California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: July 27-29, 2015

LOCATION: Department of Consumer Affairs
1st Floor Hearing Room
1625 North Market Blvd
Sacramento, CA 95834

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Deborah Veale, RPh, Vice President
Victor Law, RPh, Treasurer
Stanley C. Weisser, RPh
Greg Lippe, Public Member (7/27/15 only)
Gregory Murphy, Public Member
Allen Schaad, RPh
Ramón Castellblanch, PhD, Public Member (7/29/15 only)
Albert Wong, PharmD
Lavanza Butler, RPh
Ryan Brooks, Public Member (7/28/15 and 7/29/15 only)
Rosalyn Hackworth, Public Member
Ricardo Sanchez, Public Member

BOARD MEMBERS NOT PRESENT:

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel (7/27/15)
Michael Santiago, DCA Staff Counsel (7/28/15)
Kristy Schieldge, DCA Staff Counsel (7/29/15)
Christine Acosta, Supervising Inspector (7/28/15)
Bill Young, Supervising Inspector (7/29/15)
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting may be found at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Monday, July 27, 2015

Call to Order 12:31 p.m.

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

Vice President Deborah Veale called the meeting to order and established a quorum of the board.

Board members present: Greg Lippe, Rosalyn Hackworth, Deborah Veale, Victor Law, Stanley Weisser, Ricardo Sanchez, Gregory Murphy and Allen Schaad.

Note: Lavanza Butler and Albert Wong arrived at 12:36 p.m. Amy Gutierrez arrived at 1:05 p.m.

Board members not present: Ramon Castellblanch and Ryan Brooks

II. Closed Session

Vice President Veale adjourned the meeting into closed session at 12:33 p.m.

III. Reconvene Open Session

President Amy Gutierrez reconvened open session 3:09 p.m.

Stanley Weisser asked the board to consider creating a committee of the board to handle disciplinary matters. The board agreed that this may help expedite disciplinary cases and asked staff to research other possible solutions. There were no comments from the public

President Gutierrez adjourned the meeting for the day at 3:12 p.m.

Tuesday, July 28, 2015

IV. Reconvene Open Session

President Gutierrez called the meeting to order at 9:06 a.m. and established a quorum of the board.

Board members present: Rosalyn Hackworth, Deborah Veale, Victor Law, Stanley Weisser, Ricardo Sanchez, Gregory Murphy, Allen Schaad, Amy Gutierrez, Lavanza Butler, Ryan Brooks and Albert Wong.

Board members not present: Ramon Castellblanch and Greg Lippe.

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

Note: The board may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

Dr. Raymond Pierson, an orthopedic surgeon, asked the board to agendize a discussion on pharmaceutical access in rural communities. Dr. Pierson explained that in his rural community he has experienced difficulty with patients receiving emergency medications after hours because they did

not have access to 24 hour pharmacy.

Stanley Goldenberg, former board president, suggested creating a mentor program for new board presidents to allow former presidents to provide guidance and support as they take on the role of board president.

Ryan Brooks asked the board to agendize the duty inspector program for discussion. Ms. Herold responded that this would be discussed later in the meeting.

VI. Approval of June 3-4, 2015 Minutes

Motion: Approve the June 2015 board meeting minutes.

M/S: Weisser/Law

Support: 9 Oppose: 0 Abstain: 2

Name	Support	Oppose	Abstain	Not Present
Brooks			x	
Butler	X			
Castellblanch				x
Gutierrez	X			
Hackworth	X			
Law	X			
Lippe				x
Murphy	X			
Sanchez	X			
Schaad			x	
Veale	X			
Weisser	X			
Wong	X			

VII. Recognition and Celebration of Pharmacists Licensed for 50 Years in California

The board recognized Ronald Bode and Pierre Del Prato.

VIII. Organizational Development Committee

a. Future Board Meeting Dates

President Gutierrez reviewed the board meeting dates for the remainder of 2015 and 2016 as provided below. Ms. Virginia Herold noted that committee meeting dates would be finalized following the board meeting.

- October 28-29, 2015
- February 2-3, 2016
- April 27-28, 2016
- July 27-28, 2016
- October 26-27, 2016

b. New Committee Assignments

President Gutierrez reported that the committee membership had been reorganized. She also noted that she has appointed vice chairs for each committee. A chart with the new committee assignments may be found in the board meeting materials.

c. National Association of Boards of Pharmacy 112th Annual Meeting

President Gutierrez announced that next year the NABP will hold its 112th Annual Meeting in San Diego. The meeting is scheduled for May 14-17, 2016, and will be held at the Hilton San Diego Bayfront Hotel. Ms. Herold added that additional information will be provided as it becomes available.

d. Budget Update/Report

1. Budget Report for 2015/2016

   President Gutierrez reported that the new budget year began July 1, 2015. She explained that the board's spending authorization is $19,770,000 which is a 3 percent increase from the previous fiscal year.

   Charts illustrating the board's growth in various expenditure categories can be found in the board meeting materials.

2. Budget Report for 2014/2015

   President Gutierrez reported that Fiscal Year (FY) 2014/15 ended June 30, 2015. She noted that the final FY 2014/15 budget numbers will not be available until the beginning of August 2015; a final budget report will be provided during the October Board Meeting.

   President Gutierrez briefly reviewed the FY 2014/15 budget charts included in the board meeting materials.

   President Gutierrez explained that based on projections through the end of FY 2014/15, the board identified that it would exceed its authorized enforcement-related expenditures, including Attorney General and Office of Administrative Hearings expenditures. She noted that budget bill language allowed programs within the Department of Consumer Affairs to submit a deficiency request to increase authorized expenditures for enforcement-related costs. President Gutierrez reported that board staff, in collaboration with the Attorney General's Office and the DCA budget office, prepared the deficiency notice seeking an additional $1.4million in authorized expenditures. The request was approved in Executive Order No. E 14/15-83 and was issued on April 30, 2015.

   President Gutierrez stated that board staff does not anticipate a decrease in enforcement related costs and may need to again pursue an augmentation, if necessary.

   There were no comments from the board or from the public.

3. Fund Condition Report

   President Gutierrez briefly reviewed the fund condition provided in the board meeting materials. President Gutierrez noted that as the fund condition reflects, the board may need to pursue another fee increase to sustain operations. She added that should this be required,

it would need to be done through legislation. One of the precursors to making such a determination will be completion of a fee audit, similar to the one completed several years ago in advance of the board's 2008 fee bill. President Gutierrez concluded that board staff has begun the process of completing the fee audit as would be discussed in the next agenda item.

4. Fee Audit Update

President Gutierrez explained that the board secured a contract with a company to conduct an independent audit of the board's fee structure to determine the costs to deliver services. The intent of the audit was to address the structural imbalance of the board's current budget and to determine the appropriate fees that should be assessed for various application and renewal fees.

President Gutierrez reported that after consultation with the DCA's budget office, it is clear that the board is unable to use the draft information provided by the contractor. The board has severed its contractual relationship with the vendor.

President Gutierrez stated that board staff is working with the budget office to evaluate the current fee structure based upon the cost to deliver services to applicants and licensees. A full report will be brought to the board at the October board meeting.

5. Board Member Reimbursement and Mail Vote Information

President Gutierrez stated that the reports on board member reimbursement and mail votes can be found in the board meeting materials. She noted that the Organizational Development Committee will be considering changes to the current mail voting procedures due to the high volume of cases being brought to the board for consideration.

President Gutierrez explained that board members can choose to waive their per diem payments for work conducted for the board.

Staff member Laura Hendricks noted that at the October Board Meeting a full report of board member reimbursement would be available.

e. Personnel Update

The board congratulated Allen Schaad and Stanley Weisser for their reappointment to the board by Governor Brown.

Ms. Herold noted that Supervising Inspector Judi Nurse has retired from the board. The board thanked Dr. Nurse for her years of dedicated service to the board.

There were no comments from the public.

IX. Licensing Committee

a. Consideration of Request to Recognize Chapman University School of Pharmacy Pursuant to Title 16, California Code of Regulations, Section 1719 for Purposes of Issuing Intern Licenses

Chairperson Weisser explained that there are three levels to full ACPE accreditation status for new schools of pharmacy: pre-candidate status, candidate status and full accreditation. New schools of pharmacy reach the various stages in their accreditation process as they reach various

milestones. Pre-candidate status designates that a new program is progressing and students can be enrolled in the program. Chairperson Weisser stated that this means that the school is progressing to meet the ACPE accreditation standards but has not yet completed the entire process. In such cases, the board must recognize the schools for purposes of issuing intern licenses to allow students to secure the training required for licensure.

Chairperson Weisser reported that Chapman University School of Pharmacy was granted pre-candidate status by the ACPE and the first call of students will be admitted in the fall of 2015. In order for the school's students to progress through their education, intern licenses are needed.

Chairperson Weisser stated that on April 13, 2015, the board received a request from Chapman University asking for board recognition of its program for purposes of issuing intern pharmacist licenses to students enrolled in their program.

Dr. Ronald Jordan, founding dean of the Chapman University School of Pharmacy, provided the board with a brief overview of their pharmacy program and thanked the board for considering their request.

Motion: Recognize Chapman University School of Pharmacy Pursuant to Title 16, California Code of Regulations, Section 1719 for Purposes of Issuing Intern Licenses.

M/S: Weisser/Veale

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				x
Gutierrez	X			
Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	x			
Wong	x			

b. Competency Committee Report – Examination Development

Chairperson Weisser reported that the two Competency Committee workgroups continued to meet throughout 2015 for examination development.

Chairperson Weisser stated that both Competency Committee workgroups will convene for the annual meeting in August to discuss examination development as well as begin the transition to

the new content outline of the examination. Chairperson Weisser noted that the new content outline will go into effect in early 2016.

c. Licensing Statistics July 1, 2014-June 30, 2015 and Three Year Comparison Data

Chairperson Weisser reviewed the licensing statistics for FY 14/15 as provided in the board meeting materials.

President Gutierrez asked the Licensing Committee to evaluate the current pharmacy technician licensing requirements. Chairperson Weisser and Mr. Law agreed that the committee needs to consider increasing the minimum qualification requirements for pharmacy technicians at their next meeting.

Ms. Veale noted that it would be helpful if the board received statistics on the total number of emails received by applicants and the number of emails responded to (the current statistics only provide the number of emails responded to). Ms. Sodergren responded that staff would update the statistics to report the total number of emails received as well as the total number of emails responded to.

Ms. Veale asked the processing times for pharmacy technicians, pharmacists and pharmacies.

Anne Sodergren, assistant executive officer, provided the following processing times.

- Pharmacy Technician: *if the application has no deficiencies*- 45 days from the receipt of application to licensure
- Pharmacists: *if the application has no deficiencies* - 30 days to be made eligible for taking the exam
- Pharmacies: *the majority of pharmacy applications have at least one deficiency* – the average is 4 months from receipt of application to licensure

Dr. Albert Wong stated that it is the perception of the public that board staff does not respond to applicants in a timely manner.

Mr. Allen Schaad asked if the applicants know that the processing time for pharmacy licensure is four months. Ms. Sodergren responded that the application itself has information on processing times and the board's reception desk is provided with current licensing times so that they can instruct callers.

The board asked staff to look into the use of electronic applications. Ms. Sodergren stated that staff would reach out to the department to see if there were any possibilities for electronic applications.

Ms. Veale asked if all communications between the board and applicants occurs via mail. Ms. Sodergren explained that for site licensure staff uses email whenever possible; however, for personal licenses most communication still occurs via regular mail.

President Gutierrez asked board staff to look at making an email address a required item on the applications. Ms. Herold responded that this may require a legislative change.

President Gutierrez asked if upon licensure pharmacists' email addresses are automatically registered to receive subscriber alerts. Mr. Law responded that the board does not have authorization to submit an email address on behalf of an applicant or licensee.

Stan Goldenberg, former board president, stated that there are consultants who charge people to help them get licensed with the Board of Pharmacy because the perception is that it will take at least a year to receive a pharmacy license.

Ms. Veale asked staff to provide processing times for each application type in future board meeting statistics. Ms. Sodergren responded that staff has found some inaccuracy in the reporting of processing times and are working with the department to program a more accurate report. Ms. Sodergren added that once staff has a way to accurately report processing times they will be included in the statistics.

Ms. Sodergren reported that staff will be working with the department's Public Information Office to create a YouTube video on how to correctly fill out a pharmacy technician application. She suggested that the board web cast the next Licensing Committee Meeting where the committee will be discussing how to correctly fill out a pharmacy application. The board agreed with this recommendation.

X. Enforcement and Compounding Committee

Part I Enforcement Matters

a. Presentation by the Drug Enforcement Administration (DEA) on its Requirements for the Take Back of Prescription Medications

President Gutierrez reported that on September 9, 2014, the DEA released its regulations on the take back of drugs from the public – specifically the take back of controlled substances.

President Gutierrez explained that the final rule authorized certain DEA registrants (manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy) to modify their registrations with the DEA to become authorized collectors. She added that all collectors may operate a collection receptacle at their registered location, and collectors with an on-site means of destruction may operate a mail-back program.

President Gutierrez reported that at the committee meeting Ruth Carter from the DEA presented information regarding the DEA's regulations for the take back of prescription medications.

President Gutierrez stated that the committee heard several public comments and questions on the topic. She added that although the questions posed indicated continuing confusion about take back regulations, every commenter was thankful for the opportunity to ask questions and appreciative of the board's efforts to address the take back of prescription medications.

There were no comments from the board or from the public.

b. Discussion Regarding the Drug Enforcement Administration's Regulations for the Take Back of Prescription Medication and Development of Regulations for Pharmacies and Reverse Distributors Who Take Back Prescription Medication from Patients

President Gutierrez reported that the board has discussed drafting its own take back regulations at multiple board and committee meetings.

President Gutierrez reported that one major item of concern for the committee is the safety and durability of the liner of the take back receptacles which will be removed, sealed and provided to a DEA-registered reverse distributor for destruction. At the committee meeting Jan Harris, Director of Environmental Health and Safety at Sharps Compliance, Inc., provided a presentation regarding its receptacle take back program. Ms. Harris demonstrated the size, strength, and durability of Sharps' take back receptacle liners and also provided information regarding the cost to participate in their program.

Ms. Herold provided the board and the public with a copy of draft take back regulation language (provided immediately following these minutes). She noted that this language would be the starting point for the committee to discuss and modify at the September 9 committee meeting.

The board discussed the need to ensure that the liners are durable enough to withstand the various types of hazardous medications that the public may put in the receptacle. Ms. Herold noted that requiring a specific type of liner will increase the cost of operating the receptacles.

Mr. Ryan Brooks suggested that the board create the guidelines for the liners, and let the industry create the liners that meet the guidelines. President Gutierrez responded the draft language provided by Ms. Herold is broad enough for this to occur.

Ms. Lavanza Butler asked who pays for the operation of the take back receptacles. Dr. Gutierrez responded that a few counties are creating ordinances that would require drug companies to fund the take back programs.

Ms. Veale asked what guidelines pharmacies would need to follow until the board finalizes its regulations in order to provide take back services to their patients. Ms. Herold responded that until the board finalizes its own regulations, pharmacies must follow the DEA regulations. Ms. Veale stated that the board needs to clarify to its licensees that if they participate in a take back program, they must follow the current DEA regulations until such time as the board finalizes its own regulations.

President Gutierrez asked staff to reach out to the Department of Toxic Substance Control for their input on the draft regulation language.

Dr. Steve Gray, representing Kaiser, reported that many counties are considering making take back programs mandatory, and they are not aware of the numerous complex regulations pharmacies will have to comply with.

A representative from Stericyle commented that their company has have found that each county has different regulations regarding the disposal and transportation of hazardous drugs. It was

also noted that currently in San Luis Obispo pharmacies have to fund the take back programs.

Chis Lester, California Product Stewardship Council, stated that they will provide comments on the draft language once they have reviewed it. President Gutierrez encouraged him to attend the next Enforcement Committee meeting.

Lisa Steinman from Sonoma County asked the board to clarify the definition of "law enforcement" and "reverse distributor." President Gutierrez recommended Ms. Steinman attend the next Enforcement Committee meeting for further discussion on this topic.

Caden Hare, from the City of Santa Rosa, thanked the board for drafting the regulation language and allowing for public comment. Mr. Hare asked if in a hospital setting staff other than the pharmacist could handle the liners (1776.3 (b) and 1776.3 (f) of the draft language). Ms. Herold responded that the pharmacy staff is responsible for the receptacle.

Mr. Hare asked of the liners can be provided to the pharmacy from a vendor with a unique identification number already on the liner (1776.3(e) of the draft language). Ms. Herold responded that the vendor can provide the liners with an identification number; the pharmacy's responsibility is to record and track this number. Mr. Hare asked if a pharmacy could use a sharpie to put a unique identification number on a liner. Ms. Herold responded that this would be acceptable, as long as it was a unique number that would not be repeated for three years.

The board recessed for a break at 11:16 a.m. and resumed at 11:36 a.m.

c. Presentation by the Healthcare Distribution Management Association on Deadlines and Distributor and Pharmacy Readiness to Meet Requirements for Exchange of Transaction Information, Transaction Histories and Transaction Statements as Required by the Federal Drug Supply Chain Security Act of 2013

President Gutierrez explained that the Drug Quality and Security Act (DQSA) preempted California's e-pedigree law, and instead established national requirements for tracking drugs through the supply chain. The first round of tracking requirements became effective January 1 with requirements for drug wholesalers. The second part of the requirements for pharmacies is set to take effect July 1.

President Gutierrez reported that Scott Moody, an employee of McKesson, made a presentation on the requirements and ramifications of the DQSA at the request of board staff to the Healthcare Distribution Management Association. Mr. Moody's presentation was provided in the board meeting materials.

There were no comments from the board or from the public.

d. Proposed Regulation for Pharmacies Aimed at Reducing Losses of Controlled Substances

President Gutierrez reported that over the last few meetings, the committee has expressed concern about the significant losses of controlled substances and the need for more stringent inventory controls in pharmacies to identify losses resulting from employee pilferage. Comments from the committee included developing steps for inventory controls, which could be done either by regulation, statute or policy and perhaps reconciling the top ten drugs for the pharmacy.

President Gutierrez stated that at the January 2015 Board Meeting, the board reviewed proposed language from the committee. The proposed language was rejected by the board and sent back to the Enforcement Committee for revision.

President Gutierrez reported that at the March 2015 committee meeting, the committee reviewed the new proposed language and decided to further revise the language to require a perpetual inventory for only schedule II controlled substances. Subsequently, at the April 2015 board meeting, the board discussed requiring an inventory for the top-10 diverted drugs, and asked the Enforcement Committee to continue working on the language.

President Gutierrez explained that at the June 2015 committee meeting the members reviewed the draft language and made edits to bring before the board. The language below was approved by the committee and is being recommended to the full board for approval.

1715.55 Reconciliation and Inventory Report of Controlled Substances

Revision Date: June 24, 2015 by the Enforcement Committee

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.

(c) Perform a Periodic Inventory: A pharmacy or clinic shall perform an inventory of specific controlled substances every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and one additional controlled substance specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.

(1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.

(2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:

a. A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.

b. The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.

(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge.

(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily

retrievable form.

(1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.

(2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.

(1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Ms. Veale recommended changing section (c) to read as follows: The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year.

Ms. Hackworth stated that an outgoing pharmacist-in-charge should perform an inventory prior to leaving a pharmacy. The board amended section (d) as follows: A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).

Mr. Gregory Murphy spoke in support of the board's effort to strengthen the inventory controls in pharmacies.

A representative from DynaLabs commented that she supported the board requiring inventory on one additional controlled substance specified by the board each year as based upon loss reports made to the board in the prior year. She stated that they often see trends in the types of drugs diverted, and this requirement will allow the board to respond to these trends.

Brian Warren, with the California Pharmacist Association, recommended that the board amend section (c) as follows: "A pharmacy or clinic shall ~~perform~~ compile an Inventory Report of specific controlled substances every three months. The compilation of this Inventory Report shall require a physical count…" The board approved this amendment.

Mr. Warren asked if there was an exemption for pharmacies who use a perpetual inventory system. President Gutierrez responded that there was no exemption -- pharmacies using perpetual inventory systems must still preform an inventory as described in section (c).

The board amended section (c) as follows to allow pharmacies to perform an inventory more than once a quarter if desired. "A pharmacy or clinic shall perform an inventory of specific controlled substances at least every three months."

Motion: Approve the language as amended during the board meeting (below). Initiate a 45-day comment period.

M/S: Weisser/Sanchez

1715.55 Reconciliation and Inventory Report of Controlled Substances

Revision Date: July 28, 2015 by the Full Board

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.

(c) Perform a Periodic Inventory: A pharmacy or clinic shall ~~perform~~ compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.

(1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.

(2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:

a. A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.

b. The federal Drug Enforcement Administration biennial inventory was taken no more than

three months from the last inventory required by this section.

(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).

(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.

(1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.

(2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.

(1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			

Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

e. Data Reporting Rates of E-Prescribing Rates in the U.S. and California

President Gutierrez reported that Surescripts issued its 2014 National Progress Report which indicated a 19% growth in overall e-prescriptions. Additionally, although e-prescriptions for controlled substances increased 400 percent to 1.67 million, only 1.4 percent of providers were enabled to participate.

President Gutierrez stated that California is the second largest state for the e-prescribing of controlled substances, with 4.26 percent of all controlled substances e-prescribed. Within the state, 71 percent of California's pharmacies and only 8.58 percent of California's prescribers have systems in place to enable e-prescribing. She noted that California's percentage is greater than New York where there is a requirement that all prescriptions be e-prescribed by March 2016.

There were no questions or comments from the board or from the public.

f. Proposed Regulations for Third-Party Logistics Providers; Proposed Amendments to 16 California Code of Regulations Sections 1780 -1786

President Gutierrez explained that in 2014, the board sponsored legislation to enact provisions to license third-party logistic providers as a separate class and not as the board had previously done under the category of wholesaler. This legislation was enacted by AB 2605 (Bonilla, Chapter 507, Statutes of 2014). This legislation was needed because federal law enacted in 2013 prohibited licensure of third-party logistics providers as wholesalers.

President Gutierrez stated that at the March 2015 committee meeting, to ensure that third-party logistics providers adhere to board regulations for all drug distributors, the committee reviewed and discussed proposed regulation requirements for third-party logistics providers that originate from drug wholesalers. The committee also reviewed and discussed a proposed self-assessment form that a board inspector could use when inspecting a facility.

President Gutierrez reported that at the June 2015 committee meeting Ms. Herold provided the committee with draft language to review and approve. The committee approved the language; however they recommended initiating the rulemaking process without the self-assessment form.

There were no comments or questions from the board or from the public.

Motion (committee recommendation): Initiate the 45-day comment period without the self-assessment form.

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				x
Gutierrez	X			
Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	x			
Wong	x			

g. Update on CURES 2.0

Ms. Herold provided an update on the latest iteration of the Controlled Substance Utilization Review and Evaluation System (CURES) and indicated that the Department of Justice (DOJ) had a "soft launch" of CURES 2.0 on June 30, 2015. Currently the DOJ is working with select practitioners and organizations to beta test CURES 2.0. She added that the DOJ will run both CURES systems (1.0 and 2.0) concurrently while they continue to build and test CURES 2.0.

Ms. Herold noted that users might have difficulty accessing CURES 2.0 if they don't have current versions of internet browsers such as Chrome, Firefox, and Internet Explorer II.

Ms. Herold stated that the board will be mailing notices to pharmacists reminding them that they are required to register for CURES by January 1, 2016. The board asked staff to use the subscriber alert system to notify pharmacists of the consequences of not registering by January 1, 2016.

Steve Gray, from Kaiser, asked if the DOJ would still send a representative to meetings of 20 or more people to register users. Ms. Herold responded that she would ask the DOJ if they are still doing registration outreach events.

Dr. Gray asked if pharmacists who do not see patients will be able to keep their account active without looking up patient information. Mr. Law explained that every thirty days pharmacists must re-set their password, but it does not require any patient searches to do so. Ms. Herold added that pharmacists may need to answer security questions to reset the password, and noted that under the current system the pharmacist must remember his or her answers exactly (capitalization, spacing, etc.).

Dr. Robert Stein, pharmacist who is participating in the CURES 2.0 beta test, highlighted some of the new features of the 2.0 system which includes the ability to delegate authority to ancillary staff (pharmacy technicians) to run reports and set-up profiles for patients with pain contracts.

Dr. Gutierrez asked if board staff is able to determine if a pharmacy is submitting to CURES as required by law. Ms. Herold responded that staff is able to run a report to verify if a pharmacy is submitting information to CURES.

The board discussed issues with the data being reported into CURES by pharmacists not appearing in reports. Ms. Herold noted that she would discuss this with the DOJ as it is their responsibly to work with the third-party vendor who "cleans" the data to identify and fix the problem.

h. Enforcement Statistics

President Gutierrez reviewed the enforcement statistics provided in the board meeting materials.

Ms. Veale asked how often the contracts of pharmacists in the recovery program are reviewed. Ms. Sodergren responded that all contracts are reviewed at least once per quarter.

Ms. Veale asked what constituted a relapse. Ms. Sodergren explained when someone has an unexpected positive drug test it is considered a relapse.

There were no comments or questions from the public.

i. Future Meeting Dates

President Gutierrez reported that the next Enforcement Committee meeting would be held September 9, 2015 (re-scheduled from September 2, 2015). She noted that the December meeting date would be finalized and reported at the next committee meeting.

The board recessed for lunch at 12:30 p.m. and resumed at 1:15 p.m.

Part II. Compounding Matters

a. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 California Code of Regulations Section 1735 et seq., and 1751 et seq., Relating to Pharmacy Compounding

President Gutierrez explained that the compounding regulations were amended after review by the compounding workgroup and based on comments received during the 45-day comment period. The proposed text can be found immediately following these minutes. The proposed changes to the language are highlighted in red font.

President Gutierrez noted that this regulation will require structural changes for some organizations in order to meet the standards for handling hazardous materials (example: compounding of chemotherapy drugs). The board will allow organizations to request extensions from the board in order to make the structural changes required. Requested extensions must include an action plan and timeline for the completion of the structural changes for the board to review and approve.

President Gutierrez briefly reviewed the proposed changes to the language. She noted that a major change occurred on page 8 of the language which addresses the 72-hour prescriber office exemption. She explained that the regulation now states when preparing sterile compounds for a prescriber office, the medication cannot be dispensed to the patient to take home; instead, the

medication must be used in the prescriber's office. President Gutierrez noted that there is an exemption for veterinary offices.

Dr. Christine Acosta, Supervising Inspector, explained that in section 1751.7(e)(1) the language was changed to provide an exemption from the quarantine requirements for a 30-day supply of ophthalmic medications for a single patient. A quarantine exemption was also created for a five-day supply of self-administered inhalation medications for a single patient.

President Gutierrez explained that if the board agrees with the proposed changes, the next step would be to initiate a 15-day comment period.

Dr. Gray, representing Kaiser, expressed concern with the changes in section 1735.2 (c)(1). The board asked Dr. Gray to submit comments in writing during the 15-day comment period.

Brian Warren, California Pharmacists Association, stated that his organization will review the modified text and submit comments during the 15-day comment period. President Gutierrez encouraged Mr. Warren to include "real world" examples with his written comments to aid the workgroup in their deliberations.

Dr. Gray, representing Kaiser, noted that the change to the prescriber office use section could cause significant problems for patients who need very expensive autologous serum eye drops. President Gutierrez asked Dr. Gray to submit his comments in writing and provide examples of the expensive medications.

Dr. Gray stated that on page 1 in section 1735 (b) the board should consider amending the language to: "…drug pursuant to a manufacturer's direction(s) for oral, ophthalmic, rectal, topical, or injectable administration…" President Gutierrez asked Dr. Gray to submit his comments in writing.

Doug O'Brien, representing Kaiser, thanked the board for allowing hospitals to submit waivers to allow time to make the structural changes required for the handling of hazardous materials. He added that he would be submitting comments regarding the definition of "clean room."

Judith Brosz, PharmD, shared that due to a health condition she is unable to complete the physical component of the training required in the compounding regulation. She stated that she had submitted comments during the 45-day comment period that would amend the training requirements in a way that would allow for pharmacists with disabilities to still meet the training requirements. However, Dr. Brosz stated that she did not feel that the board had amended the language in response to her comments. Ms. Herold responded that the workgroup had reviewed the comments submitted by Dr. Brosz and had added 1735.7 (a) in response to her comments.

Motion: Notice the text as discussed at the meeting (provided following these minutes) for 15-day comment period.

M/S: Weisser/Sanchez

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Update of SB 619 (Morrell) – Licensure of Outsourcing Facilities

Ms. Herold explained that Senate Bill 619 (Morrell) would require the board to license an outsourcing facility if it compounds non-patient specific medication for patients or practitioners inside or outside of California. Other provisions of the bill would:

- Specify the activities an outsourcing facility can and cannot perform
- Apply the licensing requirement to out-of-state outsourcing facilities that ship compounded prescription drugs into the state
- Require the board to report to the Legislature by January 1, 2018 on its licensing and regulatory efforts
- Authorize the board to issue a cease and desist order to an outsourcing facility if the board determines that there is an immediate threat to public health
- Specify the fees for issuance or renewal of a license for an outsourcing facility, including a requirement that an out-of-state outsourcing facility must also provide reasonable funding to cover the costs for out-of-state inspections

Ms. Herold stated that the bill stalled on the Senate Appropriations Committee calendar. No reason was provided by committee staff. The bill might be picked up later in the year if there is more than one outsourcing facility affected and unable to do business in California. Ms. Herold stated that the bill should be taken up next year as part of the board's sunset package.

c. Discussion of Critical IQ's Article on "Quality Standards for Large Scale Sterile Compounding Facilities"

President Gutierrez explained that federal legislation has established a new regulatory category for pharmaceutical compounders that supply healthcare providers with prepared, non-patient specific medicines for use in hospitals, offices and clinics. These "outsourcing facilities" will be subject to more rigorous quality and safety standards modeled after the Current Good Manufacturing Practices (CGMPs) that apply to pharmaceutical manufacturers.

President Gutierrez noted that the paper in Attachment 9 of the board meeting materials reviews the differences between traditional and outsourced compounding and describes the key CGMP provisions that are critical to ensuring drug quality and patient safety when compounding occurs

at a larger scale. President Gutierrez recommend board members review the paper as it contains useful information on outsourced compounding.

This item was informational only. There were no comments or questions from the board or from the public.

d. Review and Discussion of the U.S. Food and Drug Administration's Draft Guidance Document on Guidance for Industry; Compounding Animal Drugs from Bulk Drug Substances

President Gutierrez explained that the draft guidance, provided in Attachment 11 of the board meeting materials, sets forth the Food and Drug Administration's (FDA) current thinking regarding compounding animal drugs from bulk drug substances by state-licensed pharmacies, licensed veterinarians, and facilities that register with the FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act.

President Gutierrez reported that the committee discussed the guidance document and recommended staff submit comments to the FDA on behalf of the board.

Motion (committee recommendation): Submit comments on the FDA's Guidance Document on Compounding Animal Drugs from Bulk Drug Substances.

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	X			
Butler	X			
Castellblanch				x
Gutierrez	X			
Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	X			
Schaad	X			
Veale	X			
Weisser	x			
Wong	x			

e. Compounding Statistics

President Gutierrez briefly reviewed the compounding statistics as provided in the board meeting materials.

There were no comments from the board or from the public.

The board recessed for a break at 2:16 p.m. and resumed at 2:30 p.m.

XI. SB 493 Committee

a. Requirements for Licensure as an Advance Practice Pharmacist

Chairperson Weisser reported that during the last board meeting, the board approved the general language of new requirements for advance practice pharmacist licensure, but asked staff to refine the language to reflect the discussion regarding section 1730.1 held at the June Board Meeting. The board then motioned for staff to draft these corrections into the regulations, directed the president and chair of the committee to review the changes, and if acceptable to them, have staff initiate the rulemaking process by securing the 45-day public notice period.

Chairperson Weisser explained that in accordance with this directive, board staff made corrections to the text of the regulation, and Chair Weisser and Board President Gutierrez approved the modifications.

A copy of this final language is provided below:

Article 3.5

Advanced Practice Pharmacist

1730 Acceptable Certification Programs

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

1730.1 Application Requirements for Advanced Practice Pharmacist Licensure

For purposes of 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and

completion, and area(s) of specialty.

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

A. Earned the clinical experience within the required time frame;

B. Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and

i. The applicant shall provide a copy of the collaborative practice agreement or protocol.

ii. If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients.

Reference: Business and Professions Code section 4052.1 4052.2, 4052.6, 4210, 4400

Authority: Business and Professions Code section 4005, 4210, 4400

Ms. Herold stated that this language is currently being reviewed by the Office of Administrative Law and would be released for 45-day public comment in the coming weeks.

Brian Warren, representing the California Pharmacists Association, asked the board if they would consider amending the language to allow for additional certificate programs to be included as a qualifying method. President Gutierrez responded that future SB 493 matters would be handled by the Licensing Committee. Ms. Herold and Chairperson Weisser added that this topic would be discussed at future Licensing Committee meetings. Ms. Veale stated that she would support the board accepting additional certificate programs.

President Gutierrez asked if any schools of pharmacy are considering developing programs to meet the requirements of SB 493. A representative from Chapman University explained that many schools are looking to develop certificate programs and will also be working with associations to develop programs. A representative from KGI School of Pharmacy stated that their school is also looking to develop certificate programs.

Dr. Gray, pharmacist, reminded the board that there is a difference between a certificate program and certification program and he recommended that the board carefully consider the differences during their future discussions.

Dr. Gutierrez stated that the board needs to consider if it is appropriate for an Advanced Practice Pharmacist to own a pharmacy. She asked the Licensing Committee to discuss this topic at a future committee meeting. Dr. Gray stated that there is a statute that specifically allows pharmacists who are prescribers to own a pharmacy, but he could not identify the code section.

b. <u>Update on Pending Regulations for SB 493 and AB 1535</u>

1. <u>Naloxone Protocol</u>
   Chairperson Weisser reported that the *emergency* regulation to establish this protocol was filed April 10, 2015, and will end (unless extended) October 2015. The board has publicized the protocol and it is prominently placed on the board's Web site.

   Chairperson Weisser stated that the Board of Pharmacy also has worked to secure the approval and adoption of the *permanent* protocol for naloxone. In April 2015 the board approved the permanent version, and the Medical Board approved it during the first week in May. He added that the regulation was released for public comment from May 22-July 13, 2015. Chairperson Weisser explained that the comments received will be discussed during the Legislation and Regulation Report at this meeting.

   President Gutierrez asked if board staff has considered compiling a list of pharmacies that provide naloxone to post on the board's Web site. Ms. Herold responded that staff will send out a subscriber alert asking pharmacies to notify the board if they provide naloxone.

   Brian Warren reported that the Drug Policy Alliance is planning to develop a Web site where the public can search for pharmacies who furnish naloxone. Mr. Warren added that the California Pharmacists Association is working with chain stores and independent pharmacies to promote furnishing Naloxone. Ms. Herold stated that the board should consider linking to the Drug Product Alliance search Web site.

   Dr. Gray stated that Kaiser is begining to plan the implementation of their naloxone program on a national level.

   A pharmacist asked if there was a Good Samaritan Law for pharmacists who administer naloxone to a patient who is overdosing. President Gutierrez explained that the protocol addresses the dispensing of naloxone not the administration. She recommended that the pharmacist discuss administration of naloxone and the Good Samaritan Law with a lawyer.

   Ms. Herold asked the board to direct staff to extend the emergency regulation with the Office of Administrative Law until the permanent regulation gets approved.

   Motion: Direct staff to extend the emergency naloxone regulation with the Office of Administrative Law until the permanent regulation is approved.

M/S: Veale/Butler

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

2. Adoption of the Protocol for Self-Administered Hormonal Contraception
   Chairperson Weisser reported that the regulation to establish this protocol was approved by both the Medical Board and Board of Pharmacy in January 2015. The regulation was noticed for public comment from May 8 to June 22. Chairperson Weisser noted that the comments received during the comment period will be discussed during the Legislation and Regulation Report of this meeting.

3. Adoption of the Protocol for Nicotine Replacement Products
   Chairperson Weisser reported that the regulation to establish the protocol for nicotine replacement products was approved by the Medical Board and Board of Pharmacy in January 2015. The regulation was notice for public comment from May 8 to June 22. Chairperson Weisser noted that the comments received during the comment period will be discussed during the Legislation and Regulation Report of this meeting.

4. Immunizations
   Chairperson Weisser reported that the requirements for pharmacists who wish to provide immunizations was approved by the board during the June Board Meeting and are awaiting release for the-45 day public comment period to initiate the rulemaking. He added that staff is waiting for Staff Counsel Freedman to review the language before filing it with the Office of Administrative Law to initiate the comment period.

5. Travel Medications
   Chairperson Weisser stated that the requirements for pharmacists who wish to provide travel medications were approved by the board during the June Board Meeting and are awaiting release for the 45-day public comment period to initiate the rulemaking. He noted that staff is waiting for Staff Counsel Freedman to review the language before filing it with the Office of Administrative Law to initiate the comment period.

XII. SB 1441 Uniform Standards Implementation Committee

Chairperson Weisser reported that in early 2011, the board directed staff to restructure and update its Disciplinary Guidelines. Subsequent to this, in April 2011, the uniform standards required in B&PC section 315 were finalized. Over the course of the following year, the board initiated a rulemaking to update the Disciplinary Guidelines and incorporate the SB 1441 uniform standards as it deemed appropriate considering comments from counsel and staff on how best to proceed.

Chairperson Weisser stated that in addition to the standards themselves, the board also received two opinions on what was required to implement the uniform standards: A copy of a legal opinion from the Legislative Counsel Bureau, an executive summary issued by the Office Of the Attorney General as well as an implementation memo from Doreatha Johnson, Deputy Director of Legal Affairs, DCA. These items were provided in the board meeting materials. Chairperson Weisser explained that the legal opinions did not provide consistent guidance and as such the board requested a formal legal opinion from the Office of the Attorney General in January 2013. The board received a response to this request on April 8, 2015.

Chairperson Weisser reported that during the April 2015 Board Meeting, the board briefly discussed the new legal opinion and was advised that the new opinion provides for some discretion by the board. This is contrary to prior guidance provided to the board. As such, members were advised that staff and counsel would work on implementation options and discuss the issue during the June board meeting.

Chairperson Weisser stated that, during the June Board Meeting, an ad hoc committee was established to allow a complete review of the proposed implementation strategy briefly discussed during the board meeting.

Chairperson Weisser reported that the first meeting of this ad hoc committee occurred on June 19, 2015. During this meeting the committee discussed in detail the proposed changes to the Disciplinary Guidelines. The proposed changes included three types of changes:

1. Consolidation of license types (into individual licenses or premise licenses) within the guidelines to improve ease of use.
2. Revisions to conform the Disciplinary Guidelines with SB 1441 standards.
3. Revisions to improve the board's ability to monitor licensees on probation with the board.

Chairperson Weisser added that the committee reviewed several areas of the proposed disciplinary guidelines at the June committee meeting and requested additional changes be drafted for consideration during its next committee meeting.

Chairperson Weisser stated that the committee met again on July 27, 2015 and reviewed the changes staff made to the Disciplinary Guidelines in response to the discussion at the June committee meeting.

Chairperson Weisser reported that on July 27 the committee approved the language and motioned to bring the proposed Disciplinary Guidelines to the full board for approval. The language as approved at the July committee meeting is provided in the board meeting materials.

At the request of the board, Ms. Sodergren briefly reviewed the changes the committee made to the Disciplinary Guidelines. Ms. Veale noted that the updated guidelines were streamlined making them easier to use.

DCA Staff Counsel, Michael Santiago, stated that he would recommend adding trigger language to give notice to the board when they are dealing with a substance abusing licensee. He cautioned the board that the lack of trigger language could result in the Office of Administrative Law rejecting the language. Chairperson Weisser expressed frustration that this issue was being raised at the board meeting rather than at the two previous committee meetings.

Doreathea Johnson, Deputy Director of DCA Legal Affairs, thanked the board for their work in updating its Disciplinary Guidelines. Ms. Johnson noted that she had not had time to review the language in its entirety, but she shared Mr. Santiago's concern that the language does not clearly define who the licensees are that will be subject to the uniform standards. Ms. Johnson stated that while it is true that the most recent legal opinion from the Attorney General's Office does provide the board with some discretion, it does not exempt the board from clearly defining what individuals will be subject to the uniform standards.

Ms. Johnson apologized for not having a representative from the DCA legal office attend the previous two committee meetings. She offered to assist the board in conducting a detailed review of the Disciplinary Guidelines. Ms. Johnson recommended that the board not approve the language, and instead send it back to the committee to allow the DCA Legal Office time to conduct its review and work with the committee.

Ms. Herold stated that it was the intent of board staff to have the Disciplinary Guidelines updated prior to the board's next Sunset Review. She added that this language was developed after extensive deliberation and consideration, and staff believes that it does include the required trigger language.

Ms. Johnson again stated her concern with the language and recommended the board send the language back to the committee.

The board elected to move forward with the language rather than sending it back to the committee. The DCA Legal Office would still have the opportunity to review the language prior to the initiation of the 45-day comment period.

Motion: Approve the language as provided in the board meeting materials. Initiate the 45 day comment period.

M/S: Weisser/Brooks

Support: 11 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Butler	x			
Castellblanch				x
Gutierrez	x			

Hackworth	x			
Law	x			
Lippe				x
Murphy	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

The board adjourned for the day at 3:50 p.m.

Wednesday, July 29, 2015

XIII. Call to Order and Establishment of Quorum

President Gutierrez called the meeting to order at 9:10 a.m. and established a quorum of the board.

Board members present: Rosalyn Hackworth, Deborah Veale, Victor Law, Stanley Weisser, Ricardo Sanchez, Allen Schaad, Amy Gutierrez, Lavanza Butler, Ryan Brooks and Albert Wong.

Board members not present: Gregory Murphy and Greg Lippe.

XIV. Executive Officer's Report

a. Medical Board Update

Ms. Herold reported that the Medical Board did not have any updates for the board at this time.

b. General Board Update

Ms. Herold reported that the 2016 Committee Meetings will be scheduled in the coming weeks, and the dates would be posted on the board's Web site once they are finalized.

Ms. Herold provided a brief update of her work on the NABP .Pharmacy Committee.

Ms. Herold reported that she recently participated in a meeting on telemedicine organized by the DEA.

Ms. Herold stated that the Centers for Disease Control invited her to attend a meeting to discuss California's compounding regulations and efforts to ensure a safe drug supply. She noted that this trip is currently being reviewed by the Governor's Office for approval.

Ms. Herold reported that on July 18, 2015, Mr. Law organized a continuing education training event. The training was conducted by Ms. Herold and the DEA and covered issues relating to drug diversion and theft of controlled substances. She added that there were approximately 240 attendees and Mr. Law is organizing another event in the San Gabriel Valley. Other board members expressed interest in organizing similar events in their areas.

Ms. Herold reported that board staff has begun working on the board's Sunset Review Report.

c. Duty Inspector Update

Ms. Herold provided a brief report to the board on the duty inspector program. A PowerPoint presentation with statistics on the number of inquiries received and the type of questions received is provided following these minutes.

The board expressed concern that the current duty inspector time frames are not meeting the needs of the board's licensees. The board asked staff to expand the duty inspector hours.

Ms. Herold reported that there will be information on the duty inspector program in the upcoming issue of the *Script*.

Mr. Brooks asked how people can reach the duty inspector. Ms. Herold responded that people can fax, email or call with questions.

The board asked staff to look at ways to improve the current phone tree system to provide information to callers on frequently asked questions and the duty inspector availability.

Board staff stated that a fact sheet is being developed to place online in an attempt to answer some frequently asked questions. Ms. Schieldge recommended placing the development of a fact sheet on a future meeting agenda.

XIV. Discussion with the Deans of the California Schools of Pharmacy and the Accreditation Council for Pharmacy Education on the Training of Students in California Pharmacy Schools on Patient Consultation

President Gutierrez stated that since the early 1990s, California has required pharmacists to consult patients (or their agents) on all new medications or medications with changed directions for use or changed dosing.

President Gutierrez stated that California law requires the pharmacist to initiate consultation; thus any patient who declines consultation must be speaking directly to the pharmacist to decline consultation. However, the board is aware that patients are not receiving consultation at the frequency required.

President Gutierrez noted that during recent board meetings, the board has discussed consultation and has decided to take a look at what barriers exist for improved patient consultation, including achieving an increased rate of consultation.

President Gutierrez explained that the board convened this forum to discuss how California pharmacy students are educated with respect to patient consultation.

Survey Results

In preparation for this forum the board used the subscriber alert system to conduct a brief survey on consultation. The board received 1,006 responses to the survey. Ms. Hendricks briefly reviewed the results of the survey. The results indicated that most pharmacists do provide consultations, however they face barriers to consultation such as inadequate staffing, patients being in a hurry, lack of reimbursement for consultation, and ancillary staff screening for consultation. The full results are provided following these minutes.

The board was pleased with the number of responses; however, they expressed the need to conduct

further surveys to obtain additional information. Dr. Castellblanch offered to assist in writing questions for subsequent surveys.

Dr. Gray, pharmacist, encouraged the board to conduct additional surveys to measure the success of any action the board takes to improve patient consultation.

Holly Strom, former board president, stated that she has found that even when a pharmacist does provide a consultation; it often does not consist of valuable patient information.

Dr. Wong stated that the root of the problem is the lack of reimbursement for patient consultation.

Mr. Weisser stated that patient consultation is critical to the health of patients, even if pharmacists are not reimbursed for providing the service.

Mr. Law stated it is important to remember the pressure pharmacists are under from managers and pharmacy owners to fill prescriptions quickly.

Mr. Brooks stated that patient consultation is absolutely necessary to patients' health therefore pharmacists have to find a way to balance their time.

Mr. Weisser asked the board to invite leaders from each of the major chain pharmacies to discuss patient consultation with the board.

Stan Goldenberg, former board president, suggested that the board consider if the current pharmacy environment makes it possible for consulting to occur in both chain and independent pharmacies.

The board thanked the pharmacists who participated in the survey as it provided valuable information to use as a starting point for the discussion on patient consultation.

Presentations from Schools of Pharmacy

President Gutierrez reported that all deans of California's schools of pharmacy were invited to attend this meeting to share information with the board about how they educate pharmacy students to perform patient consultation. The board also invited Peter Vlasses, Executive Director of ACPE, and Michael Negrete, former director of the Pharmacy Foundation of California.

In preparation for this forum Ms. Herold conducted a survey of the California Schools of Pharmacies. The survey was designed to gather information on the curriculum the schools use to teach patient consultation. Mr. Hendricks briefly reviewed the results which have been provided immediately following these minutes.

1. Chapman University School of Pharmacy

   Dr. Jeff Goad provided a presentation on Chapman University's curriculum regarding patient consultation. The entire presentation is provided immediately following these minutes.

   Mr. Weisser asked if upon graduation students are prepared to provide quality consultations. Dr. Goad responded that the curriculum is designed to provide students with the skill, knowledge and ability to provide consultations.

   Dr. Castellblanch asked if students receive instructions on providing consultations for Schedule II prescriptions. Dr. Goad responded that students receive information on Schedule II consultations in both their drug therapy classes as well as their law classes.

Dr. Castellblanch asked if students discuss the mandate to provide translation services to patients. Dr. Goad explained that students are be taught this in their law classes.

2. Peter H. Vlasses, - Executive Director, Accreditation Council for Pharmacy Education (ACPE)
   Dr. Vlasses provided a presentation on the standards the ACPE uses to accredit schools of pharmacy. The presentation focused on the standards for student education on proper patient consultation. The entire presentation has been provided immediately following these minutes.

   Dr. Vlasses stated that the students of California schools of pharmacy receive adequate education on patient consultation.

   Dr. Vlassess noted that the healthcare landscape is changing from a fee for service system to a value based system. He encouraged the board to look at Accountable Care Organizations where physicians and pharmacists are working collaboratively to achieve better patient outcomes

   President Gutierrez asked if there are any studies that show the value pharmacists add to patient care. Dr. Vlasses responded that recently the British health system has contributed 1.5 million pounds to place pharmacists in patient care offices in order to study the value they add to the patient care process. Additionally Dr. Vlasses indicated that a study was conducted in Pennsylvania that illustrated that pharmacist involvement improved patient care.

   Mr. Weisser stated that he has served as a board representative in two pharmacy school reviews conducted by the ACPE. Mr. Weisser noted that his only recommendation to improve the process would be to allow the board representative to have a more active role in the review. Dr. Vlasses explained that the board representative's roll is to observe the ACPE to ensure that they are adequately conducting the accreditation. He clarified that it is not the role of the board representative to actually conduct the accreditation review of the school. Ms. Schieldge commented that she would advise against board members being involved in a private entity's review of a school of pharmacy.

   Dr. Castellblanch asked if schools are expected to educate students on what to do if a patient does not speak English. Dr. Vlasses confirmed that schools are required educate students on what to do when a patient requires translation services.

   Dr. Castellblanch asked if students receive education on Schedule II prescriptions and prescription drug abuse. Dr. Vlasses responded that students receive education on a pharmacist's role combating prescription drug abuse.

   Dr. Gray, representing Kaiser, stated that students have a lot of knowledge when they graduate, but they often struggle to use that knowledge to provide consultations in a busy retail environment.

   The board recessed for a break at 11:10 a.m. and resumed at 11:19 a.m.

3. University of Southern California (USC)
   Dr. Glen Stimmel, Dean of the USC School of Pharmacy, stated that USC focuses on building students' knowledge and consultation skills as they move up through the pharmacy program.

   Dr. Stimmel stated that the schools already provide adequate education on patient consultation; the disconnect is occurring when the student enter a pharmacy where they only have a few seconds to provide information to patients.

Dr. Stimmel explained that patients often obtain inaccurate information about their medications from TV commercials and the internet. It is the pharmacist's job to determine what information the patient already has and to correct any inaccurate information they have about their medication.

Dr. Stimmel recommended that students be taught to open the consultation by asking the patient if they have any questions about the medication in order to start a dialog with the patient. Dr. Stimmel stated that it is also important for pharmacists to prioritize the information they provide to the patient in the limited time they have to consult.

Dr. Stimmel stated that pharmacists should be consulting not because it is the law, but because it is necessary to provide patient care.

Dr. Castellblanch asked when USC teaches students about counseling patients for Schedule II prescriptions. Dr. Stimmel responded that they have a member of faculty who specializes in pain management and designs curriculum to educate students in this area.

4. Western University College of Health Sciences

Dr. Dan Robinson, dean of Western University, briefly reviewed the school's curriculum regarding patient consultation.

Dr. Robinson stressed the importance of the pharmacist assessing the needs of the patient in the limited time they have with the patient.

Marvin Ortiz, second year pharmacy student, asked if the purpose of the forum was to determine if pharmacy students are able to provide consultations when they graduate from pharmacy school. Mr. Ortiz stated that as a second year student he is on track to have the knowledge and skills to provide consultations upon graduation. He explained that Western University uses mock consultations (which are videotaped for review) and courses on dynamic interviewing skills to help prepare students.

Mr. Ortiz explained that students see a disconnect between what they are taught in school and what is actually occurring in pharmacies. He added that students are often discouraged when they see that the important skills they are learning in schools are not being used in the field.

Mr. Ortiz reported that he co-chairs a program that teaches interested students medical Spanish through an eight week training course. He added that the course also teaches the students cultural context that pharmacists need when consulting with Spanish speaking patients.

Dr. Wong asked if Western University has any special outreach programs to recruit Spanish speaking students. Dr. Robinson explained that Western University has a pipeline program where they work with a student from the sixth grade all the way through high school to encourage them to go into the practice of pharmacy. The board expressed the need to increase diversity in pharmacy schools.

Ms. Veale asked in what year students choose if they will be specializing in clinical or community pharmacy. Dr. Robinson responded that students do not choose a certain track for their education.

Dr. Castellblanch asked when students receive education on Schedule II consultation. Mr. Ortiz responded that students receive extensive education on Schedule II prescriptions in pharmacy law classes. He noted that the education includes numerous real world examples for discussion.

Dr. Gutierrez noted that she and Mr. Law serve on the Dean's Advisory Counsel for Western University.

5. University of the Pacific (UOP)
   Dr. Phillip R. Oppenheimer, dean of the UOP School of Pharmacy, reviewed the school's curriculum which is designed to prepare students to provide consultations upon graduation.

   Dr. Oppenheimer stated that consultations are a critical part of filling prescriptions.

   Dr. Oppenheimer noted that an important part of the student's education on consultation occurs when they work with their preceptors during their pharmacy rotations.

6. University of San Diego (UCSD)
   Dr. Sara McBane, professor at UCSD, explained UCSD's curriculum regarding patient consultation.

   Dr. McBane noted that one of the core courses at UCSD is basic cultural diversity which includes information on what resources are available to the pharmacist who has a patient who does not speak English.

   Dr. McBane explained that the UCSD has received national awards for its prescription drug abuse outreach programs.

7. California Health Sciences University
   Dr. Asim Abu-Baker, representing California Health Sciences University, explained that their school has focused on determining the critical components of consultations and working to educate their students in these areas.

   Dr. Abu-Baker explained that they train students on how to provide consultations in the various practice settings they will work in. He noted that schools need to focus more on educating students on how to provide patients with critical information during the limited time they have with patients in community pharmacy settings.

   Dr. Abu-Baker commented that the school is planning to provide a course in medical Spanish in the future.

8. University of California San Francisco (UCSF)
   Dr. Joseph Guglielmo, dean of UCSF, explained that UCSF uses similar techniques mentioned by other schools to educate students on patient consultations.

   Dr. Guglielmo stated that the academic community needs to conduct studies to prove the value pharmacists' consultation adds to the healthcare community and to overall patient health.

   The board thanked Dr. Guglielmo for helping facilitate the dean's participation in the forum.

9. Keck Graduate Institute (KGI)
   Dr. Kathy Webster, dean of KGI, reported that KGI uses similar techniques the other schools of pharmacy have discussed during the forum. Dr. Webster noted that KGI looks at a student's communication skills during the application process. She explained that part of evaluating the student's communication skills is done by having applicants work in a group to evaluate a case and then present their findings to the faculty. The applicants' communication skills are evaluated by faculty during both the group discussion and the final presentation.

Dr. Robert Stein, law professor at KGI, briefly explained the law curriculum at KGI. He highlighted the education students receive on ethics, corresponding responsibility and patient consultation.

Mr. Law noted that the board often sees graduates with drug addiction or alcohol addiction problems. He asked if KGI provides education to students on the risk of personal addition. Dr. Stein responded that in the law courses students are taught what their responsibility is when they suspect a colleauge is impaired. Dr. Webster added that the school also participates in community outreach on the dangers of prescription drug abuse.

Mr. Weisser asked how KGI selects its preceptors and how they evaluate their performance. Dr. Webster briefly explained the selection process and noted that as a new school they are currently in the processing of selecting preceptors so they have not had to opportunity to evaluate the performance of any preceptors.

10. Michael Negrette – Former Director of the Pharmacy Foundation of California
Dr. Negrette provided a presentation on possible ways that pharmacies can restructure their work flow to encourage consultation. However, Dr. Schieldge explained that because the agenda states that the discussion would focus on the training of pharmacy students on consultation Mr. Negrette should be invited to discuss pharmacy work flow at a future meeting.

A copy of Mr. Negrette's presentation follows these minutes.

The board recessed for a break at 1:26 p.m. and resumed at 1:36 p.m.

Mr. Sanchez and Mr. Brooks left the meeting at 1:30 p.m.

XV. Communication and Public Education Committee

a. Update on the Redesign of the Board of Pharmacy's Web Site

Victor Perez, Board of Pharmacy employee, provided the board with a preview of the board's newly designed web site. He explained that the information on the Web site has been simplified to make it easier for licensees and consumers to find the information they need.

Mr. Perez stated that the full Web site redesign should be completed in approximately six months.

Dr. Castellblanch asked if the Web site is available in languages other than English. Mr. Perez responded that the public can use a tool provided by Google to translate the Web site to other languages.

Dr. Castellblanch asked Mr. Perez to provide him with a list of the consumer information documents currently provided on the board's Web site so that he can look at ways to make the information easier to find.

Mr. Law asked if the new Web site would have a way for applicants to track the progress of their applications. Mr. Perez responded that this would not be a function of the redesigned Web site. Ms. Herold added that this would have been a function of the BreEZe system.

The board thanked Mr. Perez for his work to update the web site.

b. Update on the Script

Chairperson Veale reported that The Summer 2015 *Script* newsletter is in the final phase of production and is expected to be completed soon. The current issue contains articles on the national track and trace program, medication errors, pharmacy owner estate planning, counterfeit security prescriptions and disciplinary actions.

c. Board Prescription Drug Abuse Video Receives Excellence in State Government Award

Chairperson Veale announced that the Board of Pharmacy received a silver award for excellence in state government communications from the State Information Officers Council for the prescription drug abuse prevention public service announcement video produced in 2014. A link to the public service announcement is below.

https://www.youtube.com/watch?v=Lw95thBpA5E

d. Report of Public Outreach Activities Conducted by the Board

Chairperson Veale stated that the board has participated in a number of outreach activities, including education programs for pharmacists. She directed the board and the public to review the meeting materials for a complete list of public outreach activities and key meeting attendance by the board.

XVI. Legislation and Regulation Committee

In Chairperson Greg Lippe's absence Ms. Veale provided a report of the Legislation and Regulation Committee as follows.

Part 1: Legislation Report

a. Board Sponsored Legislation

1. AB 1073 (Ting) Prescription Drug Labels
   Version: Amended July 8, 2015
   Location: Senate Appropriations
   Status: Hearing scheduled for August 17

   Ms. Veale explained that Assembly Bill 1073 would require dispensers to use a standardized direction for use on a label of a prescription container, when applicable. It would also permit a dispenser, upon request, to select the appropriate translated directions for use from the board's web site to include on the prescription label or on supplemental information. She added that the bill also allows for a dispenser to provide his or her own translated directions. Ms. Veale noted that drugs dispensed by a veterinarian are exempt from providing translated directions for use, and the bill makes conforming changes to section 4199 BPC for this purpose.

   Ms. Herold reported that the bill passed out of committee and was referred to the Senate Appropriations Committee where it is scheduled to be heard on August 17. Ms. Herold added that additional amendments are expected, including allowing the pharmacist to use their professional judgment to establish appropriate directions for use for the patient (in English). The board expressed their support for the provision which would allow a pharmacist's to use their professional judgment.

   Mr. Castellblanch asked if there was any opposition to the bill. Ms. Herold responded that

there is no longer any opposition to the bill.

A representative from the California Retailer's Association commented that the association is in support of the bill in its current form; however, they noted that they would not be in support of providing both the translated and English directions for use on the label.

President Gutierrez asked why veterinarians are exempt. Ms. Herold responded that the chair of the Senate Business and Professions Committee specifically asked for this exemption.

Dr. Wong asked if a dispensing physician would be exempt from the translation requirements. Ms. Herold and Ms. Schieldge responded that physicians must also comply with the translation requirements.

Dr. Wong asked if a hospital's emergency room medication supply must also have translated labels. He explained that in emergency rooms, when the pharmacy is closed, doctors often provide patients with medication that is pre-labeled to take home. Mr. Schaad commented that this is usually only the practice in rural hospitals, as doctors will send patients to a local 24-hour pharmacy to pick up medications.

President Gutierrez added that Business and Professions Code section 4068 states that: "Notwithstanding any provision of this chapter, a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (1) The hospital pharmacy is closed and there is no pharmacist available in the hospital. (2) The dangerous drug is acquired by the hospital pharmacy….(5) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

Dr. Wong stated that emergency room doctors dispense to patients after pharmacy hours in Oakland hospitals. Dr. Castellblanch noted that there are millions of Californians who live in rural areas.

Ms. Herold reported that Business and Professions Code section 4056 (f)(5) allows a doctor, in a rural hospital, to determine if it is in the best interest of the patient to dispense emergency medication. She stated that this could include the doctor determining if a translation was needed. Ms. Schieldge recommended cross referencing this section to provide clarity. Ms. Herold stated that she would continue to work with the author's office.

2. SB 590 (Stone) Pharmacy: Intern Licenses
   Version: Amended April 22, 2015
   Location: Assembly Floor (consent as of July 9)

   Ms. Veale reported that this measure would amend Business and Professions Code section 4209 to streamline the application process for graduates from an ACPE accredited school or school of pharmacy recognized by the board for purposes of confirming completion of the required pharmacy practice experience requirements.

Ms. Veale reported that SB 590 was enrolled on July 27, 2015 and added that staff will be sending a letter to the Governor asking for his signature on the bill.

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

1. AB 45 (Mullin) Household Hazardous Waste (2-Year Bill)
   Version: Amended April 30, 2015
   Location: Asm Appropriations
   Status: On suspense file (2-Year Bill)
   Board Position: Oppose Unless Amended

   Ms. Veale reported that AB 45 is now a 2-year bill. There were no comments from the board or from the public.

2. AB 486 (Bonilla) Centralized Hospital Packaging Pharmacies: Medication Labels
   Status: On Third Reading File – Senate Floor
   Board Position: Support

   Ms. Veale explained that AB 486 would provide an alternative method to maintain certain medication information that shall be readable at the patient's bedside, either via a barcode scan or human-readable, for unit dose medications prepared in a centralized hospital packaging facility. AB 486 contains an urgency clause, which would enact the provisions upon signature by the Governor and the filing with the Secretary of State.

   Ms. Veale reported that the bill is currently on the Senate Third Reading File.

3. AB 1069 (Gordon) Prescription Drugs: Collection and Distribution Program
   Version: Amended July 1, 2015
   Location: Senate Appropriations
   Status: Hearing – August 17
   Board Position: Oppose Unless Amended

   Ms. Veale explained that AB 1069 would expand the provisions under which a county established repository and distribution program allow the transfer of drugs to other counties (not just adjacent counties) and would allow for the advance repackaging of donated medications in advance of a prescription.

   Ms. Veale reported that board staff, working with the author's office, has secured some amendments to address many of the legal conflicts the measure initially contained. However, there are still some concerns with the bill in its current form.

   Ms. Veale reported that the author's office has stated that they will not move the bill in its current form and wishes to continue working with the board. She added that the author has made this a two year bill in order to allow board staff and the author's office more time to work on amendments.

   The board did not change their position of "oppose unless amended" and asked staff to continue to work with the author's office.

4. SB 671 (Hill) Biosimilar Drug Substitution
   Version: As Amended June 23, 2015
   Location: Assembly Floor – Second Reading
   Board Position: Oppose Unless Amended

   Ms. Veale explained that SB 671 would authorize a pharmacist, in his or her discretion (except when the prescriber has specified "Do not substitute" or words to that effect), where there is an identically priced or cheaper alternative interchangeable biosimilar, to select the alternative biological product when filling a prescription order for a prescribed biological product. The measure requires the pharmacist, within a specified period of time after dispensing, to notify the prescriber of exactly what was dispensed. The most recent version of the bill allows for such communication to be entered into an electronic system, as specified.

   Ms. Veale reported that given the most recent amendments, staff requests the board's direction as to whether or not the board's position should be modified.

   Brian Warren, representing the California Pharmacist Association, reported that their association has removed their opposition to the bill and now has a neutral position. He explained that the association changed its position because it was determined that a pharmacist entering the claim into a pharmacy benefit management system fulfills the prescriber notification requirement in the bill.

   Ms. Veale asked how the notification requirement would be fulfilled if a patient is paying cash for the prescription (no claims are entered into a pharmacy benefit management system for cash payments). Mr. Warren responded that the pharmacist could fax or call the prescribers office to notify them.

   Dr. Gray, from Kaiser, stated that Kaiser still has some concerns with the prescriber notification piece of the fill.

   Motion: Change the board's position from oppose unless amended to neutral.

   M/S: Gutierrez/Weisser

   Support: 6 Oppose: 0 Abstain: 3

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler			x	
Castellblanch			x	
Gutierrez	X			
Hackworth	x			
Law			x	
Lippe				x
Murphy				x

Sanchez				x
Schaad	X			
Veale	X			
Weisser	x			
Wong	x			

Mr. Weisser left the meeting at 2:20 p.m.

c. Legislation Impacting Board Operations

1. AB 1351 (Eggman) Deferred Entry of Judgment: Pretrial Diversion
   Version: As Introduced February 23, 2015
   Location: Senate Appropriations
   Board Position: Oppose

   Ms. Veale explained that this measure would change the existing deferred entry of judgment program into a pretrial diversion program. Under the pretrial diversion program created by this bill, a defendant qualifies if they have no prior conviction for any offense involving controlled substances (other than the offense that qualifies for the program), the charged offense did not involve violence, there is no evidence of a violation relating to narcotics or restricted dangerous drugs (other than a violation that qualifies for the program) and the defendant has no prior conviction for a serious or violent felony in the five years prior to the alleged commission of the charged offense.

   Ms. Veale reported that the bill has the potential to significantly increase the board's costs of prosecution or lead to the dismissal of certain disciplinary charges, to the detriment of public safety. This is because the changes proposed will allow defendants to not plead guilty. She added that this means the Board won't be able to use a guilty plea as an admission of guilt, and when a defendant participates in a pretrial diversion program, the board can't consider that an admission of guilt.

   Ms. Veale stated that staff continues to try and work with the author's office to identify language that could resolve the board's concerns. Earlier amendments offered were rejected.

   Ms. Veale reported that staff recommends that the board change its position to "Oppose Unless Amended" and that staff be directed to continue to engage with the author's office.

   There were no comments from the public.

   Motion: Change the board's position from oppose to oppose unless amended. Direct staff to continue to work with the author's office.

   M/S: Hackworth/Gutierrez

   Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	X			
Hackworth	x			
Law	x			
Lippe				x
Murphy				x
Sanchez				x
Schaad	X			
Veale	X			
Weisser				x
Wong	x			

d. Other Pieces of Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

There were no additional pieces of legislation impacting the practice of pharmacy, the board's jurisdiction or board operations. There were no comments from the board or from the public.

Part 2: Regulation Report

a. Board Approved – Awaiting Administrative Review

1. Proposal to Amend Title 16 California Code of Regulations (CCR) Section 1793.5 Pharmacy Technician Application

   Ms. Veale reported that at the July 2014 Board Meeting, the board approved a proposal to amend Title 16 CCR section 1793.5 to change the wording of the criminal conviction question on the Pharmacy Technician Application to be consistent with the wording on the Pharmacist application.

   Ms. Veale reported that the rulemaking was initiated in February, and a 15-day comment period ran from May 26, through June 15, 2015. No comments were received in response to the 15-day comment period; thus, in accordance with the board's motion, the regulation was adopted and the final rulemaking file is being prepared for submission to the Department of Consumer Affairs to start the review process.

   There were no comments from the board or from the public.

b. Board Approved – Recently Noticed

1. Proposal to Amend Title 16 CCR Sections 1784 and 1751 to Update Self-Assessment Forms 17M-13, 17M-14 and 17M-26

   Ms. Veale reported that at the October 2014 Board Meeting, the board directed staff to initiate the formal rulemaking to amend the text of 16 CCR sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference in those sections.

   Ms. Veale explained that the 45-day comment period began on March 20, 2015 and ended on

May 6, 2015. Due to issues with the Notice, a second 45-day comment period began May 29, 2015 and ended July 13, 2015. She added that no negative comments were received and, in accordance with the board's motion, board staff is compiling the final rulemaking file for submission to the Department of Consumer Affairs to begin the administrative review process.

Mr. Law asked when board staff anticipated completing the self-assessment form. Ms. Herold responded that she would expect the self-assessment form to be approved in six months. She added that currently licensees are encouraged to use the new forms, but are not required to use them until they are approved.

2. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text to Add Title 16 CCR Section 1746.2 Nicotine Replacement Products
Ms. Veale reported that at the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 CCR section 1746.5 for Nicotine Replacement Products. The 45-day comment period began on May 8 and ended on June 22, 2015, during which time the board received four comments.

Ms. Herold briefly reviewed the comments received during the 45-day comment period. A copy of the noticed text and the comments received was provided in the board meeting materials.

Ms. Schieldge asked if the Medical Board also had to review the changes and choose to accept or reject them. Ms. Herold responded that the Medical Board did not have to review the comments.

Ms. Veale explained that if the board does not believe any changes are necessary to the regulation text in response to the comments, staff would recommend that the board 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, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.2, as noticed.

The board decided that the protocol did not need to be amended in response to the comments received.

There were no comments from the public.

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, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.2, as noticed.

M/S: Gutierrez/Law

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe				x
Murphy				x
Sanchez				x
Schaad	x			
Veale	x			
Weisser				x
Wong	x			

3. Discussion and Possible Action to Make Changes in Response to Comment or to Adopt or Amend Proposed Text to Add Title 16 CCR Section 1746.3 Naloxone Hydrochloride

Ms. Veale reported that at the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 CCR section 1746.3. The 45 day comment period began on May 22, 2015 and ended on July 13, 2015, and the board received one comment in response to the noticed text.

Ms. Veale explained that if the board does not believe any changes are necessary to the regulation text in response to comment, staff would recommend that the board 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, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.3, as noticed.

Ms. Herold briefly reviewed the comments received during the 45-day comment period. A copy of the noticed text and the comments received was provided in the board meeting materials.

The board decided that the protocol did not need to be amended in response to the comments received.

There were no comments from the public.

Motion: Approve the protocol as provided in the board meeting materials. 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, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.2, as noticed.

M/S: Law/Hackworth

Support: 8 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch	x			
Gutierrez	X			
Hackworth	x			
Law	x			
Lippe				x
Murphy				x
Sanchez				x
Schaad	X			
Veale	X			
Weisser				x
Wong	x			

4. Discussion and Possible Action to Make Changes in Response to Comments or to Adopt or Amend Proposed Text at Title 16 CCR Section 1746.1 Self-Administered Hormonal Contraception

Ms. Veale stated that at the March 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 CCR section 1746.1 for Self-Administered Hormonal Contraception. The 45-day comment period began on May 8 and ended on June 22, 2015.

A copy of the noticed text, comments received, and a staff summary and possible board responses to the comments were provided in the board meeting materials.

Ms. Veale explained that if the board does not believe any changes are necessary to the regulation text in response to comments, staff would recommend that the board 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, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.1, as noticed.

Ms. Herold reviewed the comments received during the 45-day comment period, which included requests to remove the requirement for pharmacists to take a patient's seated blood pressure.

Ms. Veale stated that blood pressure had been discussed at multiple committee meetings.

President Gutierrez stated that during the committee meetings testimony was provided from pharmacists supporting taking a patient's blood pressure. She added that the Medical Board had approved the protocol with the blood pressure requirement included.

Ms. Butler motioned to approve the protocol without any amendments and to initiate the rulemaking process. President Gutierrez seconded the motion.

Dr. Mitchell Crenin, family planning specialist from the Department of Obstetrics and Gynecology at the Univeristy of Davis, stated that as an expert in hormonal contraception he would recommend that the board remove the blood pressure requirement from the protocol. Dr. Crenin explained that taking blood pressure prior to dispensing hormonal contraception is unnecessary for healthy patients and creates a barrier to those who need contraception.

Ms. Herold explained that the statute that authorizes the protocol requires the board to use the United States Medical Eligibility Criteria (USMEC) as the guideline upon which to base the protocol. Ms. Herold stated that the USMEC lists certain hormonal contraception as contraindicated for patients with elevated blood pressure; therefore, the protocol was developed to require the pharmacist to take the patients' blood pressure.

Dr. Crenin disagreed with the board's interpretation of the USMEC and stated that the USMEC does not require that blood pressure be taken, only that it be evaluated. He added that the pharmacists asking the patient if she has high blood pressure and discussing her family history would meet the evaluation requirement.

Ms. Herold reported that at the Medical Board meeting where this protocol was approved, this topic was discussed. After hearing the concerns raised, the Medical Board approved the protocol with the blood pressure requirement included. Ms. Herold added that if the board removes the requirement, the protocol will have to go back to the Medical Board for approval.

Mr. Allen Schaad and Dr. Castellblanch stated that they would recommend removing the blood pressure requirement and having the Medical Board re-approve it.

Gregory Kramer, legislative analyst for Planned Parenthood, stated that Planned Parenthood recommends removing the requirement for the pharmacist to take the patient's blood pressure.

Ms. Veale asked if doctors at Planned Parenthood take patients' blood pressure. Mr. Kramer explained that their physicians do take blood pressure, however it is not required for refills.

Dr. Crenin stated that pharmacists should not be required to take a patient's blood pressure; they should be able to use their education to determine in what cases taking blood pressure is necessary.

Brain Warren representing the California Pharmacists Association, stated that the association supports the protocol with the inclusion of pharmacists taking patients' blood pressure.

Ms. Schieldge stated that the board's mandate is consumer protection. She explained that the most legally defensible action would be for the pharmacist to take the patient's blood pressure so that the pharmacist could objectively determine if the patient currently has high blood pressure.

Ms. Butler stated that she supported approving the language without any amendments (as reflected in her earlier motion).

Dr. Castellblanch stated that the board's main goal should be to expand women's access to safe and effective hormonal contraception.

Dr. Bonnie Zell, representing Icebreaker Health, spoke in support of the comments made by Dr. Crenin and Planned Parenthood. She asked the board to allow pharmacists to use their professional judgment to determine when taking blood pressure would be appropriate.

Ms. Schieldge stated that the board needs to ensure that a patient is not receiving less medical care because they are seeing a pharmacist rather than a physician.

Mr. Law stated that he supported approving the protocol without any amendments.

Ms. Herold stated that the board could move forward with the rulemaking process without any amendments and have the Medical Board review the comments at their October 2015 board meeting. If the Medical Board determines they would like to remove the blood pressure requirement, the rulemaking could then be suspended.

Dr. Castellblanch noted that the board needs to take into account the negative consequences to public health of unintended pregnancy.

Dr. Butler stated that as a pharmacist she believed that blood pressure should be taken prior to dispensing hormonal contraception.

Ms. Veale called for a vote of the motion made by Ms. Butler.

Motion: Approve the protocol as provided board meeting materials. 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, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at section 1746.1, as noticed.

M/S: Butler/Gutierrez

Support: 4 Oppose: 4 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Castellblanch		x		
Gutierrez	x			
Hackworth	x			
Law	x			
Lippe				x

Murphy				x
Sanchez				x
Schaad		x		
Veale		x		
Weisser				x
Wong		x		

The motion failed.

Ms. Veale asked if the board could draft a motion that would allow the rulemaking to move forward and only suspend the rulemaking process if the Medical Board elects to amend the protocol after reviewing the comments. Ms. Schieldge stated that this action is not possible. She explained that when the board initiates the rulemaking process they are closing the record. The record cannot be closed if the board is seeking additional review and input from the Medical Board.

President Gutierrez motioned to send the protocol back to the Medical Board with the recommendation to allow pharmacists to use their professional judgment to determine when taking blood pressure is necessary. Dr. Castellblanch seconded the motion.

Mr. Law expressed concern that the Medical Board will not approve the protocol with President Gutierrez' proposed amendment. President Gutierrez stated that while she agrees with Mr. Law's concern and shares his opinion that taking blood pressure should be required, as the previous motion failed this compromise is the only option to move forward.

Ms. Veale stated that her no vote on the previous motion did not reflect her opposition to pharmacists being required to take blood pressure. She explained that she voted down the previous motion only because she thought that the board could suspend the rulemaking only if the Medical Board decided to amend the protocol.

Jonathan Nelson, representing Icebreaker Health, stated that the purpose of SB 493 was to expand access to healthcare. Mr. Nelson added that no other medical professional is required to take a patient's blood pressure prior to providing hormonal contraception.

Motion: Amend the protocol to allow a pharmacist to use their professional judgment to determine when taking a patient's blood pressure is necessary. Provide the amended protocol to the Medical Board to review and approve at their next board meeting.

M/S: Gutierrez/Castellblanch

Support: 5 Oppose: 3 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks				x
Butler		x		
Castellblanch	x			
Gutierrez	x			

Hackworth	x			
Law		x		
Lippe				x
Murphy				x
Sanchez				x
Schaad	x			
Veale		x		
Weisser				x
Wong	x			

President Gutierrez left the meeting at 3:30 p.m.

c. Board Approved – Awaiting Notice

Ms. Veale asked if there were any board or public comments on any of the regulations awaiting notice.

Dr. Castellblanch asked staff to prioritize the finalization of Title 16 CCR Section 1707.5(d) – written translations. The board noted that many of the regulations have been pending for over a year.

There were no comments from the public.

Ms. Veale adjourned the meeting at 3:32 p.m.

Attachments

Article 9.1

Prescription Drug Take Back Programs

Revision Date: 7/27/2015 by Virginia Herold

Section 1776

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take back collection methods. Federal, state and other law prohibit the deposit in drug take-back receptacles the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Section 1776.1 Pharmacies

(a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription medication as provided in this article. Provision of such services is voluntary.

(b) Pharmacies may provide take-back services to patients as provided in sections 1776.1 - 1776.4. Additionally, retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities, and may operate collection receptacles in skilled nursing facilities licensed under Health and Safety Code section 1250(c) as specified in section 177i6.4.

(c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.

(d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle, they are not to be separated by pharmacy staff or others.

(e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic

drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

(f) Prescription drugs that are eligible for collection in drug take back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug-take back programs.

1. Pharmacy staff shall not accept, count, sort, or handle prescription medication returned from the public.
2. A pharmacy shall not accept or possess prescription medication returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
3. A pharmacy shall not dispose of quarantined or outdated prescription drugs which it will return to a reverse distributor in a drug take back collection receptacle.

(g) A pharmacy must be licensed with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or who has had a DEA permit denied, surrendered or revoked.

(h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:

1. Any pharmacy that ceases to operate a drug take back program shall notify the board within 30 days on a form designated by the board.
2. Any pharmacy operating a mail back program or maintaining collection receptacles shall identify if it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.

1776.2 Mail Back Services from Pharmacies

(a) Pharmacies that provide prescription drug take back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

(b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

(c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription medication. Postage shall be prepaid on each envelope or package.

(d) The preaddressed envelope and package shall contain a unique identification number for each package, and certain instructions for users to mail back drugs.

(e) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.

(f) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return.

1776.3 Collection Receptacles in Pharmacies

(a) Pharmacies that provide prescription drug take back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas. In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care.

(b) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort, or handle prescription medication returned from the public, but instead direct the public to deposit the medication into the container themselves.

(c) Before establishing a collection receptacle, the pharmacy must obtain collector status from the federal Drug Enforcement Administration. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify Drug Enforcement Administration within 30 days.

(d) The receptacle shall be locked with an inner liner to contain the deposited prescription drugs. The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted, but shall be provided to a reverse distributor as provided in this article.

(e) The liner shall be made of material that is waterproof, tamper evident and tear resistant. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy.

(f) A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and witness in a log their participation in the removal of each liner from a collection receptacle. Removed liners shall not be opened, x-rayed, analyzed or penetrated.

(g) Liners that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three days.

(h) The pharmacy shall maintain a log to record information about all liners that have been

placed into or removed from a collection receptacle. The log shall contain:

1. The unique identification number of the liner
2. The date the liner is placed in the collection receptacle,
3. The date the liner is removed from the collection receptacle,
4. The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
5. The date the liner was provided to a licensed DEA-registered reverse distributor for destruction.

(i) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed distributor pick-up at the licensed pharmacy's premises.

(j) The collection receptacle shall contain text advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug-take back programs as authorized by this article.

(a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription medication by using mail back packages or envelopes based upon a request by the resident patient. The mail back package shall conform to the requirements specified in section 1776.1. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the serial number of the mail back package and the address to which the mail back envelope is sent.

(b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.

1. Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
2. Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
3. Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.
4. Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.

(c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection

receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.

(d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.

(e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.

(f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.

(g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.

(h) The receptacle shall be contained within a securely locked, substantially constructed container with a permanent outer container and a removal inner liner.

(i) The outer container shall include a small opening that allows deposit of drugs into the inside of the outer container and directly into the inner liner.

(j) The outer container shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.

(k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.

(l) The installation, removal transfer and storage of inner liners shall be performed only by:

1. One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
2. By or under the supervision of two employees of the authorized collector pharmacy.

(m) Upon removal from the collection receptacle, the liner shall be immediately sealed. Sealed inner liners may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.

(n) Liners may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.

(o) Records of the destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner

transferred, and if applicable, the names and signatures of the two employees who transferred each liner.

1776.4 Reverse Distributors

(a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.

(b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.

(c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.

(d) A reverse distributor shall not employ as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.

(e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.

(f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal section 1317.55.

(g) The number of sealed inner liners or mail back envelopes/package, including the:

1. Date of acquisition
2. Number and the size (e.g., five 10-gallon liners, etc.)
3. Inventory number of each liner or envelope/package
4. The date and place and method of destruction
5. Number of packages and inner liners received
6. Number of packages and inner liners destroyed
7. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.5 Record Keeping Requirements for Board Licensees Providing Drug Take Services

Each entity authorized by this article to collect unwanted prescription medication from patients shall maintain the following records.

(a) When obtaining unused mail-back packages and envelopes for future distribution:

1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.

(b) For sealed mail-back packages received by the reverse distributor: the date of

receipt and the unique identification of the individual package,

(c) For sealed mail back packages destroyed onsite by the collection: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.

(d) For collection receptacle liners:

1. Date each unused liner was acquired, its unique identification number and size (e.g., five gallon, 10-gallon)
2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor.

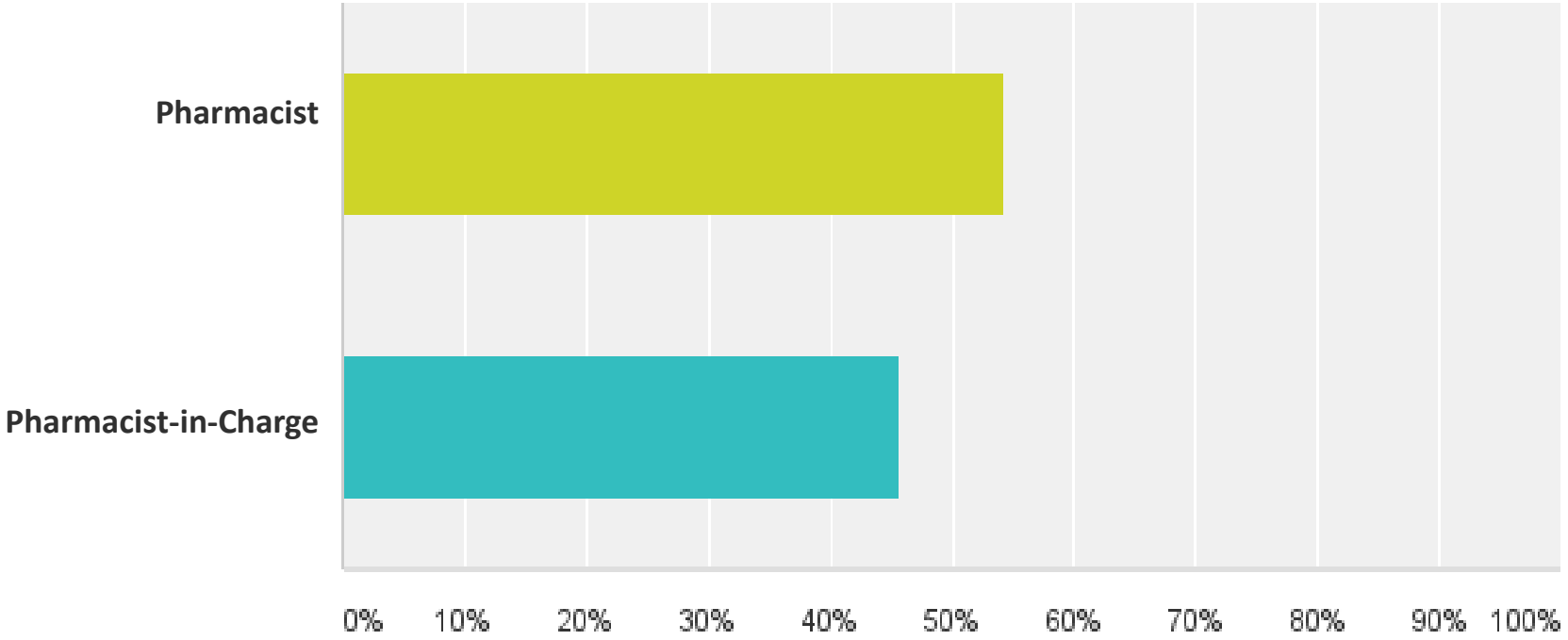
Survey for Pharmacists

1,006 total responses

Survey Date: July 20-24, 2015

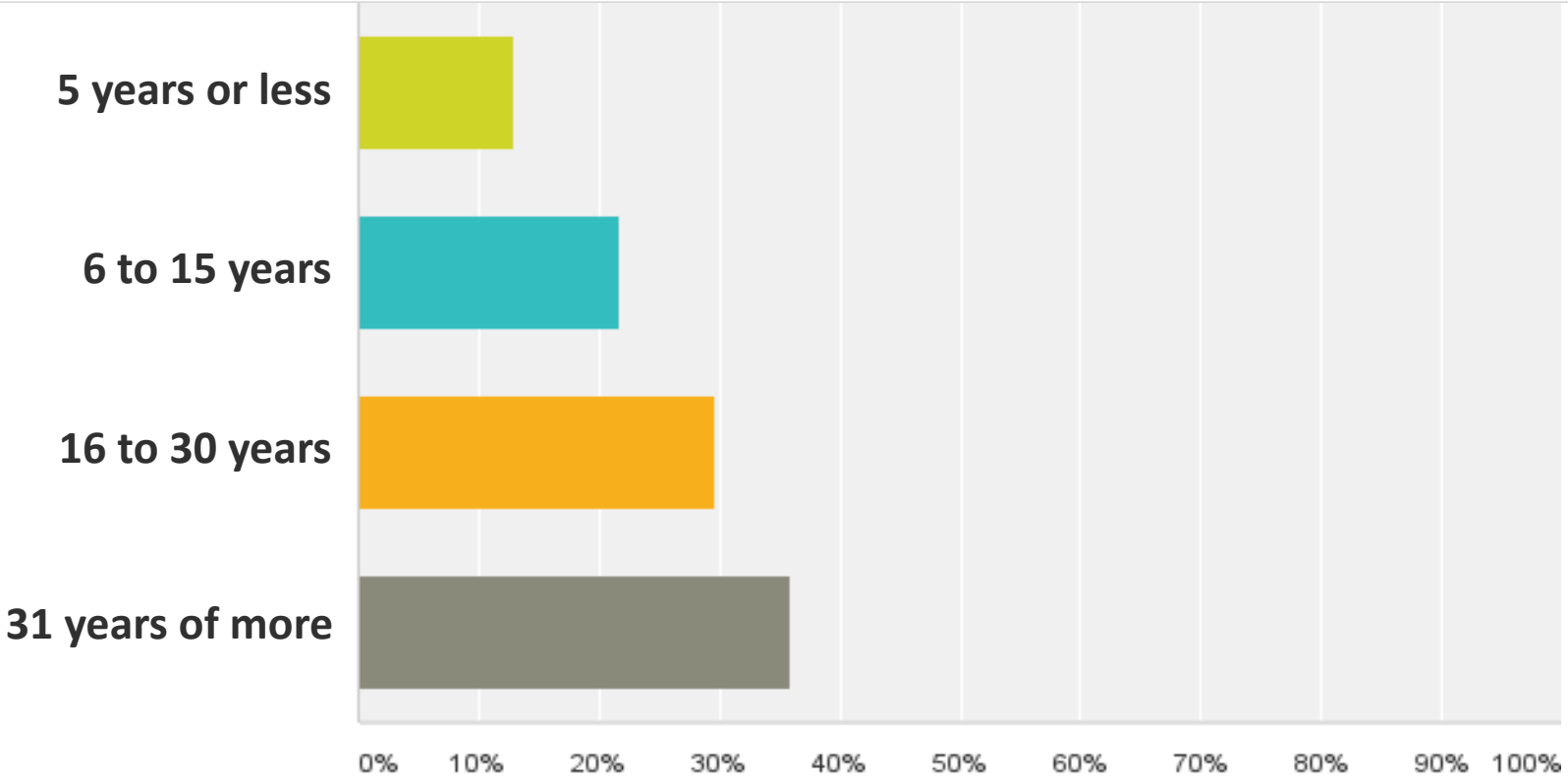
Question 1: I am a licensed California_____.

Answered: 998 Skipped: 8



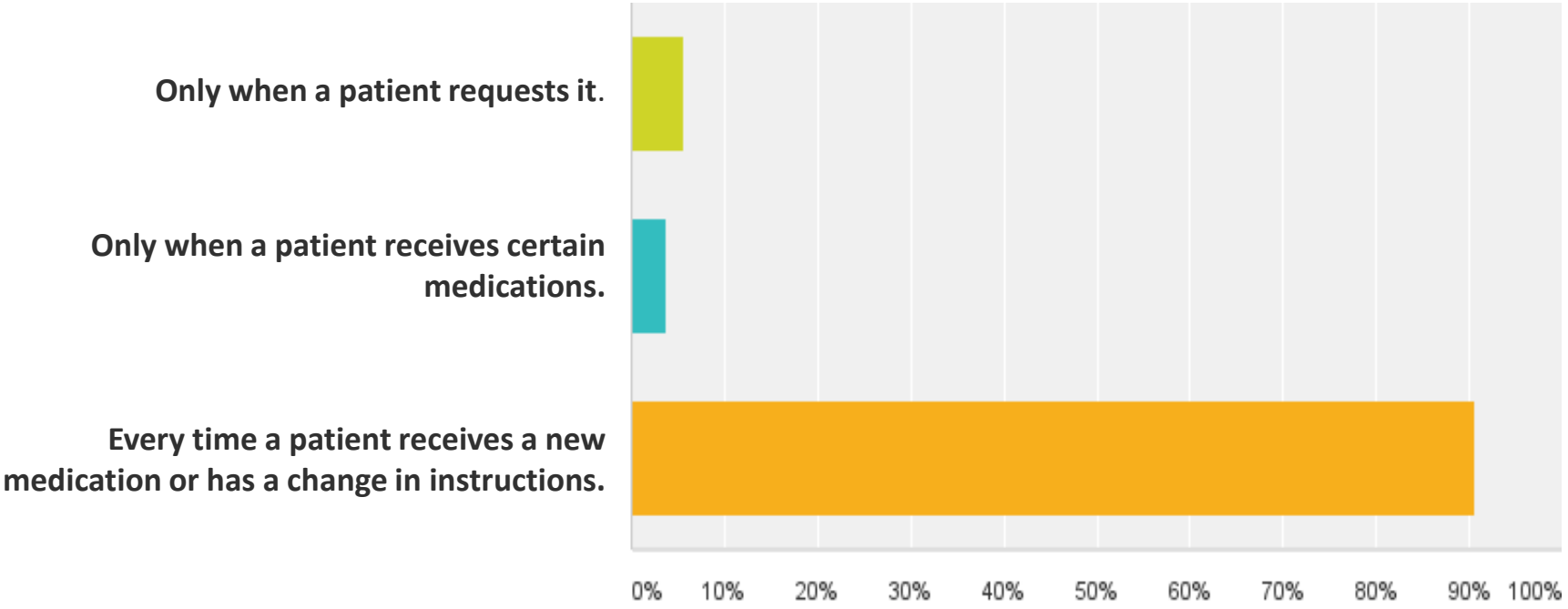
Question 2: How long have you been a pharmacist?

Answered: 1,004
Skipped: 2



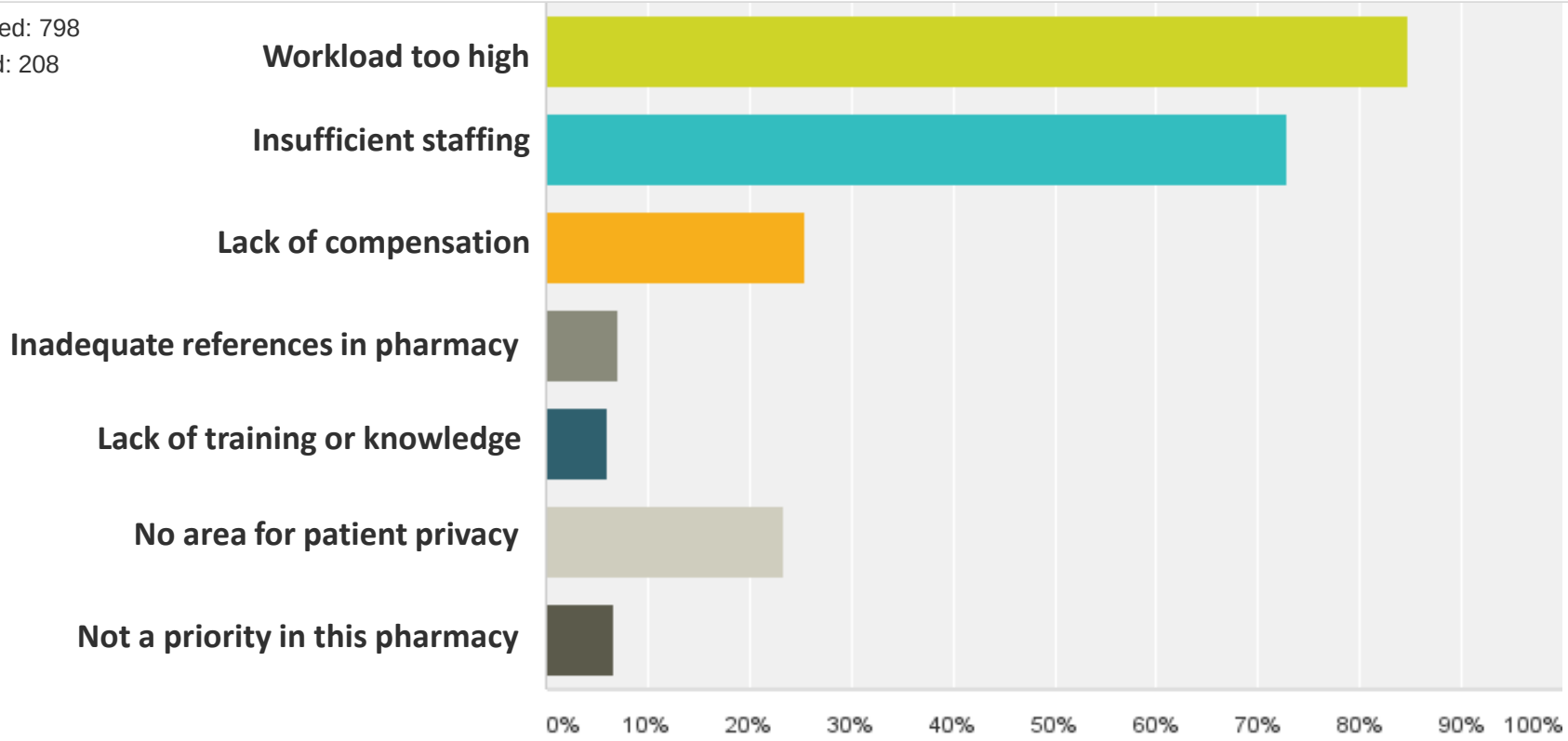
Question 3: I consult….

Answered: 897 Skipped: 109



Question 4: What barriers exist to a pharmacist initiating consultation (mark all that apply):

Answered: 798
Skipped: 208



Answers to the question: What barriers exist to a pharmacist initiating a consultation?	
None, I make it a priority to consult.	53
Patients in are in hurry and will not wait for consultation.	37
Doesn’t apply to my practice setting.	30
The pharmacist is too busy / pressure from employer to fill prescriptions quickly even if that means not consulting.	24
No reimbursement for consultation.	12
Language or other communication barriers.	12
Lack of privacy to provide consultation.	9
The clerk or technician is the one working with the patient initially and they do not tell the patient they need to wait to talk to the pharmacist.	8
Ratio of technicians to pharmacists is too low.	6
Lack of training or experienced staff.	2

California Schools of Pharmacy

Survey Results

Background

In June 2015 a letter was sent to the deans of all of the California Schools of Pharmacy. The letter invited a representative from each school to attend the Patient Consultation Forum and asked 5 survey questions regarding each school's patient consultation curriculum.

The following slides are the results of the survey.

	Does the program have a core course centered upon communication skills and consultation?
Chapman University	Yes
California Health Sciences University	No
Keck Graduate Institutes	Yes
Loma Linda University	No
Northstate University	
Touro University California	No one specific course, we provide our students with Pharmacy Practice Activities during their P1 and P2 years that center on communication skills and consultation of legend and OTC products
University of the Pacific	No
University of California San Diego	No
University of California San Francisco	No
University of Southern California	No, but patient counseling is built into the IPPE course in year 1, and into every weekly small group case conference in year 2 and year 3.
Western University of Health Sciences	Not a standalone course, but a longitudinal curriculum dedicated to communication…

School	If the program does not have a core course in communication and/or consultation, does this emphasis exist within other pharmacy practice courses?
Chapman University	N/A
California Health Sciences University	Yes, it is within a P1 first semester course (Patient Self Care) and a P1 second semester course (Pharmacy Practice Lab).
Keck Graduate Institutes	N/A
Loma Linda University	Yes. We used to have a core course, but the Curriculum Committee voted to disperse the topics of this course into other courses.
Northstate University	
Touro University California	Yes, we provide our students with Pharmacy Practice Activities during their P1 and P2 years that center on communication skills and consultation of legend and OTC products
University of the Pacific	Yes
University of California San Diego	Yes
University of California San Francisco	Yes
University of Southern California	Yes, patient counseling is built into the IPPE course in year 1, and into every weekly small group case conference in year 2 and year 3.
Western University of Health Sciences	Yes

School	Which of the following methodologies are used in the training of communication skills and consultation? Didactic, Small group discussion, OSCE, Simulation, Other
Chapman University	Didactic, Small group discussion, OSCE, Simulation, Experiential
California Health Sciences University	Didactic, Small group discussion, OSCE, Simulation
Keck Graduate Institutes	Didactic, Small group discussion, OSCE, Simulation, Role Playing, Labs
Loma Linda University	Didactic, Small group discussion, Clinical skills laboratory where each student is video-taped providing consultation to a patient actor.
Northstate University	
Touro University California	Didactic, Small group discussion, OSCE, Real life setting, High state evaluations
University of the Pacific	Didactic, Small group discussion, Mock consultations, Peer assessment
University of California San Diego	Didactic, Small group discussion, OSCE, Free clinic patient consultations
University of California San Francisco	Didactic, Small group discussion, OSCE,
University of Southern California	Didactic, Small group discussion, OSCE
Western University of Health Sciences	Didactic, Small group discussion, OSCE

School	Progression of consultation experiences: Over the entire course of pharmacy school, what is the total number of hours focused upon patient consultation?
Chapman University	111 hours (IPPE) + 120 hours (APPE) = 231 hours
California Health Sciences University	36 contact hours
Keck Graduate Institutes	3 hours in didactic + 5 hours in IPPE + 30 credits in Core APPE
Loma Linda University	Approximately 30 hours of didactic years. Much consultation takes place during APPE's, but we do not have a good method to measure the actual hours.
Northstate University	
Touro University California	Approximately 40 hours over 2 years
University of the Pacific	36 hours
University of California San Diego	57 hours over the first 3 years. This does not include APPE/IPPE patient consultation training hours in which a significant number of patient contacts including counseling are completed. Sites include Community Practice, Hospital and Clinic Practices and in Transitions of Care.
University of California San Francisco	Approximately 25 hours dedicated over 3 years. This does not include APPEs.
University of Southern California	Very difficult to calculate since counseling is part of each conference conducted weekly in year 2 and 3. Additionally, there are 18 hours of formal coursework and small group role-play sessions.
Western University of Health Sciences	We have over 60 hours dedicated to "communication skills" over 5 semesters (pre APPE).

School	Who is responsible for consultation curricula? Paid faculty, Volunteer faculty, Residents, Senior Doctor of Pharmacy students
Chapman University	Paid faculty, Volunteer faculty
California Health Sciences University	Paid faculty
Keck Graduate Institutes	Paid faculty, Volunteer faculty, Residents
Loma Linda University	Paid faculty, Residents
Northstate University	
Touro University California	Paid faculty, Volunteer faculty, Residents
University of the Pacific	Paid faculty
University of California San Diego	Paid faculty, Volunteer faculty, Residents
University of California San Francisco	Paid faculty
University of Southern California	Paid faculty, Residents
Western University of Health Sciences	Paid faculty

Pharmacist Consultations: Weak Spots & Bright Spots

Michael J. Negrete, PharmD

Disclosures & Disclaimers

- I'm a Pharmacist
- CPhA Member and former Pharmacy Foundation / CPhA Foundation CEO
- Full-Time Employee of Samuel Merritt University since 2013
  - Speaking on my own behalf
- I don't have all the answers

What's the "Right" Question?

"If I had an hour to solve a problem and my life depended on the solution, I would spend the first 55 minutes determining the proper question to ask, for once I know the proper question, I could solve the problem in less than 5 minutes."

-Albert Einstein

Every system is perfectly designed to get the results it gets

Paul Batalden, MD

Key Activities/Processes in the Patient Consultation "System"

Aspects which may contribute to the difficulty of effective patient consultations

Possible modifi-cations to the system which may* facilitate effective patient consultations

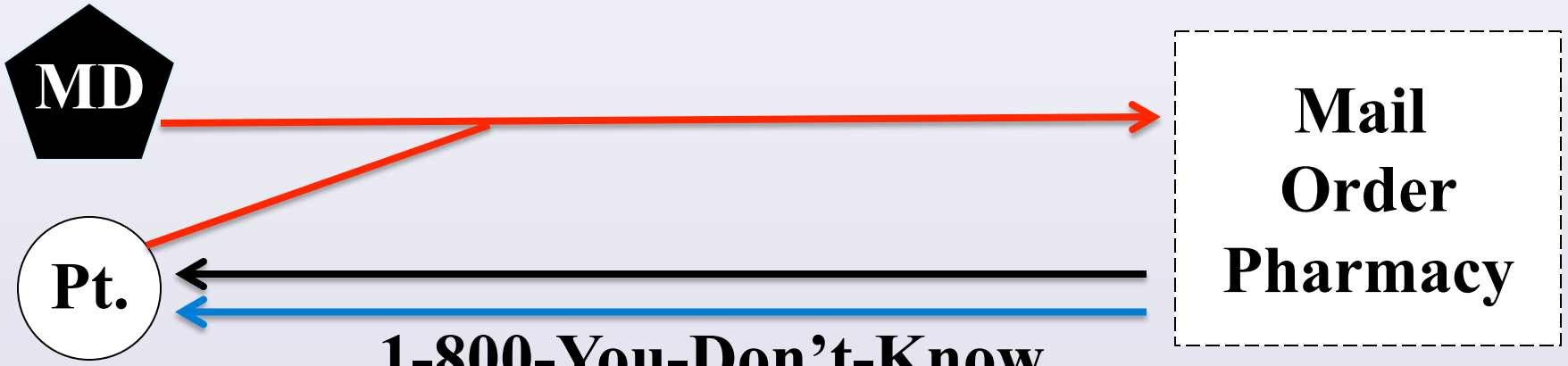
*Research may be required to assess feasibility and value

Communications which may facilitate pt. perception that:

- "My Dr. already told me about it."
- "I'm sure if there was anything important, my Dr. would've told me."

Vs.

"Make sure you speak with the pharmacist when you pick-up your prescription."



1-800-You-Don't-Know

- What % of Rxs generate a call?
- New vs. refill?
- What types of questions?

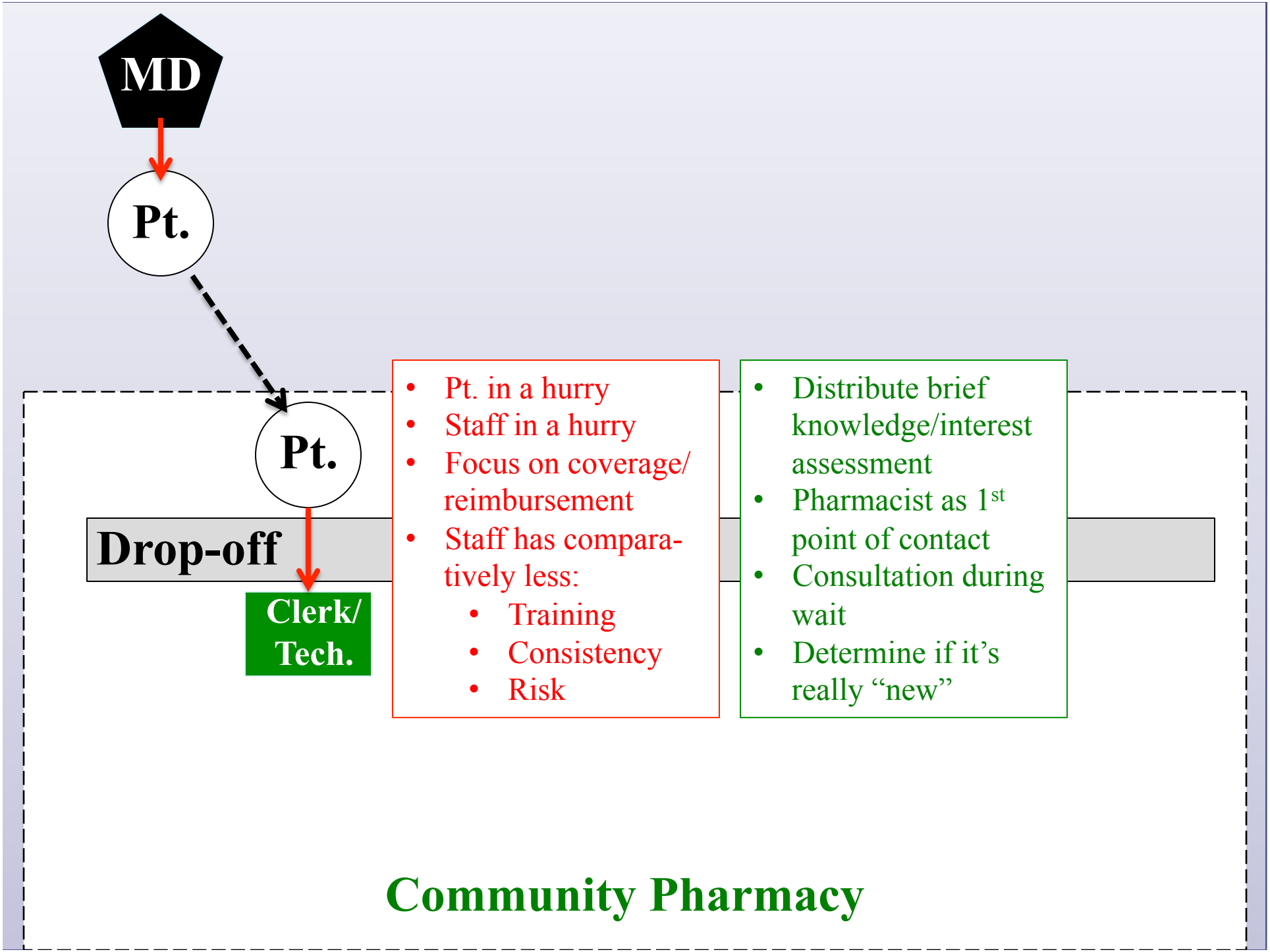
- Pt. will only speak with RPh if/when they think they need to.

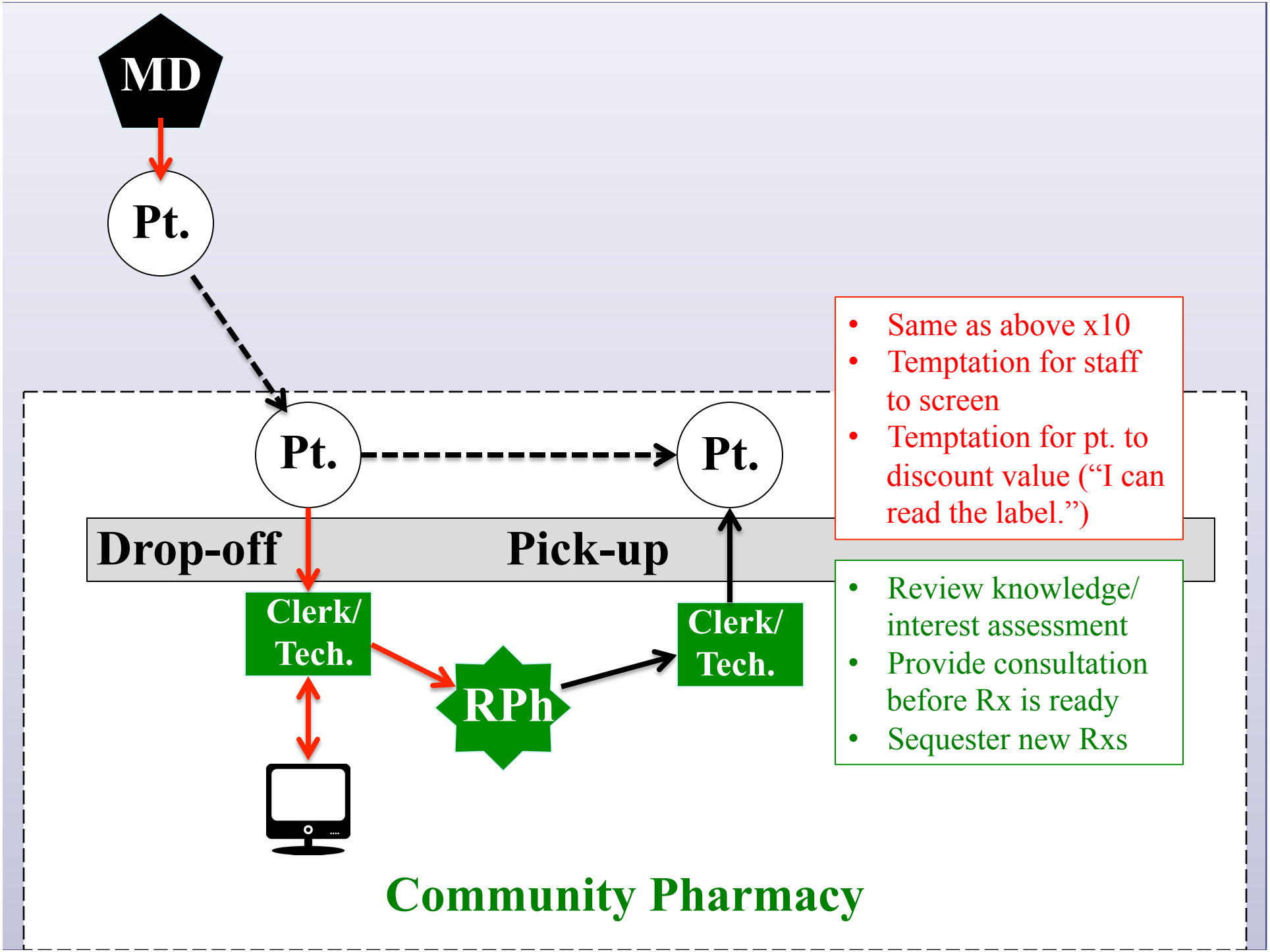
- Mandated outreach on new Rxs

MD

Pt.

Community Pharmacy

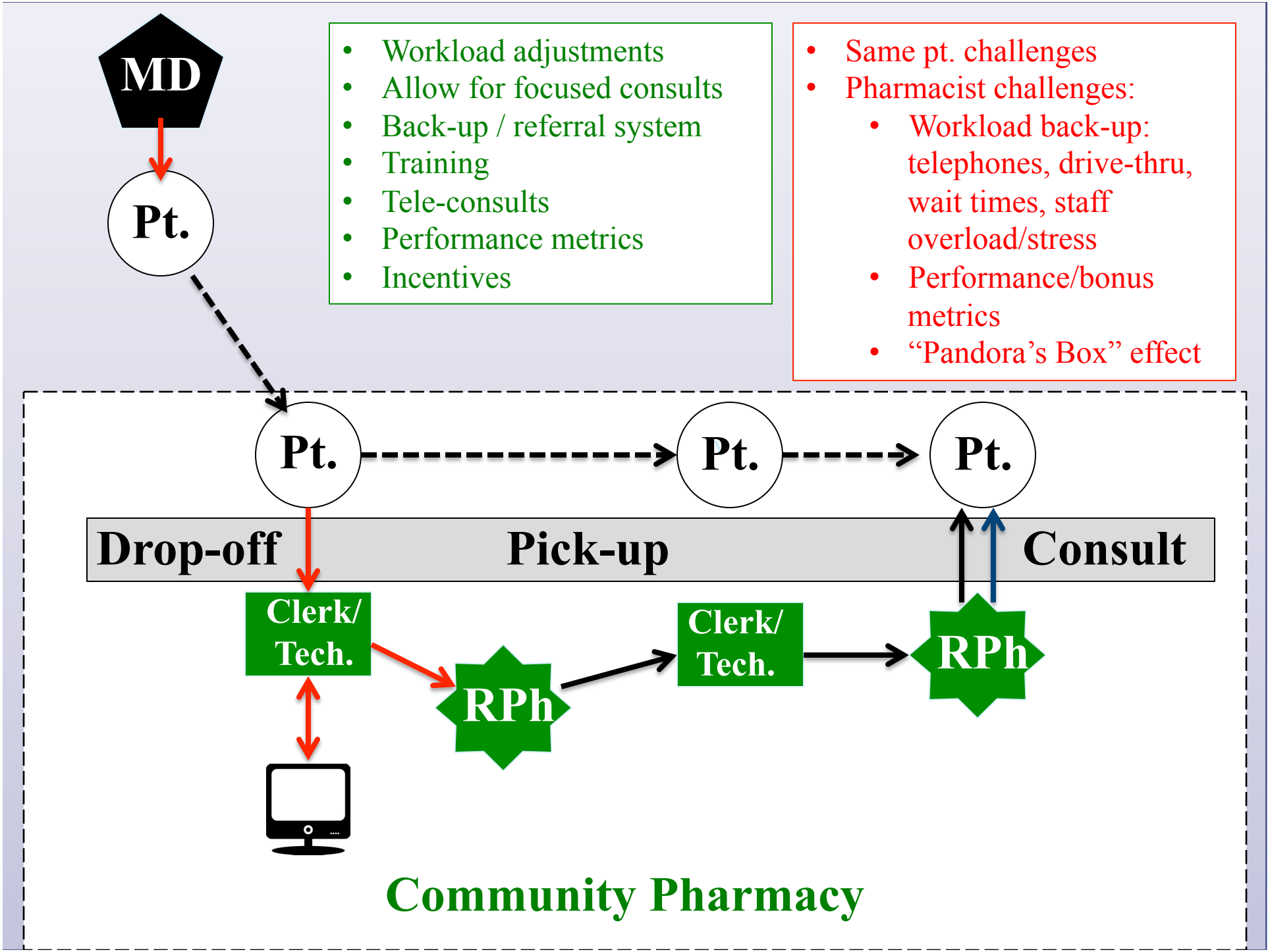

MD
Pt.
Pt.
Drop-off
Clerk/
Tech.
• Pt. in a hurry
• Staff in a hurry
• Focus on coverage/ reimbursement
• Staff has compara-tively less:
• Training
• Consistency
• Risk
• Distribute brief knowledge/interest assessment
• Pharmacist as 1st point of contact
• Consultation during wait
• Determine if it's really "new"
Community Pharmacy


MD
Pt.
Pt.
Pt.
Drop-off
Pick-up
Clerk/
Tech.
RPh
Clerk/
Tech.
• Same as above x10
• Temptation for staff to screen
• Temptation for pt. to discount value ("I can read the label.")
• Review knowledge/ interest assessment
• Provide consultation before Rx is ready
• Sequester new Rxs
Community Pharmacy

Kimberlin, et al.

J Am Pharm Assoc 2011; 51:527-534

- Sent prof. shoppers with new Rxs to 365 pharmacies in 41 states (incl. CA)
- Strongest predictor for counseling was RPhs handing meds to shoppers
- Other predictors included strict state counseling regulations
  - 43% reported that they did not receive medication information from anyone in the pharmacy


MD
Pt.
Workload adjustments
Allow for focused consults
Back-up / referral system
Training
Tele-consults
Performance metrics
Incentives
Same pt. challenges
Pharmacist challenges:
Workload back-up: telephones, drive-thru, wait times, staff overload/stress
Performance/bonus metrics
"Pandora's Box" effect
Pt.
Pt.
Pt.
Drop-off
Pick-up
Consult
Clerk/ Tech.
RPh
Clerk/ Tech.
RPh
Community Pharmacy

Testing Cholesterol for Diabetes Patients 2014-1s Edttton

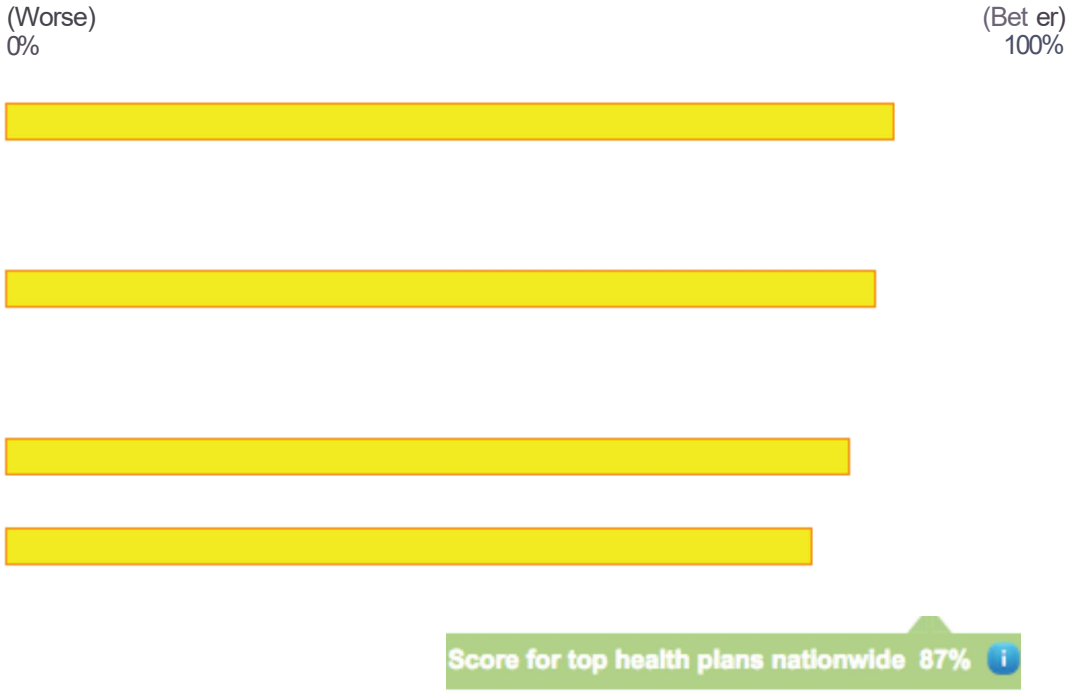
Why is ·t important to test cholestero if you have diabetes?

There are two types of cholesterol - good cholesterol (high density lipid or HDL. .. read more

8 Print this chart

Whe oom aring pla s, small d. ere ces betwee scores are expected. e larger differences are impo t.

TESTING CHOLESTEROL FOR DIABETES PATIENTS



Percentage of new Rxs (denominator) for which a consultation was not declined (numerator) ?

Questions?

Patient Counseling in the ACPE Accreditation Standards

Peter H. Vlasses, PharmD, DSc (Hon), BCPS, FCCP

California Board of Pharmacy Meeting
Sacramento, CA ▪ July 29, 2015

State Boards of Pharmacy Observers' Views Regarding the ACPE Site Visit Review and Accreditation Process

Results of a June 2014 Study conducted by a third party consultant group

Methods

- Part 1 - Online survey
  - 46 state boards of pharmacy members that had participated as observers on an ACPE site visit within the last four years sent the survey request
  - 50% responded
- Part 2 – Structured phone interview
  - 74% of responders agreed to be interviewed

Results

- Prior to participating in an ACPE site review, 43% of state board of pharmacy members were unsure of the level of objectivity and consistency in applying the standards, while after participation in at least one site visit, 96% characterized the process as substantially standardized and consistent.

Results (cont.)

- *During follow-up telephone interviews, state board members indicated*
  - *they knew relatively little about the inner workings and accreditation processes of ACPE prior to becoming involved in their first site review*
  - *an interest in having ACPE increase its interface and communications with state boards of pharmacy*

Standards 2007

Standard No. 12: Professional Competencies and Outcome Expectations (2 of 3)

- Provide patient care **in cooperation with patients**, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, **social, cultural, economic**, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences that may impact therapeutic outcomes.
- Promote health improvement, wellness, and disease prevention **in cooperation with patients**, communities, at-risk populations, and other members of an interprofessional team of health care providers.

Guideline 12.1

Graduates must possess the basic knowledge, skills, attitudes, and values to practice pharmacy independently at the time of graduation.

Must be able to:

- retrieve, analyze, and interpret the professional, lay, and scientific literature **to provide drug information and counseling to patients, their families or care givers,** and other involved health care providers

S2007 Appendix D:
Pre-Advanced Pharmacy Practice Experiences Performance Domains and Abilities

8. **Counseling** - **Educate patients and/or caregivers about drug therapy**

EXAMPLE Performance competencies

- Appropriately and accurately provide basic medication counseling to a patient or caregiver receiving a medication
- Use effective written, visual, verbal, and nonverbal communication skills to provide patient/caregiver self-management education

8. Counseling - Educate patients and/or caregivers about drug therapy

EXAMPLE Performance competencies (cont.)

- Use appropriate methods of patient education to review indications, adverse effects, dosage, storage, and administration techniques
- Assist a patient in correctly selecting an over the counter preparation
- Demonstrate and/or describe proper administration technique for various drug delivery systems (e.g., inhalers, eye drops, etc.)

Teaching Patient Counseling

- Didactic
  - Theory and methods (e.g., motivational interviewing, teach back technique)
  - Classroom practicing – students and faculty
- Simulation
  - Observed Structured Clinical Examinations (OSCE)
  - Standardized patient interactions
  - Video captured simulated counseling sessions
- Service learning – e.g., brown bag sessions
- Experiential – IPPE/APPE preceptor oversight

Standards 2016

Joint Commission of Pharmacy Practitioners (JCPP)

- **JCPP Vision**:
  - Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.

Key Differences Between *Standards 2007* and *Standards 2016*

- Based upon new AACP CAPE outcomes
  - Foundational Knowledge
  - Essentials for Practice and Care
  - Approach to Practice and Care
  - Personal and Professional Development
- Educational outcomes deemed essential to contemporary practice, interprofessional collaboration, professional accountability

Key Differences Between *Standards 2007* and *Standards 2016*

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  - Essentials for Practice and Care
  - Approach to Practice and Care
  - Personal and Professional Development
- Educational outcomes deemed essential to contemporary practice, interprofessional collaboration, professional accountability

S2016 Standard 1: Foundational Knowledge

Appendix 1 Curriculum Content

- Preparation, dispensing and administration of prescriptions, identification and prevention of medication errors and interactions, maintaining and using patient profile systems and prescription processing technology and/or equipment, and ensuring patient safety. **Educating about appropriate medication use and administration**.

S2016 Standard 1: Foundational Knowledge

Appendix 1 Curriculum Content (cont.)

Self-Care Pharmacotherapy

- Therapeutic needs assessment, including the need for triage to other health professionals, drug product recommendation/selection, and **counseling of patients on non-prescription drug products, non-pharmacologic treatments and health/wellness strategies.**

S2016 Standard 2: Essentials for Practice and Care

The program imparts to the graduate the knowledge, **skills, abilities, behaviors, and attitudes necessary to provide patient-centered care**, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

S2016 Standard 2: Essentials for Practice and Care: Key Elements

2.1. Patient-centered care – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities)

2.3. Health and wellness – The graduate is able to design prevention, intervention, and **educational strategies for individuals and communities to manage chronic disease and improve health and wellness**.

S2016 Standard 3: Approach to Practice and Care

The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to solve problems; educate, advocate, and collaborate, working with a broad range of people; recognize social determinants of health; and effectively communicate verbally and nonverbally.

S2016 Standard 3: Approach to Practice and Care: Key Elements

3.2. Education – **The graduate is able to educate all audiences by determining the most effective and enduring ways to impart information and assess learning.**

3.3. Patient advocacy – The graduate is able to represent the patient's best interests.

3.6. Communication – The graduate is able to **effectively communicate verbally and nonverbally when interacting with individuals**, groups, and organizations

S2016 Standard 10: Curriculum Design, Delivery, and Oversight

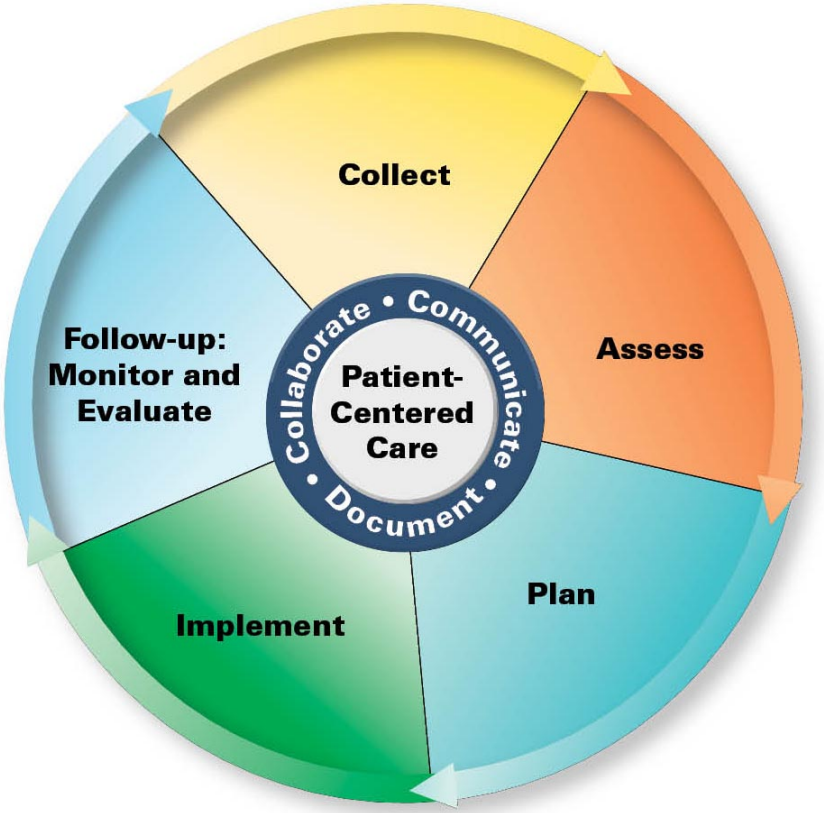
- Key Element 10.8. Pharmacists' Patient Care Process – The curriculum prepares students to provide patient-centered collaborative care as described in the ***Pharmacists' Patient Care Process*** model endorsed by the Joint Commission of Pharmacy Practitioners.

JCPP Pharmacists' Patient Care Process Workgroup

- Activities: January 2012-May 2014
  - Workgroup meetings
  - Environmental scan
  - Testing among clinicians
  - Organizational feedback

Pharmacists' Patient Care Process

- Approved by JCPP organizations in May 2014
- Supported by 13 national pharmacy organizations



http://www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf

Implement

The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

The pharmacist:

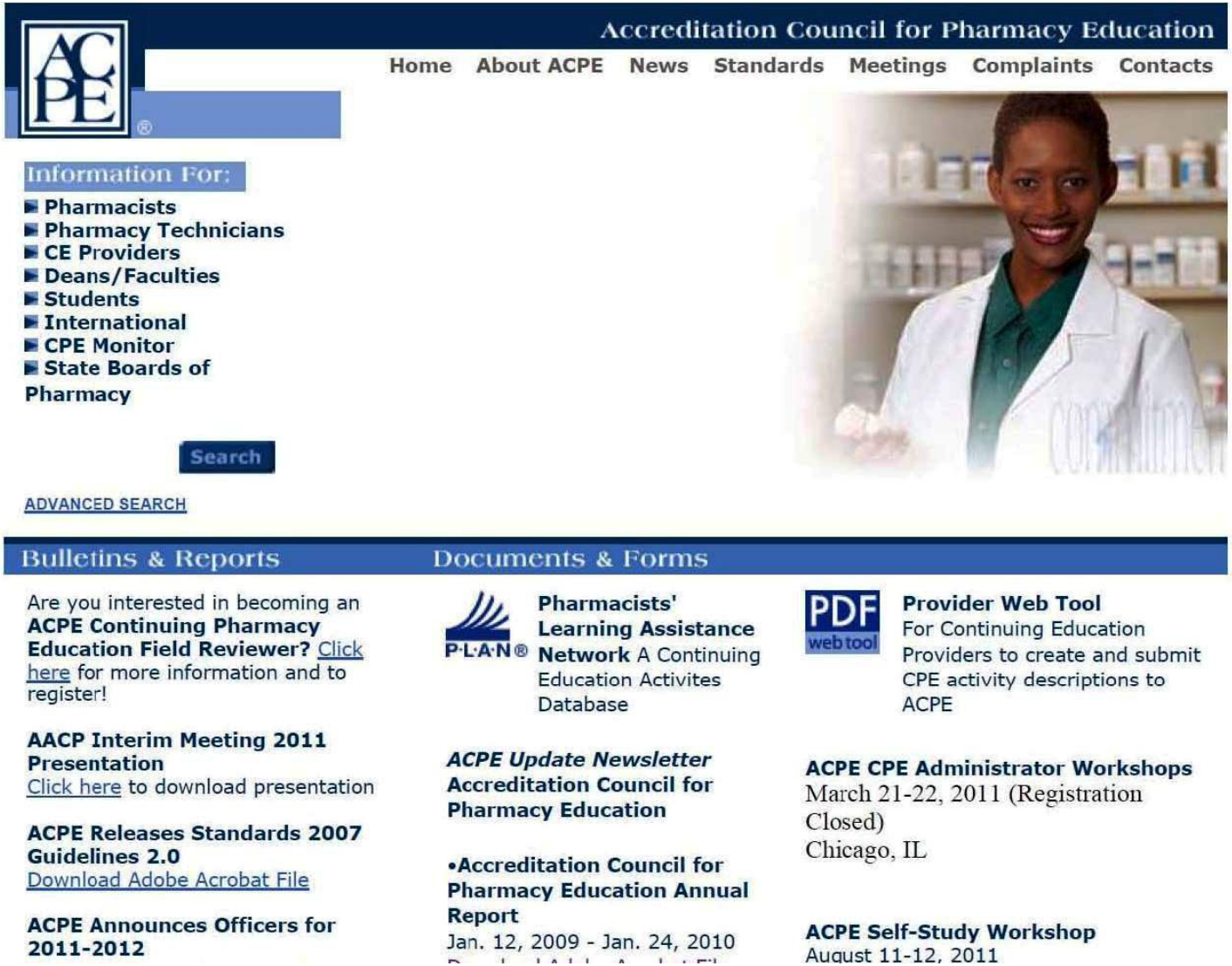
- Addresses medication- and health-related problems, and engages in preventive care strategies, including vaccine administration
- Initiates, modifies, discontinues, or administers medication therapy as authorized
- **Provides education and self-management training to the patient or caregiver**
- Contributes to coordination of care, including the referral or transition of the patient to another health care professional
- Schedules follow-up care as needed to achieve goals of therapy

Plan

The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

- Addresses medication-related problems and optimizes medication therapy
- Sets goals of therapy for achieving clinical outcomes in the context of the patient's overall health care goals and access to care
- **Engages the patient through education, empowerment, and self-management**
- Supports care continuity, including follow-up and transitions of care as appropriate

www.acpe-accredit.org



CHAPMAN UNIVERSITY | SCHOOL OF PHARMACY

A Curricular Approach to Patient Counseling

CUSP Student Learning Outcomes (SLO)

- To define the professional competencies and outcome expectations of our graduates
- CUSP SLOs are mapped to ensure the institutional and professional (Chapman Institutional Learning Outcomes, AACP CAPE 2013 Outcomes, ACPE Appendix B/Appendix I, NAPLEX competency statements) standards are met.

CUSP Student Learning Outcomes (SLO)

- The CUSP SLOs are comprised of five domains
  - Domain 1 - Personal/professional development
  - Domain 2 - Patient care delivery
  - Domain 3 - Population-based care delivery
  - Domain 4 - Inter-professional education
  - Domain 5 - Advanced biomedical pharmaceutical research and/or pharmacy practice
- Patient counseling-related SLOs
  - Direct: Domain 1.5, 2.1.1, 2.3.4, 2.4.1, 2.4.4, 3.1, 3.2, 3.4, 3.8, 4.1
  - Indirect: Domain1.6, 1.7, 2.1.3, 2.1.7, 2.2.1, 2.4.2

CUSP Multi-Dimensional Course Mapping to Guide the Curriculum

- Purpose: Ensure "breath" and "depth" of content and SLO (Vertical and Horizontal Integration)
  - Course to CUSP SLOs
  - Course to ACPE Appendix B/1
- The additional dimension (cognitive level) provides the complexity element (clinical reasoning, critical thinking) = Spiral Integration
- Cognitive levels:
  - 1F = Foundation
  - 2I = Intermediate
  - 3A = Advanced
  - 4M = Mastery

Student Learning Outcomes (SLOs) Domains			Domain 1									Domain 2						
Coding: 1F = Foundation, 2I = Intermediate, 3A = Advanced, 4C = Critical												2.1						
		Subdomains	1.1	1.2	1.3	1.4	1.5	1.6	1.7	2	1.9	2.1.1	2.1.2	2.1.3	2.1.4	2.1.5	2.1.6	2.1.7
Trimester, Course Number & Course Name		Units																
Trimester I																		
PE 501	Intro to Health Care	2	1F		1F	1F	1F	1F	1F	1F								
PE 501R	Intro to Health Care-Pharmacy Recitation	2			1F	1F	1F	1F	1F	1F								
PE 502	Healthcare Communications	2	1F	1F	1F	1F	2I	1F	1F	1F		1F						
PE 504	Health Law and Ethics	1			1F	1F	1F	1F	1F		1F							
PE 504R	Health Law and Ethics - Pharmacy Recitation	1			1F	1F	1F	1F	1F		1F							
PHS 601	Pharmacology I	2																
PHS 611	Medicinal Chemistry I	2																
PHS 631	Dosage Forms I	2				1F								1F				
PHS 631L	Dosage Forms I Lab	1				1F								1F				
PHS 641	Introduction to Pharmacokinetics	3																
TRIMESTER II																		
PHP602	Integrated Pharmaceutical Care I - Cardiology	6					2I					1F	1F	1F	1F	1F	1F	1F
PHC 671	Drug Information & Literature Evaluation	3																
PHS 651	Immunology	2													2I			
PHP 511	Self Care I	2	2I		1F	1F	2I	1F	1F	1F		1F	1F	1F	1F	1F	1F	1F
PHS 632	Dosage Forms II	2				1F								2I				
PHS 632L	Dosage Forms II Lab	1				2I								2I				
PHP 501	IPPE I and Basic Life Support Cert. (BLS)	1		1F	1F	1F	1F	1F	1F			1F	1F					
TRIMESTER III																		
PHT 602	Integrated Pharmaceutical Care II: Renal / Endocrine	7					2I					2I	2I		2I	2I	2I	2I
IPE 505	Health Screening and Assessment	2			2I	2I	2I	2I	2I			2I	2I	2I				
IPE 505R	Health Screening and Assessment-Pharmacy Recitation	1			2I	2I	2I	2I	2I			2I	2I	2I				
PHP512	Self Care II	2			2I	2I	2I	2I	2I	2I		2I	2I	2I	2I	2I	2I	2I
PHS 642	Applied Pharmacokinetics	2																
PHS 603	Biopharmaceuticals	3																
PHP 621	Drug Administration, Immunization & Advanced Cardiac Life Support Cert (ACLS)	1										3A	3A	3A	3A	3A	3A	3A
PHXXXX	Elective Track 1																	
TRIMESTER IV																		
PHT 603	Integrated Pharmaceutical Care III: GI/Pulmonary/Hepatic/Nutrition	7					2I					2I	2I	2I	2I	2I	2I	2I
IPE 506	Grand Rounds I	2			3A	2I	3A	2I	3A	3A			2I	2I	2I	2I	2I	2I
IPE 511	Interactive Learning	2			3A	2I	3A		3A	3A		3A	2I		2I	2I	2I	2I
PHS 652	Introduction to Pharmacogenomics	1																
PHC 672	Informatics, Statistics, and Research Design	3																
PHP 602	IPPE II Either Health System or Community	3	2I	2I	2I	2I	2I	2I	2I	1F	1F	2I	2I	1F	1F	1F	1F	1F
PHXXXX	Elective Track 1																	
TRIMESTER V																		
PHT 604	Integrated Pharmaceutical Care IV:Infectious Disease / Psychiatry/ CNS/ Musculoskeletal	8					3A		3A			3A	3A	3A	3A	3A	3A	3A
PHC 691	Pharmacy Management	3			3A	3A	3A	3A	3A	3A	3A							
PHP 503	IPPE II Either Health System or Community	3	2I	2I	2I	2I	2I	2I	2I	1F	1F	2I	2I	2I	2I	2I	2I	1F
PHP 611	Integrated Therapeutics I	2										3A	3A			3A	3A	
IPE 521	Team Care Sim 1	2			3A	3A	3A	3A				3A	3A	3A	3A	3A	3A	3A
PHXXXX	Elective Track 1																	
TRIMESTER VI																		
PHT 605	Integrated Pharmaceutical Care V:Infectious Disease II/Oncology/Transplant	8			3A	3A	3A	3A	3A			3A	3A	3A	3A	3A	3A	3A
PHP 612	Integrated Therapeutics II	2										4C	4C			4C	4C	
PHC 681	Pharmacoeconolcs/epidemiology	2				3A	3A		3A		3A							
IPE 507	Grand Rounds II	1			3A	3A	3A	3A	3A				3A	3A	3A	3A	3A	3A
IPE 522	Team Care Sim 2	2			3A	3A	3A	3A	3A	3A			3A	3A	3A	3A	3A	3A
IPE 513	Health Education Experiences	2	3A	3A	3A	3A	3A	3A	3A	3A		3A	3A	3A	3A	3A	3A	3A
PHXXXX	Elective Track 1																	
TRIMESTER VII & VIII																		
PHP 901	Internal Medicine APPE	6			3A	4C	3A	3A	3A	3A	2I	3A	3A	3A	3A	3A	3A	4C
PHP 902	Ambulatory Care APPE	6	3A		3A	4C	3A	3A	3A	3A	2I	3A	3A	3A	3A	3A	3A	4C
PHP 903	Hospital Pharmacy APPE	6			3A	4C	3A	3A	3A	3A	2I	3A	3A	3A	3A	3A	3A	4C
PHP 904	Community Pharmacy APPE	6			3A	4C	3A	3A	3A	3A	2I	3A	3A	3A	3A	3A	3A	4C
PHP 905	Elective APPE I	6			3A	4C	3A	3A	3A	3A	2I							
PHP 906	Elective APPE II	6			3A	4C	3A	3A	3A	3A	2I							
PHP911	Capstone Project/Presentation	2			4C	4C	4C	4C	4C	4C	4C							

CUSP Multi-Dimensional Content Mapping to Guide and Review the Curriculum

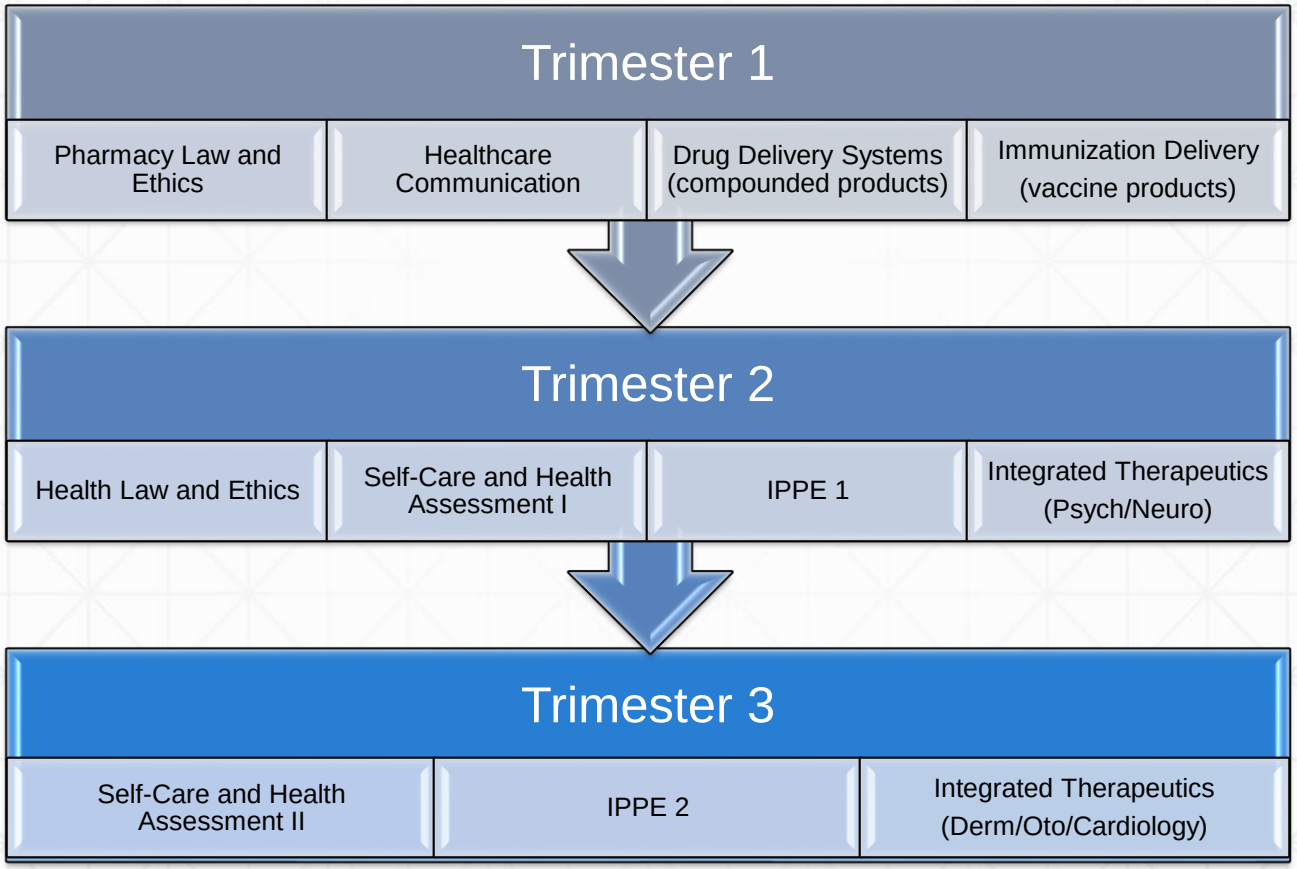
Five criteria are selected to set up the curricular content mapping.

1) Primary criteria : Course identification number, ACPE Appendix I (domains and sub-domains), and Subjects (disease states or non-disease related topics).
2) Secondary criteria: Cognitive/behavioral levels and Number of Contact Hour.

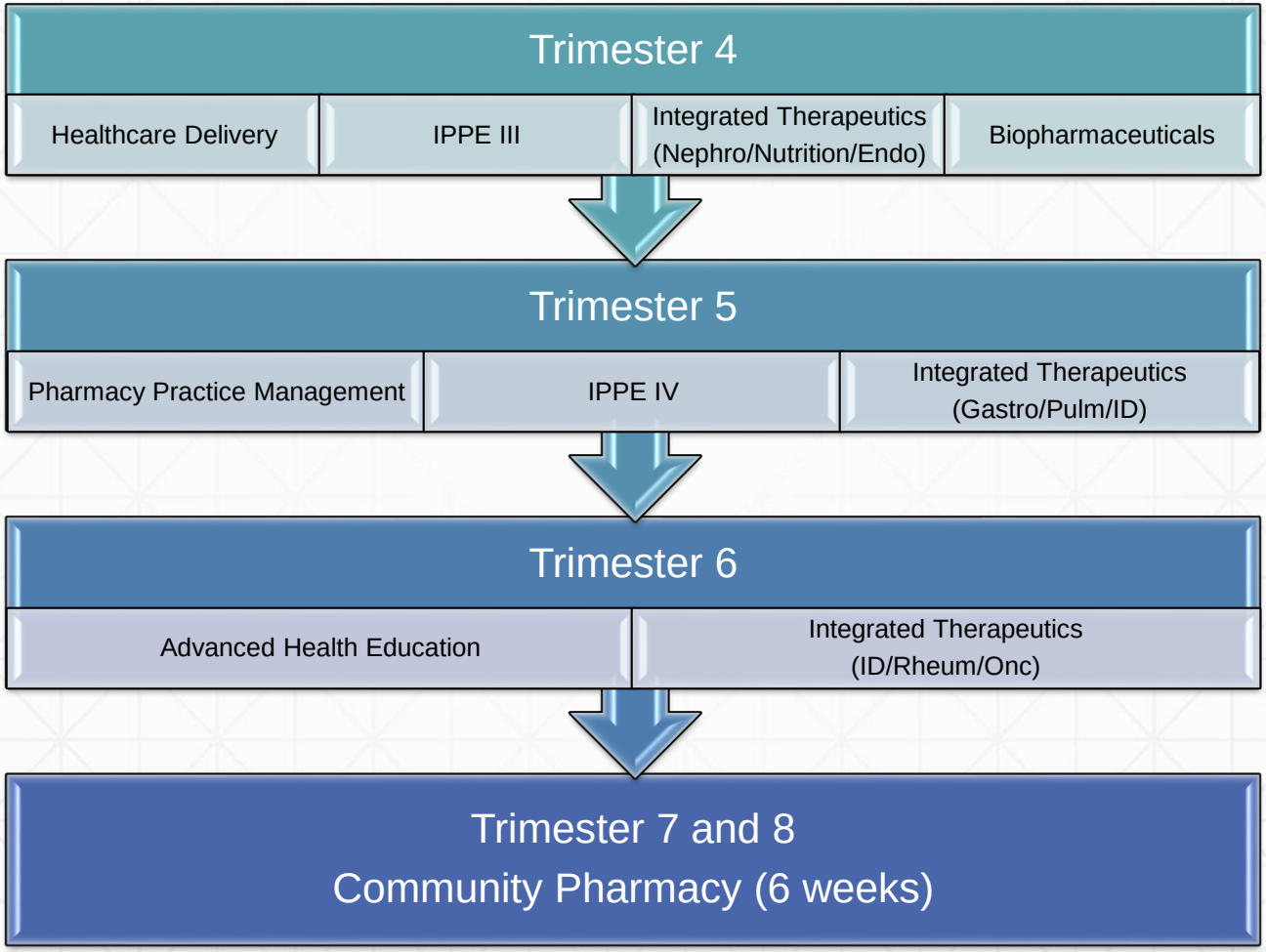
** ACPE Appendix I inclusion is for accreditation purpose*

Objective	
Horizontal Integration	
Vertical Integration	Course, Subject and # of Contact Hours
Spiral integration	Course, Subject, # of Contact Hours and Cognitive Level

First Year Curriculum: Patient Counseling Related



Second Year Curriculum: Patient Counseling Related



Details of Curricular Approach to Patient Counseling

T	Course#	Course Name	Description	# Hrs
1	581	Healthcare Communication	**Learn**: motivational interviewing, communication styles, cultural/linguistic competency **Practice**: role play in class, video recording and review	12
1	591	Pharmacy Law & Ethics	**Learn**: laws related to patient counseling and required elements of the consult **Practice**: work through cases related to the “offer to counsel”	4
1	621L	Drug Delivery Systems I	**Learn**: approach and elements of counseling on compounded products **Practice**: role play in lab; OSCE (formative)	1
1	521	Immunizations	**Learn**: federal standards for vaccine counseling **Practice**: demonstrate during workshop assessment **Experience**: Counsel patients community pharmacy and other settings on vaccines	9

Details of Curricular Approach to Patient Counseling

T	Course#	Course Name	Description	# Hrs
2	592	Health Law and Ethics	**Learn**: federal law related to OBRA90 counseling **Practice**: role play in class, video recording and review	12
2	511	Self-care & Health Assessment	**Learn**: OTC counseling **Practice:** Role play	2
2	501	IPPE I	**Practice**: patient counseling (simulation)	2.5
2	531	Therapeutics	**Learn**: drug/disease specific counseling	2
3	512	Self-care & Health Assessment	**Learn**: OTC counseling **Practice:** Role play	2
3	502	IPPE 2	**Practice**: patient counseling (simulation)	2.5
3	534/537	Therapeutics	**Learn:** drug/disease specific counseling	2

Details of Curricular Approach to Patient Counseling

T	Course #	Course Name	Description	# Hrs
4	577	Healthcare Delivery	**Learn**: medication counseling in the community/amcare setting **Practice**: Case-based workup and role playing	10
4	503	IPPE III	**Experience:** community pharmacy (lesson and syllabus planned activities) **OR** hospital	30
4	540/543	Therapeutics	**Learn**: drug/disease specific counseling	4
4	642	Biopharmaceuticals	**Learn**: drug specific counseling for biopharmaceuticals	2
5	681	Pharm Practice	**Learn**: operational aspects of community pharmacy practice including workflow and professional responsibility	2
5	504	IPPE IV	**Experience:** community pharmacy (lesson and syllabus planned activities) **OR** hospital	30
5	546/549 /552	Therapeutics	**Learn**: drug/disease specific counseling	4
6	584	Adv healthcare	**Experience**: “brown bag” sessions	4
6	555/558 /561	Therapeutics	**Learn**: drug/disease specific counseling	4
7/8	APPE	Community Pharm	**Experience:** syllabus/workbook directed and site specific patient counseling	120

Inspector Duty Calls

October 2014 – June 30, 2015

Classification by Question

Subject	N	Percent	Time (Hours)
Controlled Subst.	235	23.8	100.25
Pharmacy Related	72	7.3	27.5
Licensing Questions	67	6.8	33.25
Prescription Req.	63	6.4	27.75
Regulatory Compl.	53	5.4	27.25

Classification by Question

Subject	N	Percent	Time (Hours)
Compounding	51	5.2	23.75
RPh Duties/Respons.	45	4.5	22.75
Wholesaler	32	3.4	16.0
Labeling	26	2.6	10.75
MD Dispensing	17	1.7	8.25
Total	988		450.75

Classification by Caller

Caller	N	Percent	Time (Hours)
Pharmacist	263	39.5	160.5
Consumer/patient	102	10.3	46
Physician	71	7.3	30.8
Lawyer	44	4.6	20.5
Wholesaler	23	2.3	10.8

Classification by Caller

Caller	N	Percent	Time (Hours)
Technician	18	1.8	6.5
Intern	11	1.1	4.5
“Consultant”	21	2.1	14.3
Other Health Care	47	21.8	21.75
Total	990		

Time Spent

Caller	Time (Hours)	Percentage of Inspector Position
Oct. 2014 – June 2015	451	33.3 %