mr. Dokimos owned his own pharmacy, worked for a chain store, and now helps his two sons who own their own independent pharmacies. Stan Weisser presented Mr. Dokimos with a 50-year.

President Schell recognized Eliseo Samaniego. Mr. Samaniego was licensed in 1960. He first considered becoming a pharmacist as a freshman in high school. Mr. Samaniego discussed some of the highlights of his career. Rosalyn Hackworth presented Mr. Samaniego with a 50-year pin.

President Schell recognized Joseph Jacobs. Mr. Jacobs was licensed in 1959. He owned five pharmacies in San Diego, was a staff pharmacist for Kaiser Permanente for seven years, and was the chief pharmacist at Cal State, San Marcos for eight years. Ryan Brooks presented Mr. Jacobs with a 50-year pin.

The board resumed its discussion on Section 1707.5.

- b. Discussion and Possible Action to Adopt Section 1707.5 in Division 17 of Title 16 of the California Code of Regulations Regarding Patient-Centered Prescription Container Labels

Mr. Brooks sought clarification regarding the regulation process.

Ms. Schieldge clarified that the board's objective is to review the proposed text and to identify any changes to be made. She provided that in the event of any changes the regulation will need to be re-noticed and the public will be offered another 15-day or 45-day comment period. Ms. Schieldge indicated that the board will then need to convene another discussion.

Mr. Room provided that further opportunity for comment will not be offered if the board moves forward with the regulation without any changes.

Ms. Sodergren highlighted the board's options with respect to the regulation. She stated that the board can either adopt the regulation as it was originally noticed or consider and make changes to the regulation based upon the written comments and testimony that had been provided. Ms. Sodergren explained that dependent on the scope of any changes made, either a 15-day or 45-day comment period will be offered.

Ms. Herold clarified that non-substantive changes to the regulation will only result in a 15-day comment period.

Subdivision (a)(1)

The board discussed subdivision (a)(1). Consideration was given to the proposed alternate language for (a)(1)(C)(i). Discussion focused on a variety of issues including:

- Various font sizes (i.e. 8-point; 10-point; 12-point; 14-point)
- Possible implications of a large bottle size

- The decanting of medication by patients from large prescription containers and the potential for medication errors
- Available pharmacy technology
- Available research regarding font size
- Use of bold typeface, color, or “white space” to add emphasis to pertinent information on the label
- Establishment of a minimum standard for font size on the label
- Including the purpose or condition on the label if “requested” by the patient
- Space limitations and character restrictions on the label
- Patient ability to read and comprehend information provided on the label

MOTION: Amend and approve the language in subdivision (a)(1) to read as follows:

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point, sans serif typeface, and listed in the following order:
 - (A) Name of the patient.
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use.
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is requested by the patient.

M/S: Lippe/Weisser

Approve: 4 Oppose: 5 Abstain: 0

MOTION: Amend and approve the language in subdivision (a)(1) to read as follows:

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point, bold, sans serif typeface, and listed in the following order:
 - (A) Name of the patient.
 - (B) Name of the drug and strength of the drug. For the purposes of this Section, “name of the drug” means either the manufacturer’s trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use.
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is requested by the patient.

M/S: Lippe/Veale

Approve: 1 Oppose: 7 Abstain: 1

MOTION: Amend and approve the language in subdivision (a)(1) to read as follows:

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point, sans serif typeface, and listed in the following order:
 - (A) Name of the patient.
 - (B) Name of the drug and strength of the drug. For the purposes of this Section, “name of the drug” means either the manufacturer’s trade name, or the generic name and the name of the manufacturer.
 - (C) Directions for use.
 - (D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is requested by the patient.

M/S: Veale/Wheat

Approve: 5 Oppose: 3 Abstain: 1

Subdivision (a)(2)

Dr. Castellblanch expressed concern regarding the voluntary use of “white space” and recommended that this be made a mandatory requirement by using the word “shall.”

Ms. Schieldge provided that the word “may” is discretionary. She stated that “shall” is mandatory.

Ms. Veale sought clarification regarding whether this change would result in a 15-day comment period.

Ms. Schieldge indicated that changing “may” to “shall” will result in a 15-day comment period.

Mr. Brooks sought clarification regarding the term “white space.”

Mr. Room suggested that “blank space” be used instead of “white space.”

MOTION: Amend the language in subdivision (a)(2) to read as follows:

- (2) For added emphasis, the label shall also highlight in bold typeface or color, or use “blank space” to set off the items listed in subdivision (a)(1).

M/S: Castellblanch/Lippe

Approve: 5 Oppose: 4 Abstain: 0

MOTION: Approve the text for subdivision (a)(2) as follows:

- (2) For added emphasis, the label shall also highlight in bold typeface or color, or use "blank space" to set off the items listed in subdivision (a)(1).

Approve: 5 Oppose: 4 Abstain: 0

Subdivision (a)(3)

MOTION: Approve the text for subdivision (a)(3) as follows:

- (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in subdivision (a)(1). These additional elements may appear in any style, font, and size typeface.

M/S: Weisser/Hackworth

Approve: 8 Oppose: 0 Abstain: 1

Subdivision (a)(4)

Dr. Castellblanch expressed concern regarding possible conflicts between the prescription provided by the physician and what information the pharmacist includes on the label.

Ms. Herold provided that these instructions are intended to help alleviate conflict by standardizing the directions for use.

Ms. Veale sought clarification regarding whether this section would eliminate the use of other terms including "tablet" and "capsule" when referring to a drug on the label.

Mr. Room provided that research supports the use of the word "pill" as a more universally understood and translatable term.

The board discussed the use of the word "pill" versus "tablet" as well as possible implications involved when only using the word "pill." It was suggested that brackets be used within the requirement to dictate where the appropriate dosage form can be inserted into the directions for use.

Ms. Herold recommended that a definition for “appropriate dosage form” be incorporated into the language.

MOTION: Amend the text for subdivision (a)(4) as follows:

- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 pill at bedtime
 - (B) Take 2 pills at bedtime
 - (C) Take 3 pills at bedtime
 - (D) Take 1 pill in the morning
 - (E) Take 2 pills in the morning
 - (F) Take 3 pills in the morning
 - (G) Take 1 pill in the morning, and Take 1 pill at bedtime
 - (H) Take 2 pills in the morning, and Take 2 pills at bedtime
 - (I) Take 3 pills in the morning, and Take 3 pills at bedtime
 - (J) Take 1 pill in the morning, 1 pill at noon, and 1 pill in the evening
 - (K) Take 2 pills in the morning, 2 pills at noon, and 2 pills in the evening
 - (L) Take 3 pills in the morning, 3 pills at noon, and 3 pills in the evening
 - (M) Take 1 pill in the morning, 1 pill at noon, 1 pill in the evening, and 1 pill at bedtime
 - (N) Take 2 pills in the morning, 2 pills at noon, 2 pills in the evening, and 2 pills at bedtimes
 - (O) Take 3 pills in the morning, 3 pills at noon, 3 pills in the evening, and 3 pills at bedtimes
 - (P) If you have pain, take ___ pills at a time. Wait at least ___ hours before taking again. Do not take more than ___ pills in one day.

M/S: Castellblanch/Brooks

Approve: 1 Oppose: 7 Abstain: 1

MOTION: Amend the text for subdivision (a)(4) as follows:

- (4) When applicable, directions for use shall use one of the following phrases:
- (A) Take 1 [insert appropriate dosage form] at bedtime
 - (B) Take 2 [insert appropriate dosage form] at bedtime
 - (C) Take 3 [insert appropriate dosage form] at bedtime
 - (D) Take 1 [insert appropriate dosage form] in the morning
 - (E) Take 2 [insert appropriate dosage form] in the morning
 - (F) Take 3 [insert appropriate dosage form] in the morning
 - (G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
 - (H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
 - (I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening
- (L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
- (M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
- (N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtimes
- (O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtimes
- (P) If you have pain, take ___ pills at a time. Wait at least ___ hours before taking again. Do not take more than ___ pills in one day.

M/S: Brooks/Weisser

Approve: 8 Oppose: 0 Abstain: 1

Subdivision (b)

Ms. Wheat sought clarification regarding how the translated directions will be used.

Mr. Room provided that the directions will be used on a voluntary basis.

Ms. Veale provided that the available translations will enable pharmacies with fewer resources to have access to valid translations.

Ms. Wheat asked why this subdivision is included in the regulation if it is not mandated.

Mr. Room provided that this subdivision is not required to be in the regulation.

Ms. Schieldge provided that the board has expressed at previous meetings that its inclusion would be good public policy and adheres to the statutory directive.

Dr. Castellblanch sought clarification regarding the statutory requirements for translations.

Mr. Room provided clarification on the requirements of Business and Professions Code section 4076.5.

Discussion continued regarding the inclusion of this requirement within the regulation.

MOTION: Approve the text for subdivision (b) as follows:

- (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

M/S: Hackworth/Weisser

Approve: 5 Oppose: 2 Abstain: 2

Subdivision (c)

MOTION: Approve the text for subdivision (c) as follows:

- (c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

M/S: Weisser/Hackworth

Approve: 8 Oppose: 0 Abstain: 1

Subdivision (d)

President Schell reviewed the language for this section as well as alternate language offered for consideration.

Ms. Schieldge highlighted some the comments that have been received regarding this subdivision. She stated that clarification regarding pharmacy policies and procedures has been requested.

The board discussed changes to the alternate language to reflect the comments received.

Ms. Wheat discussed the option of pharmacies posting a notice within their facilities to inform patients that interpretive services are available.

Ms. Herold provided that this can be accomplished with a subsequent regulation.

Ms. Schieldge provided that this is a substantive change and would require either a 45-day comment period or a subsequent regulation.

Ms. Herold provided that the board can discuss the posting of this information as a requirement in Section 1707.2 at a subsequent board meeting.

Ms. Veale and Mr. Brooks expressed concern about the potential for profiling as well as concern regarding how a pharmacist would determine what language a patient speaks.

Mr. Room stated that Rite Aid has provided testimony explaining that their customers can point to their language on a sign within the store to indicate to the pharmacist what language they speak.

The board discussed requiring pharmacies to develop a means to determine the language of the patient.

MOTION: Amend the text for subdivision (d) as follows:

- (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selective means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language if interpretive services in such language are available during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

M/S: Hackworth/Wheat

Approve: 7 Oppose: 1 Abstain: 1

MOTION: Approve the text for subdivision (d) as follows:

- (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selective means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language if interpretive services in such language are available during all

hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

M/S: Castellblanch/Lippe

Approve: 8 Oppose: 0 Abstain: 1

Subdivision (e)

Dr. Castellblanch sought clarification regarding the timeframe for this subdivision.

Ms. Schiedge provided that the board does have the ability to re-evaluate the requirements before the December 2013 timeframe.

MOTION: Approve the text for subdivision (e) as follows:

- (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5

M/S: Weisser/Hackworth

Approve: 8 Oppose: 0 Abstain: 1

c. Public Comment

Meyng Cho provided comment on “Mom and Pop” retail pharmacies. She asked the board to consider the ability of these pharmacies to adhere to new label and interpretive services requirements.

Lee Worth expressed concern regarding a pharmacist’s ability to dispense correct information through an interpreter or interpretive service during consultation. He provided comment on the importance of written notices to communicate what services are available to the patient. He asked whether or not it would be acceptable to not offer service to a patient if the pharmacy is unable to adequately communicate in a patient’s language.

Missy Johnson, representing the California Retailers Association, sought clarification regarding when the new regulation language will be made available and what process will then take place.

Ms. Schiedge provided that there will be a 15-day comment period after the new language is released. She explained that the board will need to reconvene if any adverse comments are received.

Doreena Wong, representing the National Health Law Program, encouraged the board to review her submitted comments. She stated that the requirements that have been approved may not meet other federal and state requirements and may also fall short of addressing consumer needs.

Ms. Schieldge encouraged members of the public to submit comments in writing in order for their comments to be included in the record.

Ms. Herold provided that the board will hold a meeting on February 17, 2010. She stated that the language will be released at least 15 days prior to this meeting.

There was no additional public comment.

MOTION: Direct staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the amendments previously approved by the board at this meeting. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt Section 1707.5 of the proposed regulations with the modified text.

Approve: 6 Oppose: 0 Abstain: 1

V. Demonstration of an Online Research Service to Provide Multi-Language Medication Information For Patients

Charles Lee, representing Polyglot Systems Inc., demonstrated services available through Meducation, a web-based tool for pharmacies to complement existing language services for both English and non-English speaking patients.

No public comment was provided.

VI. Enforcement Committee Report and Action

- a. Presentation on the Medication Error Reporting Systems in California Hospitals, a Presentation by Loriann De Martini, Pharm.D, California Department of Public Health

Dr. Kajioka provided that reduction of medication errors is a principal concern of those in the health care professions. He stated that over the years, the Board of Pharmacy has made reduction of errors a major component of its licensee and consumer education efforts and its enforcement activities.

Dr. Kajioka provided that this board was the first state board of pharmacy to require that a thorough quality assurance review be undertaken within two business days to ensure the error is not repeated. He advised that the requirement is applicable to pharmacies in both community and hospital settings.

Dr. Kajioka provided that in hospitals, the California Department of Public Health (CDPH), which licenses hospitals, has additional requirements for the medication errors made in hospitals. He stated that for the last year, some of these errors are reported publicly on the CDPH's Web site.

Presentation - Dr. Loriann De Martini, California Department of Public Health

Dr. Loriann De Martini, representing the California Department of Public Health, provided an overview on medication errors, adverse drug events, and requirements for the medication errors made in hospitals. She reviewed the implementation of Medication Error Reduction Plans (MERP) and the issuance of administrative penalties.

A copy of Dr. De Martini's presentation is attached.

No public comment was provided.

b. **Presentation by Katherine Ellis of the Department of Justice on the Controlled Substance Utilization Review and Evaluation System Online Access for Pharmacies**

Dr. Kajioka provided that for more than 10 years, all pharmacies and health care practitioners dispensing controlled substances to patients in California have had to report information into the CURES system. He explained that CURES is a prescription monitoring program aimed at preventing diversion and inappropriate dispensing of controlled drugs.

Dr. Kajioka provided that the CURES system is actually run by the California Department of Justice. He indicated that for any controlled drug listed in Schedules II, III or IV, CURES contains information on:

- Patient, address and other identifying information
- drug name, strength and quantity dispensed
- prescriber's name and identifying information
- pharmacy name and identifying information

Dr. Kajioka provided that the system has been strongly supported by the board, and the board often accesses this information as part of its investigations.

Dr. Kajioka provided that late this summer, the CURES system made a major step forward in offering prescribers and pharmacies timely data about histories

of controlled drugs dispensed to any patient. He stated that the system now allows authorized entities online access (“real time”) to the dispensing histories of controlled drugs dispensed to any patient. Dr. Kajioka advised that the data is as recent as two or three weeks. He indicated that by reviewing this data, prescribers and pharmacies can see the total number of controlled substances dispensed to a given patient. Dr. Kajioka explained that this information can be important as to whether a prescriber should prescribe, or a pharmacy dispense, a controlled drug while the patient is still before the prescriber or in the pharmacy.

Presentation – Katherine Ellis and John Massoni, Department of Justice

Katherine Ellis, representing the Department of Justice, provided an overview of the CURES system and the new Prescription Drug Monitoring Program (PDMP). She stated that the PDMP system allows licensed healthcare practitioners eligible to prescribe controlled substances, pharmacists authorized to dispense controlled substances, law enforcement, and regulatory boards who are pre-registered the ability to access patient prescription history information at the point of care.

Ms. Ellis provided that within approximately the first three months of system access, 194 registered pharmacists requested over 7,900 patient activity reports.

John Massoni, representing the Department of Justice, provided a demonstration of the PDMP system and the registration process.

No public comment was provided.

c. Department of Consumer Affairs New Enforcement Model

Kim Kirchmeyer, Deputy Director for Board and Bureau Programs, provided an overview on the department’s Consumer Protection Enforcement Initiative (CPEI). She stated that the CPEI was developed to address problems and improve the enforcement process and reduce the time to prosecute licensees from three years down to between 12 and 18 months. Ms. Kirchmeyer explained that the CPEI is a systematic approach designed to address three specific areas including administrative improvements, staffing and IT resources, and legislative changes.

Ms. Kirchmeyer provided that the department is requesting support for CPEI and requests the board’s formal support as well as a letter of support. She stated that the department is encouraging board members to continue to monitor their board’s enforcement process and timelines.

Ms. Kirchmeyer thanked the board's executive staff for their assistance and help in drafting language for the CPEI.

Ms. Kirchmeyer provided that the SB 1441 Substance Abuse Coordination Committee has adopted the uniform standards for boards dealing with substance-abusing licensees. She stated that the department is urging the board to support the legislation and to add any standards that will require regulations prior to implementation to future meeting agendas.

Ms. Kirchmeyer asked the board to authorize the Executive Officer to implement any of the uniform standards that do not require any additional legal authority.

Board Discussion

Dr. Castellblanch asked if any studies have been conducted regarding the systematic problems that the healing arts boards experience.

Ms. Kirchmeyer provided that this research has not been done by the department.

Ms. Herold provided that the board requires any pharmacy to report any suspicion of drug or substance abuse as well as any controlled substances loss. She stated that this report triggers an audit and an inspection.

There was no additional board discussion. No public comment was provided.

d. Report of the Enforcement Committee Meeting Held December 8, 2009

1. DEA Request for Comments on a Reclassification Proposal to Move Carisoprodol into Federal Schedule IV Controlled Substances

Dr. Kajjoka provided that in November, the federal Drug Enforcement Administration (DEA) released proposed rules to reclassify Carisoprodol to federal Schedule IV. He stated that currently this drug is not scheduled either at the federal or state level.

Dr. Kajjoka provided that written comments on this reclassification were due by December 17, 2009.

Dr. Kajjoka provided that at the December 2009 Enforcement Meeting, the committee directed the Executive Officer to send comments on behalf of the board's staff supporting the reclassification of Carisoprodol to federal Schedule IV.

No public comment was provided.

MOTION: Ratify the letter regarding the board's comments to the Drug Enforcement Administration (DEA) regarding the placement of Carisoprodol into Schedule IV.

M/S: Lippe/Hackworth

Approve: 9 Oppose: 0 Abstain: 0

2. Consequences for Pharmacies Dispensing Prescriptions for Internet Web Site Operators

Dr. Kajioka provided that at the Enforcement Meeting, the Executive Officer provided a listing of the huge fines issued in the last year to California pharmacies aiding Internet providers in distributing prescription drugs without a valid prescription.

Dr. Kajioka provided that the July 2008 issue of *The Script* reminded pharmacies not to participate in such scams.

No public comment was provided.

3. Reporting of Settlements to the Board as Required by California Business and Professions Sections 800-802

Dr. Kajioka provided that the board's staff recently learned that some insurance companies and some licensees may not be aware of their responsibilities to report settlements to the board for errors and omissions pursuant to requirements in California Business and Professions Code sections 800, 801 and 802.

Ms. Herold provided that as part of the enforcement upgrades being pursued by the health care boards of the department, this underreporting will be addressed.

Ms. Herold provided that a newsletter article will appear in a future issue of *The Script*, and the board will begin enforcement actions against those who fail to report settlements to the boards. She stated that additional information will be provided on the board's Web site.

No public comment is provided.

4. Presentation by Green Rx on Drug Management Programs to Use Drugs Before They Become Outdated

Dr. Kajioka provided that during the Enforcement Committee Meeting, the committee heard a presentation by Green RX that advanced a proposal for drug management between pharmacies that would allow pharmacies to transfer drugs to other pharmacies to alleviate shortages and prevent drugs from becoming outdated.

Dr. Kajioka provided that the committee took no action based on this presentation.

No public comment was provided.

5. Update on California Drug "Take Back" Programs from Patients

Dr. Kajioka provided that the next issue of *The Script* will promote the California Integrated Waste Management Board's (CIWMB) guidelines for model programs for the "take back" or return of unwanted prescription drugs from patients. He indicated that the article will advise that the board expects pharmacies to use these guidelines if they participate in taking back drugs from patients.

Dr. Kajioka provided that staff is aware that a number of communities are establishing collection programs for unwanted prescription drugs, which under California law are considered hazardous waste. He stated that unlike other items for which recycling or specialty collection programs have been established (like used motor oil or plastic shopping bags), aggregations of prescription drugs have value. Dr. Kajioka indicated that few of the pharmacy programs comply with the CIWMB guidelines and many also violate the federal Drug Enforcement Administration's requirements for the appropriate take back of controlled substances.

Ms. Herold provided that the newsletter will be published at the end of January 2009.

Dr. Castellblanch sought clarification regarding the board's regulatory jurisdiction regarding "take back" programs.

Mr. Room provided that only licensed pharmacies are permitted to store or possess dangerous drugs.

Dr. Castellblanch encouraged the board to continue to address this issue.

No public comment was provided.

6. Consideration of Best Practices on How to Use CURES Data as Part of Drug Utilization Review

The board did not discuss this agenda item.

7. Ongoing Discussion on Prevention of Medication Errors

Dr. Kajioka provided that at the December meeting, the committee discussed medication errors. He stated that the board's new video tape for consumers on preventing a med error from reaching them was shown. Dr. Kajioka stated that the talking points for the Executive Officer's discussions involving medication errors were also discussed.

No public comment was provided.

e. Minutes of the December 8, 2009 Meeting

The minutes of the December 8, 2009 Enforcement Meeting were provided in the board packet and are available on the board's Web site.

f. Enforcement Statistics 2009-10

The 2009-10 Enforcement statistics were provided in the board packet.

g. Second Quarterly Report on Enforcement Committee Goals for 2009/10

The second quarterly report on the Enforcement Committee's goals were provided in the board packet.

h. Public Comment

No public comment was provided.

VII. Legislation and Regulation Committee Report and Action

REGULATION REPORT

a. Board Action to Adopt Amendments

Discussion and Possible Action to Adopt Sections 1721 and 1723.1 in Division 17 of Title 16 of the Code of Regulations Regarding Dishonest Conduct During a Pharmacist's Licensure Examination / Confidentiality

Mr. Lippe provided that at the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen 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 a qualifying licensing examination.

Mr. Lippe provided that this recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. He stated that according to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Mr. Lippe explained that 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.

Mr. Lippe provided that the formal rulemaking was noticed on October 30, 2009. He stated that the 45-day comment period concluded on December 14, 2009, and the board did not receive any comments to the proposed rulemaking.

No public comment was provided.

MOTION: Direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the amendments to Sections 1721 and 1723.1 as filed.

M/S: Brooks/Hackworth

Approve: 8 Oppose: 0 Abstain: 0

b. Board Adopted Regulations – Recently Approved by OAL

Title 16 CCR Repeal §1716.1 and §1716.2, Amend and Adopt sections 1751 through 1751.8 and Adopt sections 1735 through 1735.8 – Pharmacies that Compound

Mr. Lippe provided that current pharmacy law authorizes a pharmacist to compound drug products as well as compound injectable sterile drug products. He stated that as required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. Mr. Lippe indicated that there were no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. He explained that the proposal established guidelines to provide uniformity in compounding for California consumers. Mr. Lippe provided that the rulemaking incorporates by reference Form 17M-39, Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment (Rev. 01/10).

Mr. Lippe provided that draft regulatory text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. He stated that at the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

Mr. Lippe provided that at its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. He stated that the modified text was noticed on February 26, 2009.

Mr. Lippe provided that at the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. He indicated that the board again considered modifications to proposed Section 1735.3(a)(6) and subsequently voted to pursue a 2nd 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within *24 hours*, as specified. Mr. Lippe stated that the 2nd 15-day comment period was noticed on May 4, 2009.

Mr. Lippe provided that at the July 2009 Board Meeting, the board considered the comments received during the 2nd 15-day comment period, as well as a draft response to each comment. He stated that the board then voted to approve the subcommittee's recommendation to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the Office of Administrative Law (OAL) to allow for implementation. Mr. Lippe indicated that the board further moved that staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

Mr. Lippe provided that after staff compiled the final regulatory proposal, the department reviewed and approved the rulemaking which was transmitted to OAL on November 19, 2009. He stated that OAL approved the rulemaking on

January 6, 2010. Mr. Lippe indicated that as specified by the board, the rulemaking has an effective date six months following OAL approval: July 6, 2010. He advised that as directed by the board, staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

No public comment was provided.

c. Board-Approved Regulations – Currently Noticed
Title 16 CCR Sections 1707.2 – Fingerprint Requirements

Mr. Lippe provided that at the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. He stated that the proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

Mr. Lippe provided that the Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concludes February 15, 2010.

No public comment was provided.

d. Board Action to Initiate Rulemaking
Discussion and Possible Action to Authorize Initiation of a Rulemaking Regarding Amendments to Section 1746 of Title 16 of the California Code of Regulations -- EC Protocol (including correct typographical error: mcg instead of mg)

Mr. Lippe provided that in 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. He stated that the regulation became operative on December 2, 2004.

Mr. Lippe provided that board staff recommends that an error be corrected in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." He indicated that the heading should designate micrograms – not milligrams. Mr. Lippe explained that while the board deems this to be a typographical error, the

regulation (as originally adopted) specified milligrams, not micrograms. He stated that as a result, a formal regulation proposal is required to correct this heading.

No public comment was provided.

MOTION: Direct staff to take all steps necessary to initiate the formal rulemaking process and authorize the Executive Officer to make any non-substantive changes to the rulemaking package. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the Executive Officer to adopt the proposed amendments to Section 1746 as filed with the Office of Administrative Law.

M/S: Weisser/Hackworth.

Approve: 8 Oppose: 0 Abstain: 0

e. Board Approved Regulations – Awaiting Notice

1. Title 16 CCR 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

Mr. Lippe provided that the adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. He stated that this form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

Mr. Lippe provided that the draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. He stated that during the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

Mr. Lippe provided that the Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. He stated that board staff does not anticipate proceeding with this regulation change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

No public comment was provided.

2. Title 16 CCR Section 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Mr. Lippe provided that Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. He stated that Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Mr. Lippe explained that since the inception of this statute, the board has approved two such agencies.

Mr. Lippe provided that the proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

No public comment was provided.

f. Regulations Under Development

1. Title 16 CCR Section 1780 – Update the USP Standards Reference Material

Mr. Lippe provided that CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. He stated that the USP Standards is updated and published annually. Mr. Lippe indicated that this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Mr. Lippe provided that because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

Mr. Lippe provided that President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. He stated that this subcommittee has not held any meetings. Mr. Lippe indicated that board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.

No public comment was provided.

2. Title 16 CCR Section 1732.2 – Continuing Education for Competency Committee Members

Mr. Lippe provided that at the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Mr. Lippe provided that Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. He indicated that a committee member's term is generally about eight years.

Mr. Lippe provided that annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. He stated that each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Mr. Lippe indicated that committee members also participate in 2-4 writing assignments based on the examination development need. He advised that committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

Mr. Lippe provided that one of the core functions of this committee is to complete an on-line review of all test questions prior to administration. He stated that as the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Mr. Lippe indicated that the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. He explained that typically, committee members are not compensated for their time to complete this function. Mr. Lippe advised that if a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.

Mr. Lippe provided that current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. He referenced to the following CE pharmacists can currently earn:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR §1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR §1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR §1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Mr. Lippe provided that board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting and in advance of the April 2010 Board Meeting.

No public comment was provided.

3. Development of Enforcement Component of Security of Emergency Kits

Mr. Lippe provided that AB 931 amended Section 1261.5 of the Health and Safety Code to increase the number of oral dosage form and suppository dosage form drugs from 24 to 48 for storage within an emergency supplies container, as defined in Section 4119 of the Business and Professions Code. He stated that these "E-kits" are within the jurisdiction of the California Department of Public Health (CDPH), and the measure specifies that CDPH may limit the number of any doses of each drug available to not more than 16 doses of any separate drug dosage form. Mr. Lippe indicated that the bill was signed by the Governor and Chapter 491 Statutes 2009 was filed with the Secretary of State on that date. He advised that the provisions of AB 931 became effective on January 1, 2010.

No public comment was provided.

g. Public Comment

No public comment was provided.

LEGISLATION REPORT

a. Board-Sponsored

*Legislation from 2009: AB 977 (Skinner) Pharmacists
Immunization Administration - Proposal to Amend B&PC §4052.8*

Ms. Sodergren provided that in 2007, the board approved a legislative proposal to expand the conditions under which a pharmacist could administer certain immunizations to improve patient access to immunization. She provided an overview of AB 977 and indicated that significant amendments to the bill resulted in a scaled-back version of the original proposal, but still provided improved patient access to life-saving flu vaccinations.

No public comment was provided.

MOTION: Reaffirm the board's support position of AB 977.

M/S: Brooks/Weisser

Support: 8 Oppose: 0 Abstain: 1

b. Proposed for Board Sponsorship

1. AB 1370 (Solorio) Centralized Hospital Drug Distribution - Proposal to Add B&PC Article 7.6 §4128

Ms. Herold provided that during the October Board Meeting, the board heard presentations by technology vendors as well as hospital systems representatives regarding the technology available to centralize some pharmacy related functions, including the packaging of items into unit dose as well as preparation of compounded medicine for individual hospitalized patients. She stated that since that meeting, board staff has provided technical assistance to Assembly Member Solorio's office in the drafting of language that would enable hospitals under a common ownership to establish one pharmacy under which they would prepare unit dose medications for all of a hospitals' patients that may be located on different campuses. The benefit would be to attach bar coding on each unit dose prepared, which is important to reducing medication errors in hospitals. The bar code can be read at the patient's bedside before administration to ensure that the right drug and right strength is matched to the patient before being administered to the patient. Additionally, outdated and recalled drugs can be readily identified and not be administered. Use of bar coding would eliminate a significant drug distribution problem in hospitals, as highlighted by the board's 2008 heparin inspections, and prevent medication errors.

Ms. Herold advised that AB 1370 did not get out of the house of origin. She stated that there is potential for the introduction of a new bill.

Public Comment

Steve Gray, representing Kaiser Permanente, expressed concern regarding the restriction for the use of the technology by only large hospitals under common ownership. He encouraged the board to remove this restriction.

There was no additional public comment.

MOTION: Establish a position of support for AB 1370.

M/S: Weisser/Hackworth

Approve: 8 Support: 0 Abstain: 1

2. Reverse Distributors – Provisions to Specify the Operations of Reverse Distributors

Mr. Lippe provided that over the last several years the board has been involved in the issue of take-back drugs, where patients can return unwanted medicine (both OTC and prescription) to pharmacies for disposal instead of tossing them in the garbage or flushing them down the toilet. He stated that should the board vote to pursue sponsorship of such legislation, the following provisions could be included in an omnibus bill:

(a) Amend Section §4040.5 Reverse Distributor

Specifies that a reverse distributor may not accept previously dispensed medicine and specifies that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines “dispensed” for purposes of this section only. This provision was approved in concept only by the board in January 2009.

(b) Amend Section §4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines “licensed integrated waste hauler” for purposes of this section only. This provision was approved in concept only by the board in January 2009.

(c) Amend Section §4126.5 Furnishing Dangerous Drugs by a Pharmacy

Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall. (Language for the later provision will require development.) This provision has not previously been considered by the board.

Ms. Herold provided that there are no provisions within pharmacy law regarding reverse distributors other than the requirement that they are licensed. She stated that this proposal would distinguish between a reverse distributor and an integrated waste hauler.

Public Comment

Mark Harvey, representing EXP Pharmaceutical Services, provided comment on his company's experience with "take back" programs as a reverse distributor. He stated that reverse distributors would like to be considered part of the process for drug "take back" and would like consideration for a delay of inventory to relieve the burden on pharmacies.

Discussion continued regarding reverse distributor operations.

There was no additional public comment.

MOTION: Establish the Board of Pharmacy as the sponsor of a bill regarding reverse distributor provisions to specify the operations of reverse distributors.

M/S: Weisser/Brooks

Approve: 7 Oppose: 1 Abstain: 1

3. Omnibus Proposal #1 (for Senate Committee on Business, Professions and Economic Development)

Mr. Lippe reviewed to the following provisions:

- (a) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge

At its October 2008 Board Meeting, the board approved provisions to be include in the 2009 Omnibus Bill (Senate BP&ED, SB 821). The chaptered version of SB 821 contained a drafting error and the section requires clarification (to be amended as previously approved by the board).

- (b) Add §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)

In October 2008, the board approved that the sunset provision within §4200.1 be eliminated. Though the Senate BP&ED committee did approve the proposal for inclusion in the 2009 omnibus bill, the proposed text was not printed in any omnibus measure. This language has, again, been proposed to the Senate BP&ED Committee for inclusion in the 2010 Omnibus bill.

- (c) Amend §4362 – Pharmacists Recovery Program

The board approved in October 2008 the proposal to add section 4362 to the Business and Professions Code to establish a co-pay for participants in the Pharmacists Recovery Program to offset a portion of the board's administrative

fee for each participant. That proposal was not picked up for inclusion in the Senate BP&ED 2009 Omnibus bill. The board will again pursue the addition of §4362 through a 2010 Omnibus bill.

No public comment was provided.

MOTION: Establish a position of support for the provisions included in omnibus proposal #1 for inclusion in a 2010 Omnibus bill.

M/S: Brooks/Lippe

Approve: 7 Oppose: 0 Abstain: 2

4. Omnibus Proposal #2 (for Senate Committee on Business, Professions and Economic Development.

Mr. Lippe reviewed the following provisions:

Amendments to the Department's general B&P provisions -- sections 650.1 and 651 – as reflected on the agenda – were not included in the board's proposal to Senate BP&ED.

Amendments to update references to the California Department of Public Health (formerly known as the Department of Health Services) and one amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)

§4017 – Authorized Officers of the Law (references Food and Drug Branch of CDPH)

§4027(c) – References specified health care facilities licensed by CDPH

§4028 – Defines “licensed hospital” and includes any institution classified under regulations issued by CDPH.

§4037 – Defines “Pharmacy.” Subdivision (b) specifies what is not included in the definition of a pharmacy, including specified area(s) inside a facility licensed by CDPH.

§4052.3(e) – Emergency Contraception Drug Therapy; Requirements and Limitations. Subdivision (e) specifies that information provided to the recipient of the emergency contraception drugs be provided on a form that is developed in consultation with the California Department of Public Health and others.

§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions. Subdivision (d) specifies that home dialysis patients who receive drugs, as specified, shall have completed a full course of home training given by a dialysis center licensed by the CDPH, etc. Subdivision (f) requires update to reflect the reference to the Physical Therapy Board of California.

§4072(b) – Oral or Electronic Transmission of Prescription – Health Care Facility. Subdivision (b) affirms the role of the CDPH in regulating drug order processing requirements for licensed health care facilities as specified.

§4119(a) – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies. Subdivision (a) provides that a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility, as specified, in accordance with regulations of the CDPH as set forth in Title 22 and the requirements as set forth in §1265.1 of the Health and Safety Code, etc.

§4127.1(d) – License to Compound Injectable Sterile Drug Products Required. Subdivision (d) specifies that pharmacies operated by entities that are licensed by either the board or the CDPH and that have current accreditation, as specified, are exempt from the requirement to obtain a license pursuant to §4127.1.

§4169 – Prohibited Acts. Subdivision (d) states that this section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the CDPH. Subdivision (c) identifies an operative date of 2008.

§4181(a) – License Requirements; Policies and Procedures; Who May Dispense. Provides that a clinic, licensed under §4180 (nonprofit or free clinics) shall comply with all applicable laws and regulations of the CDPH relating to drug distribution.

§4191(a).- Compliance with California Department of Public Health; Who May Dispense Drugs. Provides that prior to the issuance of a clinic license under this article (surgical clinics), the clinic shall comply with all applicable laws and regulations of the CDPH and the board relating to drug distribution, etc.

Amendments to update references to the Department of Health Care Services (formerly known as the Department of Health Services)

§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; California Department of Health Care Services Utilization Review and Monitoring. Subdivisions (b) (c) and (d) reference DHCS as it relates the calculation and transmission of Medi-Cal pricing to the pharmacy.

§4426 – California Department of Health Care Services to Study Reimbursement Rates. This section specifies that the DHCS shall conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates.

- (a) General Provisions
- Amend §650.1 – Lease Prohibition – Hospitals or Prescribers
 - Amend §652 – Violation of Unprofessional Conduct
 - Amend §4017 – Authorized Officers of the Law
 - Amend §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - Amend §4028 – Definition of Licensed Hospital
 - Amend §4037 – Definition of Pharmacy

- Amend §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
 - Amend §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
 - Amend §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
 - Amend §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
 - Amend §4127.1 – License to Compound Injectable Sterile Drug Products Required
 - Amend §4169 – Prohibited Acts (also, strike operative date of 2008)
 - Amend §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - Amend §4191 – Compliance with California Department of Public Health Requirements; Who May Dispense Drugs
- (b) Provision to update section referencing Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
- Amend §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- (c) Provisions to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)
- Amend §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - Amend §4426 – Department of Health Care Services to Study Reimbursement Rates

Public Comment

Steve Gray, representing Kaiser Permanente, sought clarification regarding Section 4017.

Ms. Sodergren provided that Section 4017 updates references to the California Department of Public Health Services (formerly known as the Department of Health Services).

Mr. Gray encouraged the board to consider restrictions regarding authorized officers of the law and access in pharmacies.

Ms. Sodergren provided that the board is pursuing omnibus proposals instead of legislation in this area. She indicated that any desired changes to Section 4017 can be made during the next legislative cycle.

Board Discussion

The board discussed the possible removal of Section 4017 from omnibus proposal #2.

There was no additional board discussion or public comment.

MOTION: Remove Section 4017 from omnibus proposal #2.

M/S: Brooks/Hackworth

Approve: 2 Oppose: 3 Abstain: 2

MOTION: Establish a position of support for the provisions included in omnibus proposal #2 for inclusion in a 2010 Omnibus bill.

M/S: Weisser/Lippe

Approve: 3 Oppose: 1 Abstain: 3

c. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. DCA's Enforcement Model Changes

Mr. Lippe provided that this item is for information only and requires no action.

No public comment was provided.

2. Changes Proposed by the Board for Addition into DCA's Enforcement Model

Mr. Lippe provided that at the October 2009 Board Meeting, the board voted to pursue that the following provisions be included in the department-wide enforcement proposals.

- a. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.

- b. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure
Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of licensee’s theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.
- c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, from providing pharmacist related services to Californians.

No public comment was provided.

MOTION: Pursue changes for sponsorship by the Senate Committee on Business Professions and Economic Development as part of a board-sponsored bill.

M/S: Lippe/Kajioka

Approve: 5 Oppose: 0 Abstain: 2

d. 2009 Legislation Status:

Mr. Lippe referenced to the following legislation.

1. AB 418 (Emmerson) Pharmacy Technicians – Education and CE
2. Requirements (Staff was advised that CHSP will not be pursuing this
3. proposal.)
4. AB 484 (Eng) Licensees Not in Compliance With Judgment or Order; Enforcement; Action on a License
5. AB 583 (Hayashi) Health Care Practitioners: Disclosure of Education and Office Hours
6. AB 877 (Emmerson) (*Intent language*) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice
7. AB 1458 (Davis) Drugs: Adverse Effects Reposting
8. SB 26 (Simitian) Home-Generated Pharmaceutical Waste
9. SB 238 (Calderon) Prescription Drugs
10. SB 294 (Negrete McLeod) Healing Arts
11. SB 341 (DeSaulnier) California Department of Public Health. CDPH to Contract with UC to Study/Evaluate the Safety and Effectiveness of Prescription Drugs
12. SB 389 (Negrete McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus

- 13. SB 484 (Wright) Ephedrine Products / Schedule V
- 14. SB 638 (Negrete McLeod) DCA Regulatory Boards; Sunset Reviews; Operations; Report Requirements

No public comment was provided.

- g. Second Quarterly Report on Legislation/Regulation Committee Goals for 2009/10

The second quarterly report on the Legislation/Regulation Committee's goals were provided in the board packet.

- h. Public Comment

No public comment was provided.

VIII. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

No public comment was provided.

Recess for Day

The board meeting was recessed at 6:15 p.m.

The board reconvened at 8:00 a.m. on January 21, 2010.

Closed Session

- a. The board moved into closed session pursuant to section 11126(a) of the Government Code to evaluate the performance of the board's Executive Officer.
- b. The board moved into closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary decisions.

Open Session

IX. Licensing Committee Report

- a. Report of the Committee Meeting Held December 3, 2009
 1. Request to Modify Title 16 California Code of Regulations Section 1713(d) Regarding the Requirement that Automated Dispensing Machines Be Adjacent to the Secure Pharmacy Area

Mr. Weisser provided that in 2005 and 2006, the board discussed and eventually promulgated a regulation to allow automated dispensing machines in pharmacies to dispense refill medications -- if requested by the patient and approved by the pharmacist. He stated that this was a use of emerging technology and several pharmacies had sought the board's authority to install such machines in their pharmacies to provide patients with afterhours access (as well as access during times when the pharmacy was open) to refills. Mr. Weisser explained that a patient could pick up refill medication, if approved by the pharmacy, from a vending-like machine using a credit card for payment and not specifically deal with the pharmacy staff. He advised that the machine was to be located near -- specifically adjacent -- to the physical area of the pharmacy.

Mr. Weisser provided that a number of conditions were built into the regulations to provide for assurance patients would not be required to use these machines for refills if they were not supportive.

Mr. Weisser advised that this regulation was promulgated cautiously. He stated that throughout 2006, the board modified and adopted the regulation now in effect as section 1713. Mr. Weisser provided that in January 2007, the regulation actually took effect.

Mr. Weisser provided that during the meeting, the committee heard a presentation from Phil Burgess, representing Asteres, one vendor of these automated delivery devices. He stated that Mr. Burgess is seeking a waiver to the requirements in 1713 (d)(6) which requires that the delivery device be located adjacent to the secure pharmacy area. Mr. Weisser explained that in making the request, Mr. Burgess stated that they would like to place the device in a secure area that is readily accessible to the patient and that a telephone would be placed adjacent to the device for patients that wished to speak with a pharmacist.

Presentation - Phil Burgess and Mike de Bruin, Asteres

Phil Burgess, representing Asteres, provided an overview of ScriptCenter, a 24/7 automated pharmacy prescription pick-up machine including the registration and authorization process. He reviewed patient safety and security benefits and

added that ScriptCenter has successfully delivered over 450,000 prescriptions without one delivery error.

Mr. Burgess requested that the board waive regulation Section 1713(d)(6) regarding the placement of automated medication dispensing machines in hospitals.

Board Discussion

Mr. Brooks sought clarification regarding how a pharmacy obtains a ScriptCenter machine.

Mike de Bruin provided that there are multiple methods of acquisition strategies.

Burgess provided that each machine will have a phone located adjacent to the machine to allow the patient to immediately contact the pharmacist.

Mr. Lippe asked if the patient will be charged a transaction fee.

Mr. Burgess provided that no transaction fee is charged.

Mr. de Bruin provided that the machine will collect the patient's insurance co-pay.

Ms. Herold sought clarification regarding if it is intended for the machine to be made available to both hospital staff and patients.

Mr. Burgess indicated that Asteres would like the machine to be available to both hospital staff and patients. He provided that only refill prescriptions would be filled and the machine would only be located on the hospital campus in a secure environment, not necessarily in a hospital.

Mr. Room asked if any machines have been installed outside of a hospital campus.

Mr. de Bruin provided that machines have been installed in other areas in other states.

Mr. Room provided that this request may not be granted under a Section 1713 waiver.

Discussion continued regarding the ScriptCenter system and its applicability to pharmacy law and Section 1713. Advantages and disadvantages of the system were evaluated. Concern was expressed that this process may depersonalize the pharmacist and prescription service. It was clarified that in the event a waiver is granted, the waiver would be granted to the licensed facility and not to Asteres.

Public Comment

Dr. Allan Schaggs, representing Catholic Healthcare West (CHW), provided that CHW would like to provide ScriptCenter as a service to their employees.

Dr. Castellblanch sought clarification regarding why the waiver is also being requested for patients.

Mr. Burgess provided that the machine can benefit the spouses of employees and children of employees.

Discussion continued regarding the request and the placement of the machine in a secure area on the hospital campus. Concern was expressed that the request does not specify placement of the machine.

Dr. Steve Gray, representing Kaiser Permanente, offered support for the ScriptsCenter concept. He encouraged the board to grant a waiver under Section 1713 (b) for employees and to consider further discussion of a waiver for other patients.

Mr. Weisser sought clarification regarding mail order prescriptions and patient requests for phone consultations with a pharmacist.

Dr. Gray provided that in the rare event that a patient does have a question, they can often get their question answered faster by calling a pharmacist than if they were to wait in line at a pharmacy.

Mr. Burgess provided that the ScriptsCenter machine allows for a pharmacist to be available to the patient when the adjacent pharmacy is closed during off hours.

Ms. Herold provided that pharmacies using such a device are required to provide immediate access to a telephone for patients to contact a 24-hour pharmacy in the event their pharmacy is closed.

Ms. Herold indicated that board staff will provide some guidelines to assist Asteres with providing the required clarification regarding their request.

There was no additional board discussion or public comment.

2. Final Review on Parameters for Recalls in Hospitals

Mr. Weisser provided that during the spring of 2008, the board identified 94 hospital pharmacies with recalled heparin still within the facilities, two to three months following the last recall.

Mr. Weisser provided that over the last year, the board convened a two-board member task force to work with relevant associations, regulators, hospitals, wholesalers and patient advocates on ways to improve recalls, and other changes needed to provide for improved drug distribution and control within a hospital. He stated that three meetings were held, and at the last meeting in September, a draft Best Practices document was refined. Mr. Weisser advised that a draft document establishing the parameters for recalls in hospitals was one major outcome of these meetings.

Board Discussion

Ms. Herold provided an overview of the draft Best Practices document. She suggested that the board consider removing several attachments from the document. Ms. Herold recommended that the board adopt the document as general guidelines.

Mr. Weisser provided that the Licensing Committee is asking the board to accept the draft document with attachment 1.

Dr. Castellblanch sought clarification regarding how the recall policies will address the problem.

President Schell provided that industry has expressed concern regarding the lack of guidelines for recalls. He stated that the document will provide guidance and information for facilities wishing to establish their own programs in this area on a voluntary basis. President Schell explained that these guidelines are offered as educational information and can not be mandated due to the process variance in hospitals.

Dr. Kajjoka provided comment regarding the challenges encountered by inpatient directors and the possible role industry could play in promoting changes to title 22.

Mr. Room provided that the board does not have authority to promulgate regulation to change title 22, which is under the regulatory jurisdiction of the California Department of Public Health.

Ms. Herold stated that this document can provide closure and guidance for recalls as a public health issue.

There was no additional board discussion. No public comment was provided.

MOTION: Accept the draft document regarding parameters for recalls in hospitals with attachment 1.

M/S: Weisser/Castellblanch

Approve: 9 Oppose: 0 Abstain: 0

3. Emergency and Disaster Response Planning: Update on the H1N1
Emergency Response Activities in California

Mr. Weisser provided that for more than one year, health care providers, policy makers and governments worldwide have been dealing with the H1N1 flu worldwide pandemic.

Mr. Weisser provided that board staff continues to work closely with the Department of Public Health to assist in ways that will benefit the public.

Mr. Weisser provided that in order to ensure that the board can act quickly to activate the board's emergency response policy in response to a sudden declared crisis, at the October Board Meeting, the board voted that:

In the event that the board is not able to convene a public meeting on regular notice or pursuant to the emergency meeting provisions of the Open Meetings Act, any three members of the board may convene a meeting by teleconference, by electronic communication (e.g., email), or by other means of communication to exercise the powers delegated to the full board pursuant to Business and Professions Code section 4062.

No public comment was provided.

4. Impact on Patient Care Caused by Diverse Supply Issues Impacting the
Availability of Medication to Hospitals

Mr. Weisser provided that several months ago Chad Signorelli, PharmD, Assistant Director of Pharmacy Services, Lompoc Valley Medical Services, contacted the board with concerns regarding the abundance of medications that are unavailable due to various manufacturer supply issues.

Mr. Weisser provided that Dr. Signorelli offered possible solutions to this issue including issues regarding pedigree laws and price gauging laws.

Mr. Weisser provided that Dr. Signorelli was encouraged to file a complaint in the event he is aware of any illegal activity.

No public comment was provided.

5. State of California's Right Care Initiative

Mr. Weisser provided that during the late summer, the Department of Managed Health Care convened a meeting to describe its development of a Right Care Initiative (RCI), which seeks to improve patient care related to blood pressure, diabetes, and lipid control.

Mr. Weisser provided that the Pharmacy Foundation of California led the California Pharmacy Council in providing comments in support of a pharmacist's role in medication therapy management. He indicated that the board is a member of the California Pharmacy Council.

Mr. Weisser referenced to the copy of the California's Pharmacy Council's letter to the Department of Managed Health Care, signed by all members of the council contained within the board packet.

Mr. Weisser provided that during the committee meeting, the committee ratified the Executive Officer's decision to sign this letter on behalf of the board. He recommended that the board consider ratification of this letter as well if they wish to establish a formal position on the Right Care Initiative with endorsed medication therapy management.

MOTION: Adopt the Licensing Committee's motion to ratify the California's Pharmacy Council's letter to the Department of Managed Health Care and the Executive Officer's decision to sign this letter on behalf of the board.

Approve: 9 Oppose: 0 Abstain: 0

6. Update: Psychometric Assessment of the PTCB and ExCPT Pharmacy Technician Exams

Mr. Weisser provided that during the April 2009 Board Meeting, the board voted to direct staff to take the necessary steps to secure a vendor to complete the necessary psychometric assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT). He stated that the psychometric assessment of the examination is needed to ensure for compliance with Section 139 of the Business and Professions Code.

Mr. Weisser provided that the results of the review would ensure that these applicants who qualify for licensure as a pharmacy technician have passed a validated exam.

Mr. Weisser provided that board staff was hopeful that the Office of Examination Resources would have staff to perform these evaluations; however we were recently advised that this is not feasible. He advised that board staff will resume

discussion on contracting options with the department to determine possible avenues to facilitate this review.

Ms. Herold provided that the assessment process is quite costly. She stated that board staff believes that each respective firm should pay for this assessment as they are the beneficiary. Ms. Herold indicated that the department's contract unit is evaluating how the board should proceed. She confirmed that each firm will need to be assessed.

No public comment was provided.

7. Reporting and Accounting of Intern Hours for California Pharmacy School Students

Mr. Weisser provided that under current law, an intern must possess 1,500 hours of intern experience under the supervision of a pharmacist before he or she can be made eligible to take the pharmacist licensure examinations in California.

Mr. Weisser provided that board regulations specify that a minimum of 900 hours of pharmacy experience must be earned under the supervision of a pharmacist in a pharmacy. He indicated that the remaining 600 hours can be granted for experience under the supervision of a pharmacist substantially related to the practice of pharmacy, but not specifically earned within a pharmacy. Mr. Weisser advised that California pharmacy students typically earn the 600 "discretionary" hours for school-related experiential training (clinical clerkship).

Mr. Weisser provided that after extensive consideration and based on further review of the statutory requirements detailed in pharmacy law, such a change would require statutory amendment and is not possible at this time. He stated that the following statement was placed on the board's Web site to respond to questions from students and schools of pharmacy regarding the change.

Recently the Board of Pharmacy considered changes to the application process for pharmacist licensure. This change was in response to the fact that some states no longer verify intern hours to other states.

Please note that the intern hours requirements in California remain unchanged. All applicants for the pharmacist licensure examination must earn 1,500 hours of internship (or have been licensed as a pharmacist in another state for one year.) For states that do not validate or transfer intern hours, applicants must submit proof of their intern experience on board affidavits (form 17A-29) as part of their exam application.

Likewise, the board will continue to require submission of intern hours on board affidavits (form 17A-29) as part of the application process for the exam.

No public comment was provided.

8. Processing Timelines and Work Flow of the Board

Ms. Sodergren provided that board and executive staff continue to evaluate our most mission critical functions for the board's licensing unit staff. She stated that even with changes, processing times are extending well beyond the board's strategic objectives detailed in the strategic plan and will continue to grow. Ms. Sodergren indicated that the current processing times for pharmacy technician applications is about 90 days and is about 60 – 75 days for all other application types. She advised that while this is not where we want to be organizationally, it is reality for the near future.

Ms. Sodergren stated that to allow staff to focus on the most important functions of their jobs, processing applications and issuing licenses, executive staff twice previously authorized a temporary stop in responding to applicants calling on the status of a pending application. She explained that this temporary stop allows staff to focus on reducing the backlog of new applications as well as complete a file inventory.

No public comment was provided.

9. Competency Committee Report

Mr. Weisser provided that effective December 1, 2009, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). He stated that board staff hopes to complete this review and release results by the end of January 2010.

Mr. Weisser provided that each Competency Committee workgroup met this fall and focused on examination development and item writing. He stated that additional workgroup meetings are scheduled throughout 2010.

No public comment was provided.

10. Job Analysis for the CPJE Underway in December 2009

Mr. Weisser provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically

which serves as the basis for the examination. He explained that to complete this analysis, the committee recently developed a job analysis with the board's contracted psychometric firm. Mr. Weisser stated that the information learned from this survey will determine if changes are necessary to the content outline of the CPJE.

Mr. Weisser provided that the survey was released in December 2009 to a random sample of pharmacists before the end of year and a link was posted on the board's Web site. He indicated that subscriber alerts were sent out encouraging all pharmacists to participate in the survey. Mr. Weisser stated that pharmacists that completed the survey will be awarded three hours of continuing education.

Mr. Weisser provided that the competency committee will begin evaluating the survey results in February 2010. He stated that a new content outline for the exam will be made in August 2010.

Ms. Herold provided that board members will be offered an opportunity to participate in this process.

No public comment was provided.

11. Summary of the December 3, 2009 Licensing Committee Meeting

Mr. Weisser referenced to the meeting summary from the December 3, 2009 Licensing Committee Meeting provided within the board packet.

b. Second Quarterly Report on Licensing Committee Goals for 2009/10

Mr. Weisser referenced to the second quarterly report on the Licensing Committee's goals contained within the board packet.

c. Public Comment

No public comment was provided.

X. Organizational Development Committee Report and Action

a. Budget Update/Report

1. Budget Reports for 2009/10

President Schell provided that the new fiscal year started July 1, 2009. He stated that the board received a budget augmentation of \$650,000 this year to establish 6.5 new positions to review and investigate criminal convictions of board licensees – a unit necessary due to the exponential increase in the number of criminal conviction reports the board has received in recent years (from about 300 to nearly 3,000 annually). President Schell indicated that the augmentation also includes enforcement expenses for anticipated added enforcement actions.

President Schell referenced to the following estimated budget figures (including the 15% reduction) for 2009-10:

- Revenue: \$8,647,000
- Expenditures: \$9,812,000

No public comment was provided.

2. Fund Condition Report

President Schell provided that according to a fund condition report prepared by the department, the board will have the following fund conditions at the end of the identified fiscal years:

2008/09	\$11,001,000	13.8 months in reserve (actual)
2009/10	\$9,836,000	8.7 months in reserve
2010/11	\$5,592,000	4.9 months in reserve
2011/12	\$1,013,000	-3.2 months in reserve

President Schell provided that the fund conditions represented above include the new fees (at their statutory minimums) as included in AB 1071(Chapter 270, Statutes of 2009).

Board Discussion

Dr. Castellblanch sought clarification regarding the board’s fund condition.

Ms. Herold provided that the board has the opportunity to increase its fees to the statutory maximums.

Ms. Sodergren provided that the board’s budget is reassessed after the release of each executive order. She stated that the fund condition report reflects

projections and do not reflect the cost savings that will be realized from the 5% salary reduction pursuant to the most recent executive order.

There was no additional board discussion. No public comment was provided.

3. Budget Change Proposals for the 2010/11 Budget

President Schell provided that on January 8, the governor released his proposed budget for 2010-11. He indicated that included in this budget is an augmentation to add two licensing technicians to address the significant growth we have experienced over the past several years.

President Schell stated that also included in the governor's budget are 22.5 positions to review and investigate consumer complaints.

4. Reimbursement to Board Members

President Schell referenced to the expenses and per diem payments to board members contained within the board packet provided.

No public comment was provided.

5. BreEZe (I-Licensing) Progress

President Schell provided that for a number of years the department has worked to replace and/or enhance the legacy licensing and enforcement tracking systems. He indicated that a few years ago, the department initiated an I-Licensing project which would offer online application and renewal of licenses (a much needed relief from mail-in renewals). President Schell stated that the new computer system envisioned by the department as part of the Enforcement Program upgrade is being designed to offer online application and renewal submission. This will replace I-Licensing and is about three years away.

No public comment was provided.

b. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

President Schell provided that since July 2005, the board has acknowledged more than 895 pharmacists with 50 or more years of licensure as pharmacists in California. He stated that the board may consider reducing this recognition to only twice a year, instead of quarterly, as the majority of the board meetings are being conducted in Northern California.

No public comment was provided.

c. Personnel Update

1. Board Member Changes

Ms. Herold provided that there are currently three board member vacancies. She indicated that the Governor recently made two appointments.

No public comment was provided.

2. Staff Changes

Ms. Herold provided that the board received 22.5 positions for enforcement efforts in the Governor's proposed 2010/11 budget.

Ms. Herold provided that two inspectors retired in December – Dolly Harris who has been a board inspector for 25 years, and Ralph Orlandella, who has been with the board for about six years. She stated that the board hopes to conduct civil service interviews for inspector positions in February.

Ms. Herold referred to the following staff changes:

- Debi Mitchell has been hired as a manager over those who process applications for individual licenses (technicians, interns, pharmacists).
- Denise Davis has accepted a full time position to assist with the processing of pharmacy technician applications. Ms. Davis was previously in a part-time position.

No public comment was provided.

d. Second Quarterly Report on the Committee's Goals for 2009/10

President Schell referenced to the second quarterly report on the Organizational Development Committee's goals contained within the board packet.

No public comment was provided.

e. Public Comment

No public comment was provided.

XI. Public Comment for Items Not on the Agenda/Agenda Items for Future Meetings

Dr. Michael Negrete provided comment regarding patient access to a pharmacist when picking up a refill prescription. He highlighted patient knowledge statistics and stated that patients need tools and information to ensure they are safe. Dr. Negrete encouraged the board to address this issue.

XII. Petitions for Reinstatement

1. Robert Brower
2. Eric Weiss

Closed Session

Pursuant to Government Code section 11126(c)(3), the Board convened in closed session to deliberate on disciplinary decisions and the petitions for reinstatement.

The meeting was adjourned at 1:47 p.m.



Polyglot Systems, Inc.

Presentation to the California Board of Pharmacy

January 20, 2010

The Company

“polyglot”[®]

- Polyglot Systems - developer of technology-based language solutions for the healthcare industry.
- Headquarters in Research Triangle Park, NC
- Founded in 2001 by Dr. Charles Lee. Polyglot’s mission is to help the US healthcare community care for the growing diverse population unable to communicate effectively in English. Polyglot’s goal is to develop cost-effective, scalable solutions that eliminate communication barriers during a medical encounter – improving the experience of both the patient and health care provider.

The Challenge

- **Limited English Proficient (LEP) Customers ... a Growing Challenge**

26 million people in the United States speak limited or no English... this number grew 52% between 1990 and 2000. One of every five persons in California cannot speak English effectively. Pharmacies are struggling to provide quality care for LEP customers ... caring for this population is expensive.

- **Miscommunication Leads to Medical Errors and Jeopardizes Patient Safety**

With 4 billion prescriptions being filled each year, making sure that every patient takes their medication correctly is critical to patient safety and for positive health outcomes.

Communication is not just a language issue; addressing low health literacy is equally important.

According to the Centers for Disease Control and Prevention (CDC) medication mistakes are the most common form of medical errors in the United States and result in 3.6 million office visits, 700,000 emergency room visits, and 117,000 hospitalizations each year. In addition, approximately 90 million adults in America possess limited health literacy skills and experience difficulty understanding their medication instructions (Report by the Institute of Medicine).

Regulatory Environment

- **Federal Rules mandate that all entities receiving federal funds (e.g. Medicare and Medicaid) must provide free access to language services for LEP patients:**
 - Title VI (DOJ, OCR)
 - Executive Order 13166
 - Department of Health and Human Services (DHHS) provides written guidance for healthcare service providers to ensure language assistance for LEP persons
- **Recently, individual states have initiated their own enforcement for provision of language services to their population at retail pharmacies**
 - The Office of the New York State Attorney General has demanded that medication instructions be made available in multiple languages in chain pharmacies by March 31, 2010.
 - California has recently enacted SB472, which requires its Board of Pharmacy to promulgate regulations that require, on or before January 1, 2011, a patient-centered drug label that, among other provisions, considers the needs of those patients with limited English proficiency.
 - New York City passed legislation in September 2009 requiring pharmacies within city limits to provide language services to their customers
 - Washington State is currently investigating regulations to ensure language services at WA pharmacies.
- **The Office of Civil Rights settles complaint against Medco**
 - In June 2009, Medco agreed to improve access to its pharmacy services for its LEP members
 - Settlement includes developing a language services plan, identifying customers' preferred language, providing written communication and outbound calls in preferred language, and conducting ongoing assessment of language services
 - NY State is evaluating strengthening its language requirements to include mail order pharmacies

Meducation



- **Meducation is a new web-based tool for pharmacies to complement existing language services for both English and non-English speaking patients. Meducation incorporates best-practices research on health literacy, document readability, education, and language.**
- **Meducation includes features to:**
 1. Speak phrases to non-English speaking customers at the retail pharmacy counter
 2. Print easy-to-read, written medication instructions that address low health literacy. These instructions can be given to customer
 3. Visually demonstrate proper techniques for complex medications - patient can view demonstrations during counseling or from home - all in their language
- **Software-as-a-Service (SaaS) model allows immediate access for pharmacies - improves service to customers and instantly complies with language service requirements.**
- **Subscription pricing plan includes unlimited use and free online access for their customers. Low price helps pharmacies meet their customers needs, cost effectively, and encourages use.**

Meducation

Meducation www.meducation.com | sign in

English << Press this button if you speak English

Español << Presione este botón si usted habla Español

한국어 << 한국어를 사용하시려면 이 버튼을 누르십시오

普通话 << 如果您是讲普通话的, 请按这个按钮

國語 << 如果您講國語, 請按這個按鈕

粵語 << 如果您會說粵語, 請按此按鈕

Русский << Нажмите эту кнопку, чтобы выбрать русский язык

عربي << اضغط على هذا الزر اذا كنت تتكلم اللغة العربية >>

Meducation www.meducation.com

HRSA

Illustration of a hand holding a pill and two pill containers.

Meducation www.meducation.com

HRSA

Home Phrases RxCen Demos Prefs Language: Cantonese

Accupril Tablet 10 mg
本藥物用半片或全片。

服用方式
口服藥物, 一天服用一次。

☀	☀	☀	☾
早餐	午餐	晚餐	就寢時
1			

每次服用一(1)片。
您應持續服用本藥物, 直到醫師指示停止服用為止。

說明
請直接吞服本藥物, 勿壓碎或咀嚼藥物。
請務必每天服用同樣劑量的本藥物。這將確保藥物發揮最佳效果。
以正確方式吞服藥物, 避免過度熱度及光線。
使用任何代用品或其他品牌產品之前, 請徵詢醫師的意見。
切勿服用任一劑量的藥物時, 即使並未感到身體不適, 仍請持續服用。
若經過服藥時間, 請儘早補服該劑藥物。如果已經接近下次服藥的時間, 則請跳過此次服藥的劑量, 因為對您的某些劑量時間, 切勿一次服用二劑劑量。
若有服用任何其他處方藥, 非處方藥, 藥物或基於保健目的而服用的其他藥物, 請告知醫師或藥師。

警告
若您對其他藥物出現嚴重的過敏反應, 請向醫師或藥師諮詢是否應避免服用本藥物。嚴重過敏反應的症狀包括呼吸困難, 皮膚起疹子, 暈車, 腫脹或嚴重頭痛。
本藥物請勿使用超過指示用量。

Copyright © 2007-2009 Phyllo Systems, Inc. All Rights Reserved. Designated trademarks and brands are the property of their respective owners. Use of this Web site constitutes acceptance of the [Polyglot User Agreement and Privacy Policy](#). Meducation was funded by a grant from the National Institutes of Health, National Center on Minority Health and Health Disparities (R64MD001212).

- Meducation was developed with funding from the National Institutes of Health - over 4 years in development
- Current available languages include English, Spanish, Korean, Mandarin, Cantonese, Russian, and Arabic. French, Italian, Haitian-Creole, and Bengali will be available in Q2, 2010. Over 30 languages are planned.

THANK YOU

Meducation can be accessed at <http://www.meducation.com>

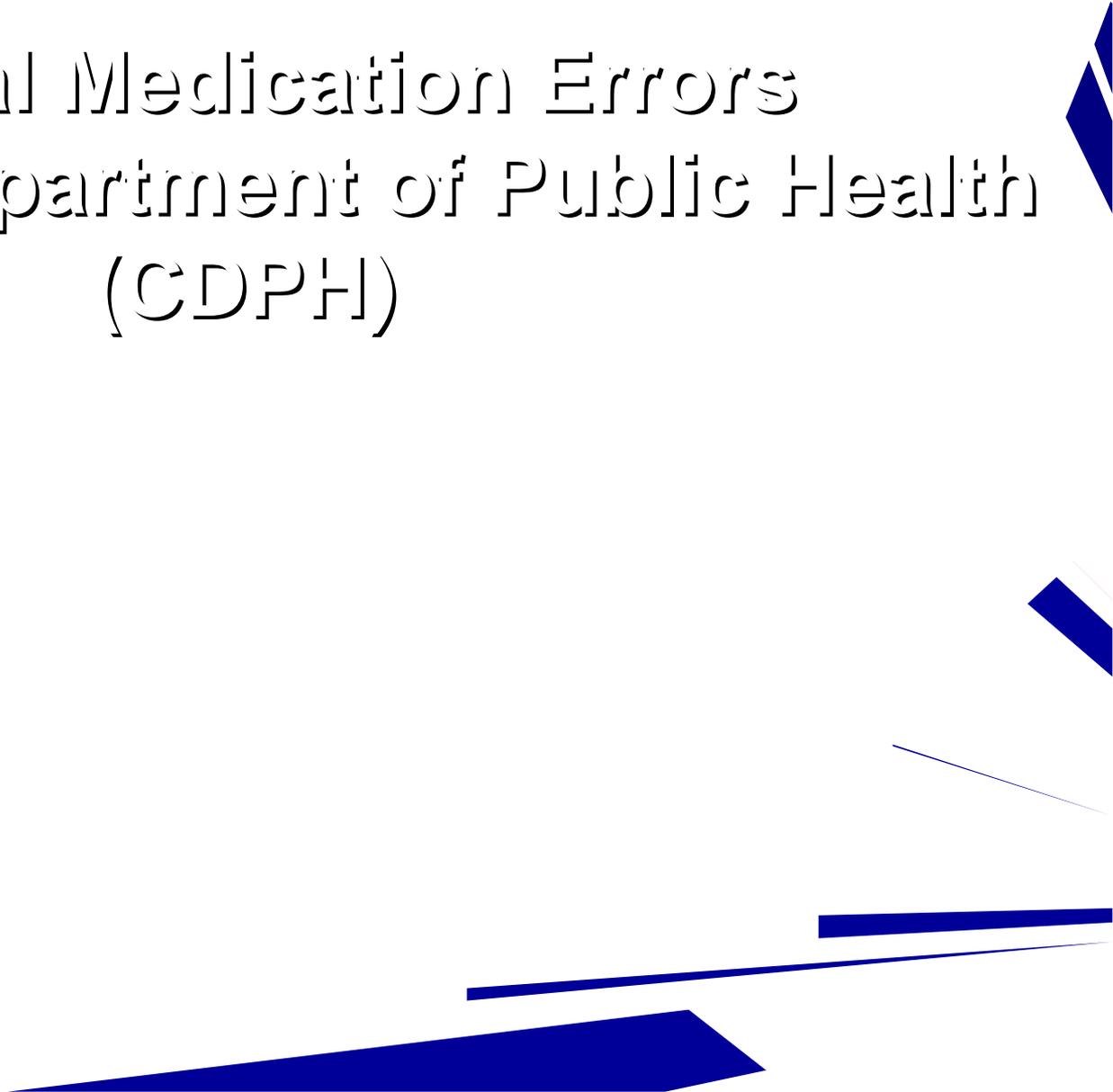
A demonstration of Meducation is available at Polyglot Systems' website
(www.pgsi.com)

For more information, please contact:

Charles Lee, MD
Founder & President
Polyglot Systems, Inc.
2000 Aerial Center Parkway, Suite 101
Morrisville, NC 27560
phone: 919-653-4380
email: lee@pgsi.com

Hospital Medication Errors

California Department of Public Health (CDPH)



CDPH Organizational Structure

■ Five centers:

- Center for Chronic Disease Prevention and Health Promotion
- Center for Infectious Disease
- Center for Family Health
- Center for Environmental Health
- Center for Healthcare Quality
 - Licensing and Certification Program

Licensing and Certification

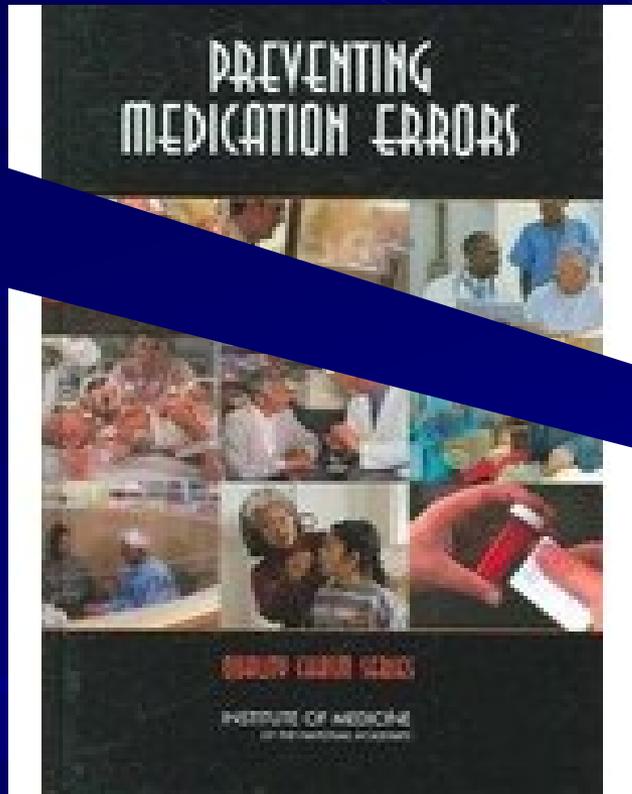
- Licenses and certifies 30 different types of healthcare facilities and agencies.

Operations Branch:

Employs 1,000 dedicated surveyors in 15

- Highly skilled and qualified Registered Nurses, Medical, Pharmaceutical and Nutritional Consultants.

Medication Errors & Adverse Drug Events (ADE)



1.5 million Americans sickened, injured or killed by avoidable medication errors

Institute of Medicine Report "Identifying and Preventing Medication Errors" July 2006

IOM Report

- SNFs – 800,000
- Outpatient Clinics – 530,000
- Hospitals 400,000
- Hospitals ONE medication error/patient/day
 - Treatment of medication related injuries in hospitals 3.5 billion/year

State Regulations

- Must develop policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs. [CCR Title 22 70263(c)(1)]
- Medications and treatments shall be administered as ordered. [CCR Title 22 70263(g)(2)]
- Pharmacist has overall responsibility [CCR Title 22 70263]

Medication Error Reduction Plan (MERP)

- Condition of licensure General Acute Care Hospitals and Surgical Clinics adopt a formal plan to eliminate or substantially reduce medication-related errors (Health & Safety Code 1339.63)
- Facility MERPs submitted to CDPH by January 1, 2002 – for review and approval.
- Must be implemented by 2005
- CDPH required to monitor implementation

CDRH ERP Survey Process

- ▶ Started in January, 2003
- ▶ Surveys are completed by
Management of CDRH pharmaceutical
Manufacturing Unit
- Approximately 32 hospitals/quarter

MERP Survey Summary 2009

- 385 - Hospitals to be surveyed
- 131 – Selected to be surveyed (35%)
- 108 – Completed surveys (55%)
- 89 – Noted deficiencies (82%)
- 17 – In compliance (16%)
- 2 – Awaiting data (2%)

Data as of 10/28/2009

MERP Survey Summary

- During a MERP survey violations to the Health and Safety (H&S) Code and/or the California Code of Regulations, Title 22 may be cited.
- On average three (3) different deficient practices are cited per non-compliant Statement of Deficiencies issued.
- Common deficiencies
 - Title 22 - 70263(c)(1) - 50%
 - H&S Code - 1339.63 (e)(1)(2) - 24-26%

Regulation/Law

- CCR Title 22 – 70263(c)(1) Must develop policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs.
- Title 22 – 1239.00, (1)(2)
 - Identify weaknesses or inefficiencies that could contribute to errors
 - Conduct an annual review to assess effectiveness of the implementation of MERPD

MERP Survey Findings

- Unsafe use of high risk medications
 - Fentanyl, Insulin
 - Improper storage of medications
 - Medication Reconciliation
- Substance Abuse / Diversion
- Lack of Pharmacist Intervention
 - Failure to clarify unclear orders, identify contraindications

Mandatory Reporting

- Mandatory reporting of 28 types of Adverse Events (AE) to CDPH – July 1, 2007 [Health and Safety Code 1279.1]
- Medication Related AEs
 - Patient death or serious disability associated with a medication error
 - Patient death or serious disability directly related to hypoglycemia
 - Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility

AEs – July 2008 – June 2009

Adverse Event Category	
Abduction of a patient of any age	0
Adverse event or series of AEs	52
Care by impersonating licensed provider	2
D/D due to electric shock	1
Death associated with a fall	42
Death during or 24 hrs after surgery	42
D/D associated with use of restraint/bedrails	7
D/D due to spinal manipulative therapy	1
D/D related to hypoglycemia	6
D/D due to a burn	6
D/D due to disappearance	5
D/D due to intravascular air embolism	3
Death/injury from a physical assault	5
Failure to identify/reat hyperinflation	0

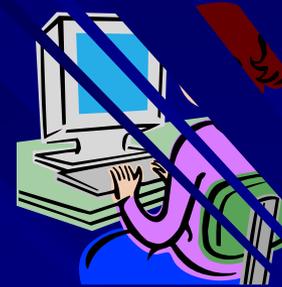
Adverse Event Category	
Hemolytic reaction	
Infant discharged to the wrong person	
Line contaminated or use for wrong gas	0
Maternal D/D due to labor/del/post	8
Medication error	30
Retention of a foreign object	201
Sexual assault on a patient	34
Stage 3 or 4 ulcer	1047
Suicide/attempted suicide	12
Surgery performed on a wrong body part	26
Contaminated drug, vaccine or biologic	0
Use of device other than as intended	3
Wrong patient surgery	4
Wrong surgical procedure	16
Grand Total	

D/D = Death or Series of

Administrative Penalties

- Effective January 1, 2007 – CDPH may issue Administrative Penalties (AP) to hospitals [Health and Safety Code 1280.1]
- AP is a civil monetary penalty for a deficiency constituting an **Immediate Jeopardy**.
 - Immediate Jeopardy is a situation in which the hospital's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

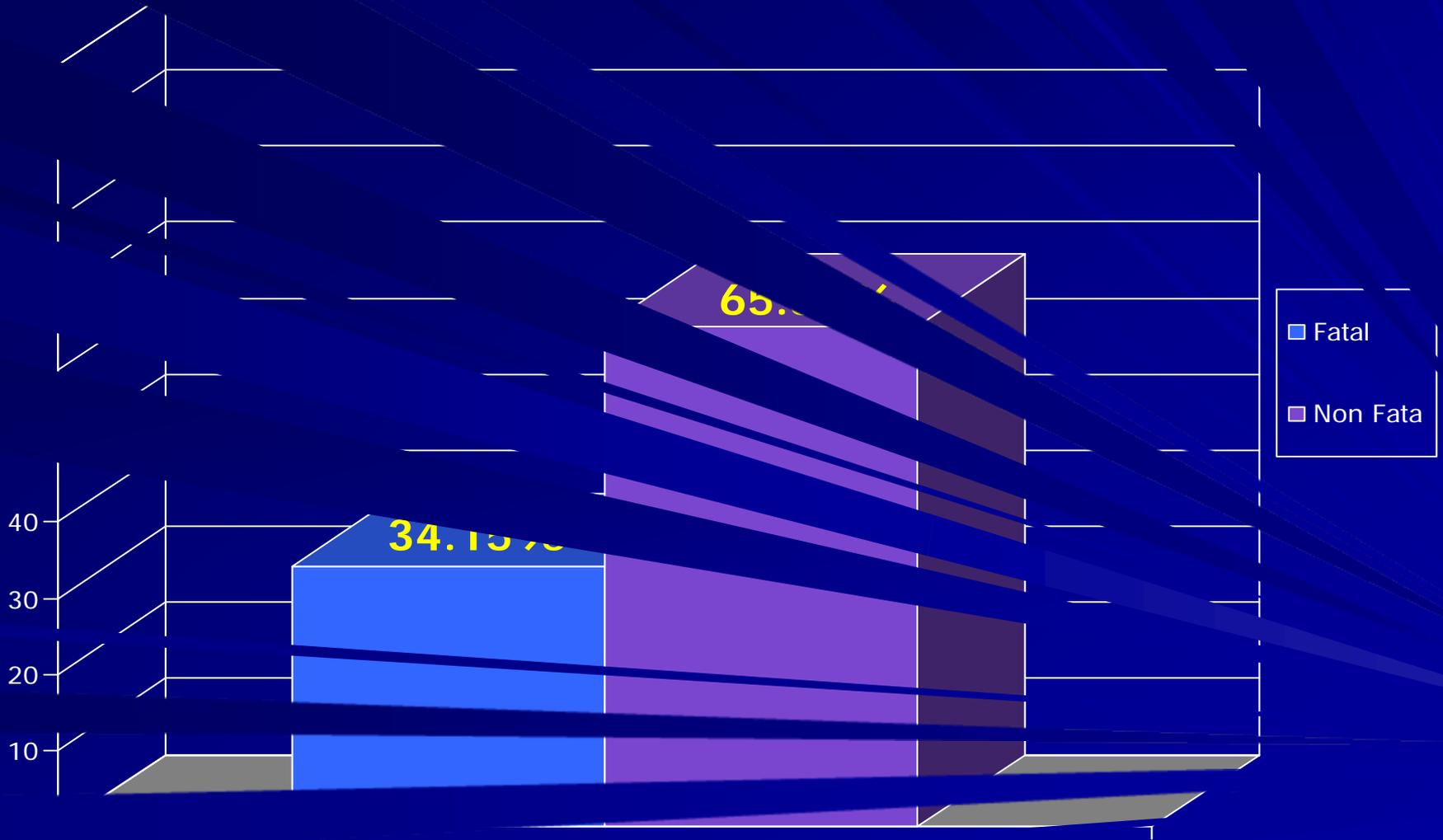
A look at the data...



- There were 82 Administrative Penalties (APs) issued between January 2007 to August 1, 2009
- These 82 AP's contained 106 regulatory deficiencies which were sorted into regulatory groupings as listed in California Title 22 for General Acute Care Hospitals.

Client Outcomes Associated with AP's

▲ of 82 AP's associated with death



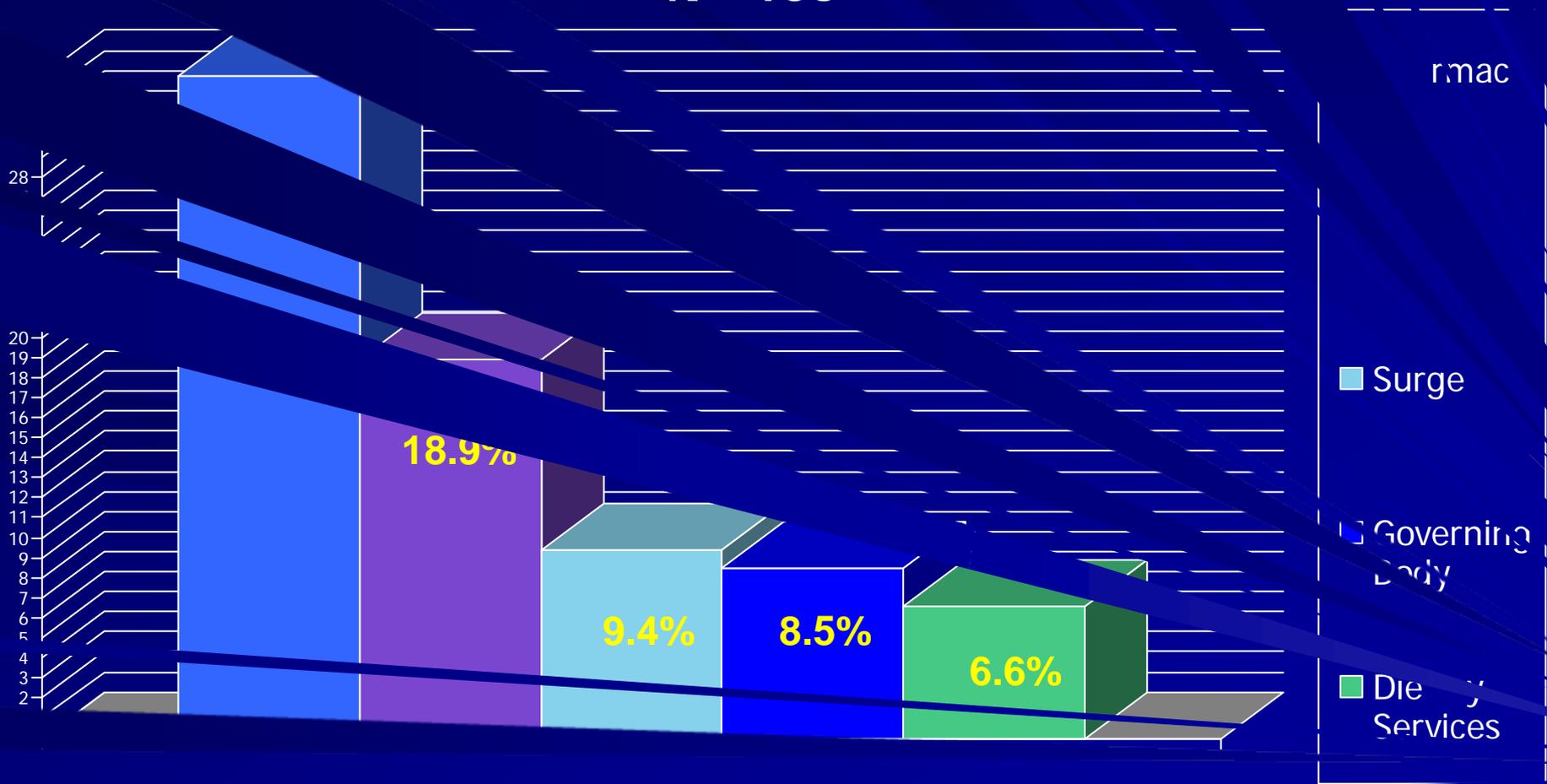
29 of 22 Administrative Penalties (35.1% of 29)
at the result of Pharmacy Regulatory Grouping deficiencies



These 29 Administrative Penalties generate
35 of the 106 (33%) regulatory deficiencies
analyzed in this study

Distribution of Deficiencies by Title 22 Regulatory Grouping

N= 106



Pharmacy and Nursing = 51.9% of all deficiencies.

Pharmacy Regulatory Groupings

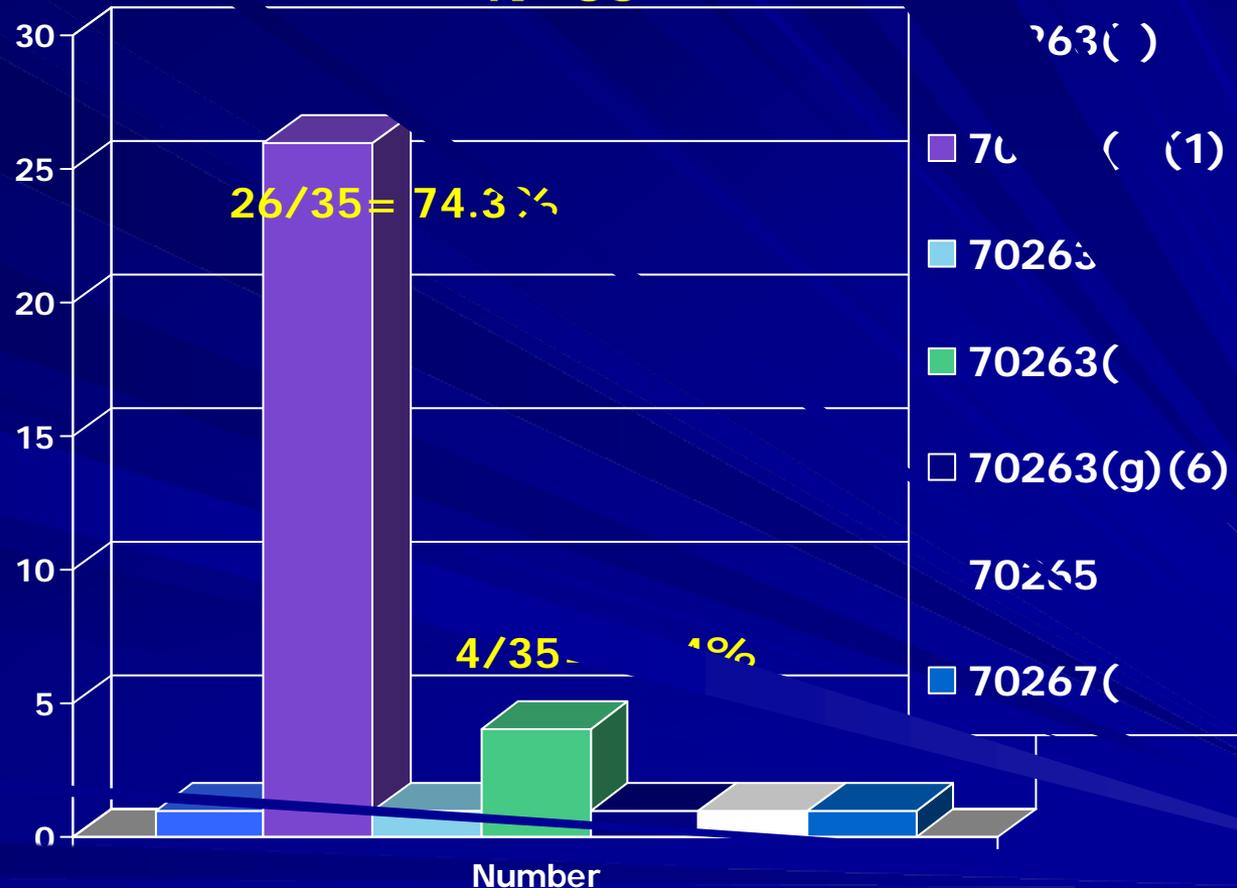
70263(C)(1)

Shall develop and implement policies and procedures for safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals

70263(g)(2)

Medications and treatments shall be administered as

N=35



Questions?

California State Board of Pharmacy- January 2010 Meeting

Respectfully Submitted



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CONFIDENTIAL



Agenda

Introduction

Pharmacy Benefit

Patient Safety & Security

Pharmacy Process

Convenience

Experience

Questions?

Benefits to Pharmacy

24/7 Automated Pharmacy Services™

- ▶ Will call security system
- ▶ Photo & signature audit trail
- ▶ Automated Return To Stock compliance
- ▶ Auto check-in from Central Fill
- ▶ Right Rx → Right Patient

Photo Capture Log

Filter: Date Signed is between 6/25/2008 and 6/26/2008

Rx #	PN	Date Signed	Med-Cal Relationship	Total Party	Co-Pay	Overhead Cost	POS ID	Photo
200002	1	6/25/2008 1:32:52PM	OBHA		\$2.00			 100-0000
200022	1	6/26/2008 8:27:18AM			\$10.00			 00000000
200002	2	6/26/2008 9:40:05AM	OBHA		\$10.00			 00000000
200001	1	6/26/2008 9:47:36AM	CAE		\$9.00			 00000000
200006	1	6/26/2008 10:24:21AM	FACE		\$10.00			 00000000

Photo Capture Log - Web Demo Room June 26, 2008 1:40 pm

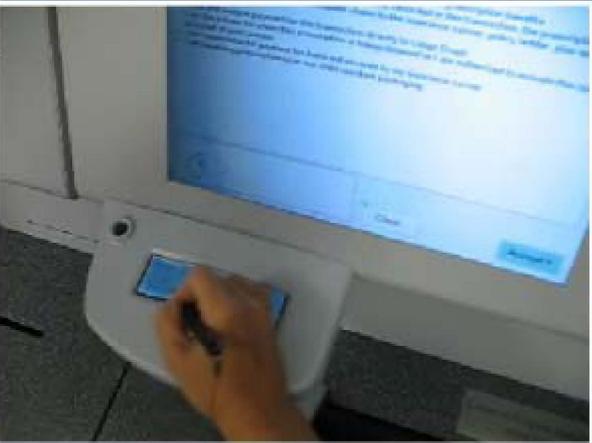
ScriptCenter captures the signature electronically to recognize HIPAA requirements which can also be forwarded to a 3rd party (PBM) for claim adjudication if needed.

ScriptCenter Quit

Sign to Acknowledge Privacy Practices

Copies of our Notice of Privacy Practices are available for you in a bin to your left on the ScriptCenter machine or at the pharmacy counter.

By signing below, I acknowledge that I have received a copy of your Notice of Privacy Practices.



Sign below or touch *Decline* and sign later.

Sign on the pad below ↓

Clear Accept > Decline

Safety & Security Features

- ▶ Rx tracking from fill to delivery
- ▶ Bar code assures patient/Rx match
- ▶ Automated return to stock
- ▶ Photo & signature audit trail
- ▶ Equipped with floor bolts and door locks
- ▶ Alarm interface



Mary Smith

Rx 2500302 7/19/09 9:46:09AM \$10.00



Biometric
Staff Login
& Tracking



Barcode Rx
Tracking

ScriptCenter Fingerprint Login



ScriptCenter Pharmacy Process

Order

Fill

Bag

Load

- ▶ Customer orders prescription as usual
- ▶ Pharmacist fills prescription as usual
- ▶ Prescriptions put in ScriptCenter bag and scanned
- ▶ Bags individually or batch loaded



Pharmacy Workflow Process



Fill Bag



Seal



Scan Bag



Scan Rx

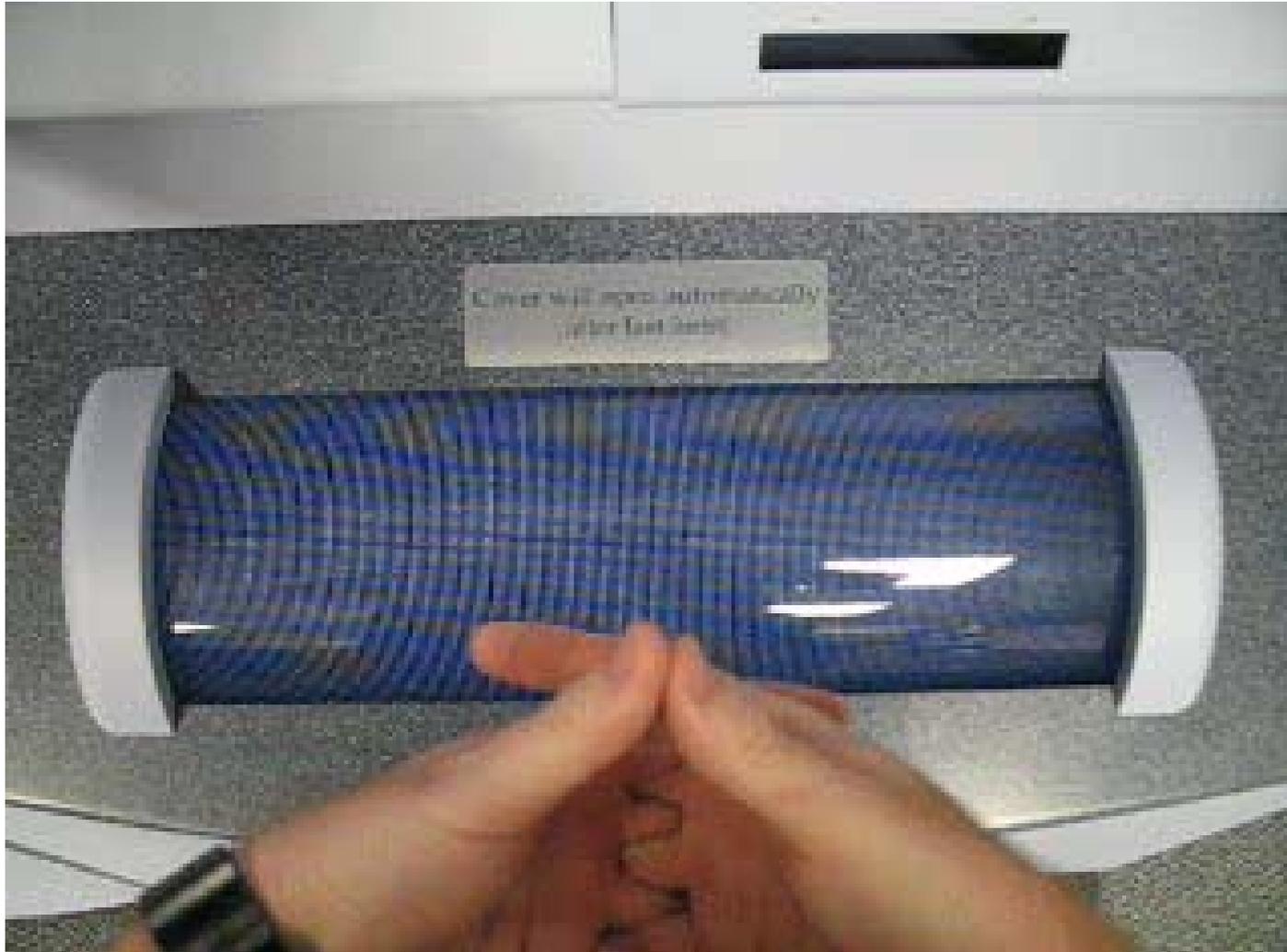


Pharmacy Workflow Process Cont.



Single or Batch load as desired

ScriptCenter Prescription Pickup



Patient Convenience

“Very few patients using APDS or the regular counter asked to speak to a pharmacist about their refill medications, although almost all patients believed that they could speak to a pharmacist if they had wanted to do so. Because the majority of patients agreed that their wait time was not long and that the overall prescription pick-up process was convenient, no perceived barriers to pharmacist access appear to exist; patients simply did not perceive the need to ask the pharmacist questions about their refill.”

“Patient request for pharmacist counseling and satisfaction: Automated prescription delivery system versus regular pick-up counter” JAPhA • 49 :1 • Jan / Feb 2009 pgs. 73-78

-Jan D. Hirsch, Austin Oen, Suzie Robertson,
Nancy Nguyen, and Charles Daniels

ScriptCenter Installations



Military (Commissary)



Rite Aid



Military (BX)



Safeway



Ahold (Giant)



Hospital Outpatient

ScriptCenter Facts & Figures

32,719 = customers that have used ScriptCenter

468,738 = total prescription refill deliveries

48,261 = total prescription refill deliveries after hours

11% = % of ScriptCenter refills delivered after hours

Experience



ScriptCenter has
successfully delivered over
450,000 prescriptions
without one delivery error!

Safety:



ScriptCenter has never been accessed by unauthorized persons or had an attempted break-in.



Questions?

Thank You
Respectfully Submitted