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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING
MINUTES

DATE: September 26, 2011

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

COMMITTEE MEMBERS PRESENT: Ryan Brooks, Public Member, Chair
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

COMMITTEE MEMBERS NOT PRESENT: Shirley Wheat, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Office
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Ryan Brooks called the meeting to order at 1:31 p.m.

A roll call was conducted. Committee Members Brooks, Hackworth and Veale were present.

President Stanley Weisser was in attendance in the audience.

1. Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels

Chair Report

Chair Brooks provided that the board's requirements for patient-centered prescription drug container labels took effect on January 1, 2011, as required by statute. He stated that since June 2010, when the board finalized its work on the regulation, the board has been publicizing its requirements to the board's licensees. A copy of the regulation is attached, following this meeting summary.

Chair Brooks provided that in addition to the actual text of the requirements, the regulation also contains several directives to the board. He reviewed the following directives from Section 1707.5:

> (b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
>
> (c) Beginning in October 2011, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
>
> (e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Chair Brooks reviewed the following discussion items with respect to each directive.

- Re: subdivision (b): Translations are available for addition to the Web site.
- Re: subdivision (c): The board already has examples of labels available on its Web site and has published these in its newsletter.
- Re: subdivision (e): The committee may want to begin discussions of the existing requirements to determine whether modifications to the requirements are needed.

Discussion

Executive Officer Virginia Herold reported that the translations will be posted on the board's Web site in advance of the October 2011 deadline. She indicated that the translations were developed and vetted by the California Endowment.

Committee Member Deborah Veale suggested that the board discuss the existing requirements in about six months after all requirements are in place.

Chair Brooks spoke in support of this suggestion and indicated that this will allow for comments and feedback to be submitted by the public.

Public Comment
Steve Gray, representing Kaiser Permanente, expressed concern regarding delaying the discussion of the requirements. He stated that several unintended consequences have been identified as a result of the labeling requirements including noncompliance by out-of-state pharmacies. Dr. Gray discussed other unintended consequences and indicated that generic names are being truncated and the size of the description of the medication and other important information is being significantly reduced in order to comply with the requirement that certain information be clustered into one area of the label. Dr. Gray urged the board to address these issues.

Committee Member Ramón Castellblanch arrived at 1:41 p.m.

Ms. Herold stated that the board has not been notified of these issues. She urged Dr. Gray and any other individuals aware of such problems to file a complaint with the board.

Dr. Gray provided comment regarding the increase in generic products on the market. He stated that pharmacies use the label as a mechanism to indicate generic substitution. Dr. Gray indicated that the labeling requirements are limiting the ability of pharmacies to put this information on the label.

The committee discussed these issues and the required report to the Legislature on the implementation of the patient-centered labels by January 1, 2013. It was the consensus of the committee to review all issues comprehensively in preparation for the report.

Chair Brooks indicated that additional comments and feedback can be submitted to Executive Officer Herold.

2. Review of USP's Guidance for Patient Prescription Container Labels

Chair Report
Chair Brooks provided that earlier this year, the United States Pharmacopeia (USP) completed its work on standards for prescription container labeling.

Chair Brooks reviewed the following comparison chart of the requirements which highlights the board's regulation with the USP standards. He stated that USP considered the board's initial draft requirements at an early stage in the development of their standards.

	USP	Board Regulation
Organize label to emphasize patient info	X	X
• Patient's Name	X	X
• Drug Name & Strength	X	X
• Instructions in Clear & Simple Language	X	X
• Standardize order	O	X
• Dedicate 50% of label	O	X
• Require Purpose if on Rx	O	X
• Require Mfg if generic drug	O	X
Place all other required elements elsewhere so not as to interfere with the above	X	X
Use standardized pat-centered translations of directions for use "when appropriate"	X	X
Separate dose from timing of dose	X	X (in stnd. directions)
Use numeric, not alphabetic characters	X	X
Purpose for use if desired by patient and use simple terms	X	O
Purpose for use if written on Rx	O	X
Limit Auxiliary information/labels	X	O
Standardize terms & placement	X	O
Validate use of icons	X	O
Labels should be in language of Patient	X	Bd provided translations of directions In 5 additional lang.
or should have interpreter services available	X	X
Labels should be easy to read	X	X
Use high contrast ink	X	X
Simple uncondensed fonts	X	
Large Font size	X	
e.g., (not specified one type)		
12-point Times New Roman	X	O
11-point Arial	X	X
Use san serif (e.g, Arial) 10 point	O	X
Or 12 point if requested	O	X
No font smaller than 10 point	X	X
Use sentence case (not all caps)	X	O

Use Adequate white space	X	X
Use white space to separate directions from pharmacy info	X	X
Use horizontal text only	X	O
Minimize need to turn container to read	X	O
Do not truncate information	X	X
Use highlight, gold and typo cues to emphasize pt. centric or adherence (e.g., ordering)	X	X
Limit number of highlight colors	X	O

Discussion

Chair Brooks provided comment in support of the guidelines but discussed that some are not needed and may be too prescriptive.

Dr. Castellblanch sought clarification regarding the standardized directions for use provided in Section 1707.5. He asked why pharmacies are not being required to use these on prescription labels.

Ms. Herold clarified that the regulations specifies that these directions are to be used "when applicable."

DCA Staff Counsel Kristy Shellans indicated that a statutory change would be needed in order to require use of the standardized directions for use on the label. She provided background on this issue and indicated that the board had discussed whether it wanted to control the judgment and discretion of pharmacists to use the directions and the consensus was to provide flexibility in this area. Ms. Shellans discussed that if questioned by the board, pharmacists will have to provide justification for why they are not using the directions provided in the regulation.

Ms. Herold stated that the board's inspection team can open investigations based on questionable labels. She stated that findings from these investigations can be reported back to the board to be addressed for the report to the Legislature due in 2013.

Chair Brooks reminded the committee that these issues should be addressed in a comprehensive manner.

Ms. Veale asked whether a pharmacist is permitted to change directions for use as indicated by the physician to the standardized directions provided in the regulation.

Ms. Shellans provided that a pharmacist should use his or her professional judgment and consult with the physician.

Ms. Herold suggested that this issue be discussed with the Medical Board and also be addressed in *The Script*.

Public Comment
Steve Gray, representing Kaiser Permanente, discussed that the regulation conflicts with Section 1716 which states that a "pharmacist shall not deviate from the requirements of a prescription." He stated that this conflict creates confusion and the requirements of Section 1716 should be changed to allow a pharmacist to utilize his or her professional judgment.

Dr. Gray also provided comment on e-prescribing and indicated that the information inputted by the prescriber is what will print out on the label. He suggested that in addition to modifying Section 1716, the board should also pursue regulatory change to require that the purpose of a medication be included on the label.

Michael Negrete, representing the Pharmacy Foundation of California, suggested that in addition to discussing this issue with the Medical Board, the board should also hold discussions with organized medicine. He provided comment on Cal eConnect and the development of standards for E-prescribing systems.

A member of the public provided comment on Script Your Future, a national campaign to raise awareness about medication adherence. She encouraged the board to involve consumers, pharmacists and physicians to promote language that is understandable for patients.

Chair Brooks discussed the importance of consumers to be actively involved in identifying and solving problems in this area.

The committee discussed differences between the board's requirements and the standards established by USP (refer to items indicated with an "O" in the chart provided above). The committee encouraged additional feedback in order to address improvements for the 2013 report to the Legislature.

3. Review and Discussion Surrounding the Developed Translations of Directions for Use for Patient Medication as Specified in16 California Code of Regulations Section 1707.5

Chair Report
Chair Brooks provided that the California Endowment, to support ensuring quality labels for those who do not read English, funded a project with national PhD patient literacy researchers Stacy Bailey and Michael Wolf to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. He stated that the translations were vetted in CA (and IL) communities with a survey of native speakers.

Chair Brooks provided that the regulation requires that the board place these translations on its Web site by October 2011. He advised that they will be posted by this deadline.

Chair Brooks provided that the translations have been made in Spanish, Korean, Russian, Vietnamese and Chinese.

Discussion
Dr. Castellblanch discussed that at least one major chain currently has a system to provide translations. He stated that the system allows the pharmacist to see both the label in English and in the translated language.

Chair Brooks discussed that there are errors that can be made when utilizing a translation service. He encouraged licensees to utilize the vetted translations that will be available on the board's Web site.

Public Comment
Missy Johnson, representing the California Retailers Association (CRA), confirmed that there is a major chain that is currently providing translations. She discussed that this chain has built a verification element into their system and has devoted resources to ensure the validity of the system.

Sarah Mercer, California Pan-Ethnic Health Network (CPEHN), encouraged the board to work with CPEHN to solicit feedback from community groups on the translations. She asked how pharmacies will be notified once the translations are posted on the board's Web site.

Ms. Herold suggested that all labeling information dealing with patient-centered labels, including the translations, be posted on the board's Web site in one central location.

Dr. Castellblanch provided comment in support of Ms. Herold's suggestion.

A member of the public provided comment regarding the importance of providing translations to ensure that patients understand how to take their medication.

4. Discussion Regarding the Future Design of New Notice to Consumers Posters (Pending 16 California Code of Regulations Section 1707.6)

Chair Report
Ms. Herold provided that at the July 29, 2011 Board Meeting, the board completed its work on a new regulation to house all notice to consumer elements in one place. She discussed that while waiting for the regulation to take effect, the committee can begin to discuss the design for the new poster(s), concepts for the video display, and concepts for interpreter services (likely a separate poster).

Ms. Herold provided that Kim Brown from the department's press office has been assigned to work with the board to develop concepts and prototypes for the new posters.

Discussion

The committee discussed the required notice language in Section 1707.6 and how best to design the poster so that important information is emphasized. Consideration was given to a concern regarding the volume of language required and ensuring that important information is communicated effectively to consumers.

Ms. Veale recommended that the committee review the new notice language and identify important information that should be emphasized. She provided that she believes the information regarding patient education and what a patient should know before taking their medication is the most important information and should be emphasized. Ms. Veale also suggested that the following language be used as a header for this information:

> "California law requires a pharmacist to speak with you every time you get a new prescription."

Chair Brooks suggested that important information be displayed with the use of bullet points, bolding, or underlining.

Dr. Castellblanch discussed that the language regarding the availability of interpreter services is important and should be emphasized.

Ms. Veale provided that information regarding interpreter services can be provided on a separate notice as the regulation requires that this information be provided on a handout or flyer or on a video screen that is positioned so that a consumer can easily point to their language. She discussed that the Notice to Consumers should focus on patient safety and medication adherence.

Ms. Veale and Committee Member Rosalyn Hackworth expressed that the remaining notice language is important but is of lesser importance than the information regarding what a patient should know about taking prescription medication.

Dr. Castellblanch provided that he believes the information regarding the patient's right to labels in 12-point font is the second most important piece of information.

Chair Brooks suggested that the committee direct board staff to develop a poster based on the committee's discussion that promotes consumer protection to be reviewed by the committee at a future meeting.

Ms. Veale asked whether the committee has the same priority for the video screen display of the notice.

It was the consensus of the committee that the paper form and video screen display notices will have the same priority for important information to be emphasized.

Public Comment
Michael Negrete, representing the Pharmacy Foundation of California, reviewed information submitted to the board by Beccah Rothschild, MPA, Director of Health Literacy Projects at the University of California, Berkeley, regarding health literacy, readability, and consumer testing to assess usability of consumer notices.

Ms. Herold indicated that Ms. Rothschild has indicated an interest to work with the board to conduct consumer testing for the new notices.

Sarah Mercer, California Pan-Ethnic Health Network (CPEHN), provided comment in support of providing information regarding interpreter services on a separate notice. She asked whether the Notice to Consumers will be translated into different languages.

Ms. Herold provided that the notice will be available in other languages and will be provided in a smaller size like the current translated notices.

Ms. Mercer indicated that CPEHN is interested in working with the board to perform a focus group testing to solicit feedback on the new notices. She asked how noncompliance or failure to utilize the interpreter service notice will be addressed by the board.

Dr. Castellblanch provided that consumers should report noncompliance to the board.

Ms. Herold discussed that the board will educate all licensees regarding this requirement during inspections, in *The Script,* and via subscriber alerts.

Chair Brooks asked for an anticipated timeline for completion of the sample posters.

Ms. Brown indicated that the sample posters should be completed within the next 2-3 months.

5. Proposal to Review and Recommend Approval of an Update of the Emergency Contraception Protocol Regulation (16 California Code of Regulations Section 1746)

Chair Report
Chair Brooks provided an overview of the revised protocol for pharmacists furnishing emergency contraception. A copy of the protocol is attached, following this meeting summary.

Discussion

Ms. Herold discussed that the protocol has been revised to reflect changes submitted from CPhA's representatives (a women's health specialist, Pharmacist Katherine Besinque from USC, and two representatives of the American College of Obstetricians and Gynecologists (Shannon Smith Crowley and Phillip Diamond, MD) regarding changes in the availability of emergency contraception medication, the manufacturers who produce the medication, and to correct a typo (mcg instead of mg).

Ms. Herold provided that after the board reviewed the proposed changes at the July 2011 Board Meeting, the revisions were subsequently reviewed and approved by the Medical Board. She stated that the Board of Pharmacy will now need to proceed with a rulemaking to update the requirements as a regulation.

Ms. Veale asked whether the revisions address a concern that was raised at the July 2011 Board Meeting regarding inconsistencies with the use of the terms "patient," "man," and "woman."

Ms. Herold provided that the patient information fact sheet, which is required to be provided to patients by the pharmacists using the protocol to dispense emergency contraception, will be modified to address this issue.

Dr. Castellblanch left the meeting room at 3:14.

Mr. Brooks offered a proposal to recommend that the board approve the updated protocol. He advised that if the board moves forward with the regulation changes, the regulation will be released for the formal 45-day comment period.

No public comment was provided.

MOTION: Recommend to the board to initiate a rulemaking to repeal and amend 16 California Code of Regulations Section 1746 to be consistent with the proposed update of Emergency Contraception Protocol Regulation.

M/S: Brooks/Hackworth

Approve: 3 Oppose: 0 Abstain: 0

6. Discussion Surrounding a Proposal to Develop a Standardized Form for Pharmacies to Use to Request Refills

Chair Report
Chair Brooks provided that the board recently received a proposal from Assembly Member Feuer that had been submitted to him by a constituent as a possible legislative proposal. He stated that the problem is that physicians receive numerous refill requests via fax daily from pharmacies that are not standardized, and there is potential for a physician to make an error when reviewing and approving such diverse refill requests daily that could impact patient safety. Chair Brooks indicated that the proposal is to require use of a specific form.

Discussion
Ms. Veale discussed that she believes that requiring a specific form may create problems and may not create a lot of benefit overall. She discussed that each software program has its own format.

Dr. Castellblanch returned to the meeting room at 3:17 p.m.

Public Comment
Steve Gray, representing Kaiser Permanente, provided that this proposal comes from the prescriber's point of view. He stated that developing a standardized format would be a lengthy process and would require a lot of changes for pharmacies. Dr. Gray discussed that this proposal would detract from efforts by the National Council for Prescription Drug Program (NCPDP) and Cal eConnect regarding electronic health information exchange.

Ms. Herold provided that she brought the proposal and sought the reaction or need from Cedars Sinai (where the MD constituent practices), from the California Pharmacists Association and the California Retailers Association, and various board inspectors. She indicated that no one was opposed, but no one was especially motivated either. Ms. Herold advised that the prescription document is currently not standardized.

7. Update on an Assessment of the Board's Public Education Materials

Report
Ms. Veale reported that she and Committee Member Castellblanch have been working to improve the board's Web site design and placement of its public education materials. She reviewed the following categories that have been identified to improve the current layout of the Web site:

1. Public Information
2. Professional Information
3. Applicant Information
4. Board Information
5. Regulation Information

Dr. Castellblanch provided that these changes will be implemented when the board's Web site migrates to the new state government web design.

There was no committee discussion or public comment.

8. Update on The Script

Chair Report
Chair Brooks provided that the next issue of *The Script* has been written and has been with legal for review for a while. He indicated that work on the January issue has begun and will focus on new laws.

There was no committee discussion or public comment.

9. Public Outreach Activities Conducted by the Board

Chair Report
Chair Brooks referenced the following public and licensee outreach activities performed during the first quarter of Fiscal Year 2011/12:

- July 8: Executive Officer Herold and President Weisser attend the CSHP's Board of Directors Meeting in Sacramento to provide an update on board activities.
- August 18: Executive Officer Herold provides a Webinar on California's e-pedigree requirements to a conference hosted by the National Coalition of Pharmaceutical Distributors (NCPD).
- September 14: Executive Officer Herold attend a California Pharmacy Council Meeting to discuss pharmacist manpower today and in the future.

NOTE: Since late spring, state government has been subject to a travel freeze that restricts all but the most essential travel. Moreover, the Department of Consumer Affairs has to preapprove all travel where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach.

There was no committee discussion or public comment.

10. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 3:29 p.m.

Order of Adoption

Board of Pharmacy

California Code of Regulations

Specific Language to Add Section 1707.5.

Add Section 1707.5. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

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

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

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take ___ [insert appropriate dosage form] at a time. Wait at least ___ hours before taking again. Do not take more than ___ [appropriate dosage form] in one day

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

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

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in

subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

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

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code.
Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

Pharmacists Protocol for Dispensing Emergency Contraception

Pharmacists may furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California (section 4052.3(a)(2) of the California Business and Professions Code).

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit in emergency contraception .

Additionally pharmacists may furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber (section 4052.3 of the California Business and Professions Code).

Pharmacists may also furnish levonorgestrel emergency contraception without a prescription or a physician protocol to a man or woman aged 17 or older pursuant to FDA requirements.

This statewide protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by California law.

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide timely access to emergency contraceptive medication and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception, the pharmacist will ask and communicate the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.
- EC use will not interfere with an established or implanted pregnancy.
- If more than 72 hours have elapsed since unprotected intercourse, the use of ella® (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

The pharmacist shall provide a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced Provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

Documentation*:* Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1: Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception				
Brand		Dose	Ethinyl Estradiol per dose (mcg)	
One Dose Regimen				
PlanB-OneStep		1 tablet	0	1.5mg levonorgestrel
Ella		1 tablet	0	30mg ulipristal
Two Dose Regimen				
NextChoice		1 tablet per dose	0	1.5mg levonorgestrel
Oral Contraceptive Pills				
Brand		Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per dose(mcg)	Levonorgestrel per dose(mg)
Levora		4 white tablets	120	0.6
Ovral		2 white tablets	100	0.5
Ogestrel		2 white tablets	100	0.5
Nordette		4 light-orange tablets	120	0.6
Tri-Levlen		4 yellow tablets	100	0.5
Alesse		5 pink tablets	100	0.5
Aviane		5 orange tablets	100	0.5
Triphasil		4 yellow tablets	120	0.5
Levlen		4 light-orange tablets	120	0.6
Trivora		4 pink tablets	120	0.5
Levlite		5 pink tablets	100	0.5
Lo/Ovral		4 white tablets	120	0.5
Low-Ogestrel		4 white tablets	120	0.6
Ovrette		20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

** In addition to the products listed above, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available

Appendix 2 --~~Sample list~~ List of Anti-Emetics for Use with Emergency Contraception.

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Appendix 3 – Title 16, Section 1707.1 of the California Code of Regulations

§1707.1. Duty to Maintain Medication Profiles (Patient Medication Records).

(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.

(A) The patient's full name and address, telephone number, date of birth (or age) and gender;

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;

2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;

3. The date on which a drug was dispensed or refilled;

4. The prescription number for each prescription; and

5. The information required by section 1717.

(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.

(D) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

(2) The patient medication record shall be maintained for at least one year from the date when the last prescription was filled.

Authority cited: Sections 4005, 4121 and 4122, of the Business and Professions Code.

Reference: Sections 4005, 4121 and 4122, of the Business and Professions Code.