

Memorandum

To: Board Members

Date: October 23, 2008

From: Anne Sodergren
Board of Pharmacy

Subject: Regulation Hearing – Proposal to Repeal 16 CCR § 1716.1 and 1716.2, and Amend §§ 1751-1751.8, and Adopt §§ 1735-1735.8

At this meeting the board will conduct a regulation hearing to hear testimony about the proposed regulation that establishes requirements for pharmacies that compound medications.

Current pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding.

In 2004 the Board of Pharmacy formed a Workgroup on Compounding comprised of board members, board staff, and industry representatives. The workgroup recognized that current pharmacy regulations addressing compounding only govern the physical circumstances, procedures and record keeping requirements for general compounding and do not address quality, strength or purity. At the conclusion of this workgroup, recommendations to change the current regulations were provided.

Since that time, largely since 2006, the board has continued to refine the language based on subsequent comments from interested parties during board and committee meetings as well as included changes recommended by counsel.

This regulation was noticed on August 22, 2008 and the 45-day comment period was closed on October 6, 2008.

The board received a significant number of comments, however many comments share a common theme but submitted by different people. For you review are copies of the comments submitted.

During the regulation hearing additional testimony will be provided for board consideration. At the conclusion of the hearing the board may consider revising the language. Any changes to the language will result in either an additional 15-day comment period or a new 45-day comment period depending on the scope of the changes.

Board staff are preparing responses to comments submitted and will provide the responses and any recommended changes if necessary to the board for consideration at part of the hearing.



Stephan Flascha
<flascha@ca.rr.com>
09/04/2008 06:25 AM

To karen_cates@dca.ca.gov
cc
bcc
Subject 30 year veteran hospital pharmacist concerned about
documentation requirements.

Dear Ms. Karen Cates:

As a hospital pharmacist licensed since 1978, 30 years, I am really concerned about the documentation requirements in Compounding in an IV room in a major hospital. We are required to prepare there are probably a thousand items involved in one shift which are activated.

Just consider a t supermarket check out counter you want the cash register noted Manufacturer, Expiration Date and Lot number of every item you buy. We do that if we compound bigger bactaches like a manufacturer but most items are for a personalized use.

Please consider this requirement as undoable. It will make the environment so "crazy-Busy" that you will have more centennial events.

Sincerely

Dr. Stephan Flascha R.Ph. Pharm.D.
Kaiser Sunset



"Baertsch, Suzanne"
<BaertsS@sutterhealth.org>
09/04/2008 12:15 PM

To <Karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Board of Pharmacy new compounding regulations

I just heard about the proposed compounding regulations, and while I understand the concern for patient safety, I think these regulations will have the opposite effect.

I work in a hospital where we compound hundreds of IVs daily in a sterile environment. The additional time it would take for all this record keeping would mean we would have to cut back in other areas. We are already stretched too thin, and this will make it worse for overall patient care, with little benefit.

I am especially concerned about 1st dose antibiotics or cardiovascular drips. This may result in a further delay to patient therapy.

I understand it is valuable to be able to trace back how something is made, but remember, this still does not PREVENT an error. It only allows you to see what the error is.

In summary, I strongly feel these new regulations will be a detriment to patient care and our healthcare system as a whole, especially in regard to IV medications.

Suzanne Baertsch
NICU Pharmacist
Alta Bates Summit Medical Center
Berkeley, CA 94705



"Hass, Deborah"
<DHass@stanfordmed.org>
09/05/2008 12:54 PM

To karen_cates@dca.ca.gov
cc philip@cshp.org
bcc
Subject New Board of Pharmacy Regulations regarding IV
Compounding

Dear Ms. Cates: I am a clinical pharmacist at Stanford University Hospital in Stanford, CA. I am writing to strongly object to the newly proposed regulations regarding compounding sterile IV products:

I would agree with the CSHP (and am quoting them) in asking for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the thousands of records daily that would be generated here at Stanford to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

I would urge you to seriously reconsider passing this proposed regulation.

Respectfully yours,

Deborah A. Hass, Pharm.D., BCOP
Hematology/Oncology Clinical Pharmacist
Stanford Hospitals and Clinics
300 Pasteur Drive
Room H0301, M/C 5616
Stanford, CA. 94305
Central Pharmacy Phone: 650-723-5970
Central Pharmacy Fax: 650-725-5028
Satellite Pharmacy Phone: 650-725-5299
Pager: 650-723-8222 ID 16045
E-mail: DHass@stanfordmed.org <mailto:DHass@stanfordmed.org>



"Sloan, Steve"
<steve.sloan@cpspharm.com>
>

09/10/2008 09:27 AM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Board of Pharmacy

Dear Ms. Cates,

This is intended to state our concerns about proposed compounding regulations by the Board of Pharmacy. The proposed regulations do not take into consideration emergency situations where the additional logging and labeling requirements will be burdensome and cause delays in therapy. Our position, and that of the California Society of Health-System Pharmacists, is that these requirements do not improve patient safety because the dose is administered immediately after compounding. Please make an exception for emergency use.

Karen Nishi
Director - Regulatory Affairs
3750 Torrey View Court
San Diego, CA 92130
858.617.5966 tel
karen.nishi@cardinal.com

2008 SEP 15 PM 5:28



September 12, 2008

California State Board of Pharmacy
Attn: Ms. Karen Cates
1625 North Market Boulevard
N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

RE: 16 CCR § 1735.3 Records of Compounded Drug Products - Proposed Compounding Regulations; Request for Comments

Dear Ms. Cates:

Cardinal Health commends and supports the Board of Pharmacy for their efforts to improve patient safety by strengthening the regulations surrounding compounding. We would like to offer our comments and suggestions regarding the proposed regulations for pharmacies that compound and provide sterile injectable preparations. We appreciate the efforts of the Board of Pharmacy committee who wrote the initial draft of the proposed rules and we have attempted to use the framework they created in making our suggested changes to the rules.

Suggestions for changes to the general language:

Since the proposed regulations are for compounded medications, we believe the term "expiration date" should be changed to "beyond use date" to better track with the language used by the United States Pharmacopeia (USP) and the Joint Commission.

References to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be updated to the Joint Commission.

The National Institute for Occupational Safety and Health (NIOSH) and the Joint Commission often refer to "cytotoxic agents" and "chemotherapy" as "hazardous drugs".

16 CCR § 1735.3 – Records of Compounded Drug Products

This section details the pharmacy record requirements for each compounded drug product. The section does not differentiate between routine scheduled drug products and those injectables prepared for stat or immediate use. We would agree that information such as the master formula, the date compounded, identifiers of who compounded and checked the product, as well as the quantity of each component are essential. However, documenting data elements indicating the supplier, lot number, equipment used, assigned pharmacy reference number and "expiration date" may slow the preparation and delivery of emergency medications. The latest USP Chapter 797 has a special section related to "Immediate Use Compounded Sterile Products" which supports the distinction from a scheduled administration. We believe the Board could follow the same path as USP 797 by delineating fewer record keeping requirements for injectables prepared for immediate patient administration.

We would like to suggest the following provision be added to the proposed regulations:

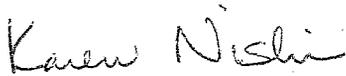
§ 1735.3 Records of Compounded Drug Products

(e) Immediate use injectable products needed for stat or emergency patient administration will be exempt from 6-9 above.

By recognizing the difference between a stat life saving administration and a non-urgent one, pharmacists can provide the appropriate patient care and comply with the necessary record keeping requirements.

If you have any additional questions, please feel free to contact me at (858) 617-5966 or e-mail at karen.nishi@cardinalhealth.com. On behalf of Cardinal Health, we thank you for considering our comments and the efforts the Board has made in drafting the proposed regulations.

Sincerely,

A handwritten signature in cursive script that reads "Karen Nishi".

Karen Nishi
Director of Regulatory Affairs

cc: Jack Coffey



"Miller, Ray - SFMH"
<Ray.Miller@chw.edu>
09/15/2008 05:39 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>, "Yee, William - SJMC"
<William.Yee@chw.edu>
bcc
Subject Proposed Compounding Regulations

Dear Ms. Cates:

The CSHP has alerted hospital pharmacists that the BOP is considering amending the California Code of Regulations by adding and/or amending sections 1735 thru 1751.8 of Division 17 of Title 16.

A careful reading of the proposed language does not make it clear to me whether it is the intention of the BOP to include hospital pharmacies who compound admixtures for immediate use on inpatients in these changes. The proposed self assessment that was distributed is titled "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" which implies that it is not intended for hospitals that are accredited by TJC.

Please make sure that the language of these revisions makes it clear that hospital pharmacies accredited by TJC are not bound by these provisions. Although, we comply with many of the quality initiative suggested, the volume of work done in a hospital, as well as the immediate nature of our work would make it difficult to comply with any requirement that every ingredient's lot number, manufacturer etc. be recorded.

Thank you for your consideration.

Ray Miller, Pharm. D.
Director of Pharmacy
St. Francis Memorial Hospital
900 Hyde Street
San Francisco, Ca 94109
(415) 353-6451



"Hendrick, Lynn"
<Lynn.Hendrick@chomp.org>

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

09/16/2008 10:26 AM

bcc

Subject Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Lynn Hendrick, PharmD

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
Confidentiality Notice:

This is a transmission from Community Hospital of the Monterey Peninsula. This message and any attached documents may be confidential and contain information protected by state and federal medical privacy statutes. They are intended only for the use of the addressee. If you are not the intended recipient, any disclosure, copying, or distribution of this information is strictly prohibited. If you received this transmission in error, please accept our apologies and notify the sender.

Thank you.



CALIFORNIA SOCIETY OF
HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

September 16, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications. However, CSHP has concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only

for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, *CSHP requests all proposed additional pharmacy record requirements be exempted from the pharmacy records. CSHP also requests an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.* CSHP believes that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. CSHP hopes the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate Bryce Docherty at (916) 446-4343.

Respectfully,



Dawn Benton
Executive Vice President, CEO

cc. Bryce Docherty



"Hayashi, Joanne S"
<Joanne.Hayashi@chomp.org>

09/16/2008 12:54 PM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful. It may also compromise patient safety since the focus will be shifted from the real task at hand - safe, aseptic compounding of CSPs to the task of record keeping!!

Thank you for your consideration,

Joanne Hayashi, PharmD

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula
Confidentiality Notice:

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Thank you.



"Chopyk, Rob"
<Rob.Chopyk@chomp.org>
09/16/2008 02:07 PM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

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Thank you for your consideration,

Rob Chopyk RPh
Clinical Pharmacist
Community Hospital of the
Monterey Peninsula
(831) 625-4905

8-27
North Coast Society of Health-System Pharmacists



C/O

Michael W. Sanders, Chapter President
128 Alderbrook Drive
Santa Rosa, CA 95405-4602
(707) 545-0742

September 15, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

RE: Proposed changes to 16-CCR 1716.1 and 1716.2

Dear Karen,

On behalf of the members of our C.S.H.P.-affiliated chapter, I wish to voice my objection to certain language changes or omissions pertaining to your proposed revisions to these regulations.

Health system pharmacies, especially in hospitals, must prepare numerous 'stat' or 'now' compounded IV and other products for acutely ill patients. Without exempting immediate or one time use compounded products from §1735.1, Compounding Definitions, the board is placing unreasonable and unnecessary recordkeeping and labeling requirements on already overburdened health care systems in California.

We pharmacists and pharmacy technicians of the North Coast Chapter of C.S.H.P. therefore ask you to rescind these regulatory changes without first making accommodation for immediate and one time use compounded products. Your affirmative action in response would be much appreciated.

Michael W. Sanders, Pharm.D. President, North Coast Society of Health-System Pharmacists
CC: 1) Board of Directors, 2) CSHP, 3) File



"Yi, Man"
<Man.Yi@chomp.org>
09/17/2008 09:10 AM

To <karen_cates@dca.ca.gov>
cc <philip@cshp.org>
bcc
Subject Proposed changes for medication compounding

September 17, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
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"I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

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I totally agree with my colleague's concerns above.
Thank you for your consideration,

Man Yi
R.ph, MS.
Clinical Pharmacist at the Community Hospital of the Monterey Peninsula



"Fukano, Robert"
<Robert.Fukano@chomp.org>
>

09/17/2008 03:08 PM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

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In addition, there are dozens of hospital in California without 24 hour pharmacy services in which nurses are compounding and mix intravenous products

without the aid of any sterile preparation area or laminar flow hood/biological safety cabinet. Why the separation of record-keeping of pharmacy-prepared versus nurse-prepared or physician-prepared (thinking of anesthesiologists who prepare medication in the operating room)?

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration.

Robert M. Fukano, PharmD
Intensive Care Unit/Critical Care Unit Clinical Pharmacist
Community Hospital of the Monterey Peninsula
Monterey, California



"Berger, Alex \(\OCH\)"
<AlexBerger@dochs.org>
09/18/2008 09:48 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Action Requested: New Compound Sterile Injectable
Products Regulations

Hello Karen Cates,

This is a TERRIBLE new regulation that will jeopardize patient's care! We do not have time to for more documentation when an IV medication is needed STAT. STAT means medication is needed now, or the patient will die.

This regulation should exempt IVs for immediate /STAT administration.

Alexander Berger,

Staff pharmacist O'Connor Hospital, San Jose



"Jones, Kimberly J"
<Kimberly.Jones@chomp.org>

09/20/2008 11:00 AM

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

bcc

Subject: Proposal for medication compounding

September 20, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Kimberly Jones, PharmD

Clinical Pharmacist at the Community Hospital of the Monterey Peninsula

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Thank you.



"Naidu, Dharma R"
<Dharma.Naidu@chomp.org>

To <karen_cates@dca.ca.gov>

cc <philip@cshp.org>

09/24/2008 07:28 AM

bcc

Subject FW: Proposed changes for medication compounding

September 16, 2008

Dear State Board of Pharmacy and Karen Cates,

I have reviewed the proposed changes to regulations for medication compounding, including:

- * Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
 - * Labeling must include a statement that the product was compounded by the pharmacy; pharmacy reference number or lot number must be provided for each dispensed IV.
 - * Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
 - * Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.
 - * Records of all supplies and ingredients purchased, used or destroyed are maintained.
 - * All records and logs are maintained for a minimum of 3 years.
 - * Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes, methodology of determining expiration dating, etc.
 - * Limits supply to MD offices to 72 hour supply of compounded medications.
- Sterile Injectable Compounding Changes (in addition to those above)
- * Written policies/procedures on disposal of infectious materials and cytotoxics.
 - * Labeling of each compounded product to include route and rate of administration.
 - * Quality Assurance to include sterility testing of any batch prepared products.

I have some serious concerns pertaining to the proposed changes for medication compounding regulations, specifically with IV medications preparation and the urgent needs of some of these medications. I would ask for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.

It is unreasonable to think that every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic and wasteful.

Thank you for your consideration,

Dharma Naidu, Pharm.D

Pharmacy Supervisor

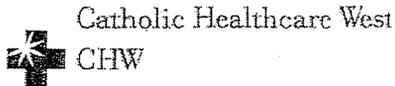
Community Hospital of the Monterey Peninsula

P Please consider the environment before printing this e-mail

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Thank you.



September 26, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

On behalf of 34 of our hospitals in California, Catholic Healthcare West (CHW) appreciates the opportunity to provide comment on the proposed requirements for pharmacies that compound medications. As California's largest non-profit hospital system, we are committed to our mission of providing compassionate, high quality healthcare to all.

While CHW supports the California Board of Pharmacy (Board) for its efforts to strengthen regulations for pharmacies that compound medications, we have serious concerns regarding the new labeling and pharmacy record requirements on certain compounded IV medications, particularly for pharmacies in acute care facilities dispensing one-time and immediate-use (STAT) medications.

Pharmacies in acute care facilities are charged with the timely preparation of emergency compounded medications for the treatment of conditions that require quick treatment and response, such as heart attack, stroke, and other life-threatening situations. These conditions require STAT medications, such as alteplase, epinephrine, or diltiazem for treatment. **CHW is concerned the added documentation requirements will delay preparation and delivery, placing patients at risk for no additional patient safety benefit.**

CHW sees the value of documenting pharmacy reference numbers or lot numbers on the label of each dispensed IV as well as providing additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. However, CHW suggests this information is not useful when the medication is dispensed on a one-time, immediate-use basis. **CHW urges the Board to exempt one-time, immediate-use sterile products in the final regulation, including the requirement to provide:**

- The manufacturer or supplier and lot number or each component;
- The equipment used in compounding the drug product;
- The pharmacy assigned reference or lot number for the compounded drug product;
- and,
- The expiration date of the final compounded drug product.

There is some president to exempting STAT products from pharmaceutical regulations. In fact, in the recently updated United States Pharmacopeial Convention (USP) Chapter 797, there is a section related to *Immediate-Use Compounded Sterile Products*. In this section, these types of products are considered under separate requirements because they are used in situations where there is a need for emergency or immediate patient administration of a compounded product.

Finally, CHW is concerned the minimum 3-year record retention policy is unrealistic, considering the hundreds or thousands of products compounded daily, whether STAT or non-urgent. **CHW requests this timeframe be reevaluated and take into account common record retention policies.**

Thank you for your consideration of these comments. Please feel free to contact me at (916) 851-2007 or via email at Clara.Evans@chw.edu.

Respectfully,



Clara E. Evans
Director, Public Policy & Fiscal Advocacy

Board of Pharmacy
Attention: Karen Cates (Proposed compounding regulations)
1625 Market Blvd. N219
Sacramento, Ca 95834

September 27, 2008

Dear Board of Pharmacy,

I am writing as a pharmacist with a 27-year history in the practice of Hospital Pharmacy. I am writing to pass along my strong opposition to your proposed compounding regulations, which, if not edited or clarified would have a significant negative impact on established pharmacy practice.

The standard of practice in hospital pharmacy for preparing IV admixtures is one that has been refined and continually updated by the pharmacy profession. Most recently, the extensive changes of the USP 797 requirements have further defined and altered the hospital pharmacy practice of preparing IV admixtures. The major problem with the proposed regulations by the Board of Pharmacy is the definition and distinction of what is considered a compounded item. It is my strong belief, and one I believe is shared by anyone in the hospital pharmacy profession, is that IV admixture preparation practice should be not bundled in with compounded prescriptions, such as topical, oral, or injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider.

The most significant problem is with regulations 1735.3 and 1751.1 – the proposed recordkeeping regulations and they should NOT be passed. If the regulations are passed as proposed, and the intent is to apply it to all IV admixtures prepared in a hospital pharmacy environment, it would be a recordkeeping nightmare. The majority of IV admixtures prepared in the hospital setting fall within the low to medium risk category as well defined and described by USP 797. If for every IV admixture prepared the Board would expect to see LOT #, manufacturer, equipment used, personnel identity, pharmacist identity, pharmacy lot number, expiration dating, quantity, etc as described in 1735.3, the treatment of acutely ill patients would be at risk. Even in a small, rural critical access hospital we often mix over 100 IV admixtures in a day. In a larger institution, this number would be 10-20 times higher and the recordkeeping requirements, which the regulations imply, would be overwhelming and create an enormous burden on pharmacy professionals. Furthermore, I believe this extensive recordkeeping would not significantly improve medication or patient safety.

I strongly recommend that you **do not pass** the proposed regulations as they are currently written and you evaluate the intent of the regulations for all aspects of professional pharmacy practice. Specifically, please consider the recommendations and consultation of pharmacy professionals within hospital pharmacy practice and how the “sterile compound” regulations pertain to the practice of IV admixture services.

In addition to the above considerations, please reconsider the language of 1751.5, 1751.6 and 1751.7. It would seem prudent to follow the practice guidelines for USP 797 in the areas such as training, cleaning, garbing, and quality assurance as these standards have reviewed by a group of nationally recognized individuals.

Thank you for your consideration of this letter.

Sincerely,

Lois F. Leister, RPh, M.S., M.B.A.
Practicing hospital pharmacist, Member of CSHP
29930 Sherwood Road
Fort Bragg, CA 95437
Email lfander@mcn.org



"David F. Elder"
<DElder@skdh.org>
09/29/2008 02:40 PM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Compounding Regulations

To The California Board of Pharmacy:

I agree with CSHP's concerns below. We already keep adequate records of compounded items in our logs. Items that must be used immediately in a code or other emergency are also documented adequately on the patients profile.....keeping records for 3 years and generating all the policies required below is not necessary, since compounding skills already are defined and this is tedious work that does not do anything to protect the patient, rather, all the labeling will adversely affect our patients. In addition to CSHP's concerns, I have placed my comments below. I also agree with the concerns of CSHP in addition to mine!

Thank you for considering my point of view. I do not agree with the Board on this issue.

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.
Reedley, CA 93654
(559) 638-8155 Ext. 334
(559) 637-7556 (FAX)
(559) 707-5143 (CELL)
delder@skdh.org

All compounding (each prescription vial/product or IV medication)

- Master formula must be in writing and to include QA required and expiration date requirement for each product compounded.
- Labeling must include a statement that the product was compounded by the pharmacy; **pharmacy reference number or lot number must be provided for each dispensed IV.**
- Chemotherapy labeling must include "Chemotherapy - Dispose of Properly"
- **Pharmacy Logs must include date, personnel, each ingredient (drug, dose, manufacturer and lot #), equipment used, pharmacy reference or lot number, expiration date, quantity, etc. for each compounded product.**
- Records of all supplies and ingredients purchased, used or destroyed are maintained.
- **All records and logs are maintained for a minimum of 3 years.**
- **Written policies/procedures reviewed annually and to include procurement of ingredients/supplies, methodology of compounding, personnel training, competency, equipment/facilities, cleaning, quality assurance, recall process, communication of changes,**

methodology of determining expiration dating, etc.

- Limits supply to MD offices to 72 hour supply of compounded medications.



Sterile Injectable Compounding Changes (in addition to those above)

these

items are already being done or are written in existing policies and on labels etc. This is just un-necessary duplication.....

- **Written policies/procedures on disposal of infectious materials and cytotoxics.>>>>>>***
- **Labeling of each compounded product to include route and rate of administration.....***
- **Quality Assurance to include sterility testing of any batch prepared products.....***

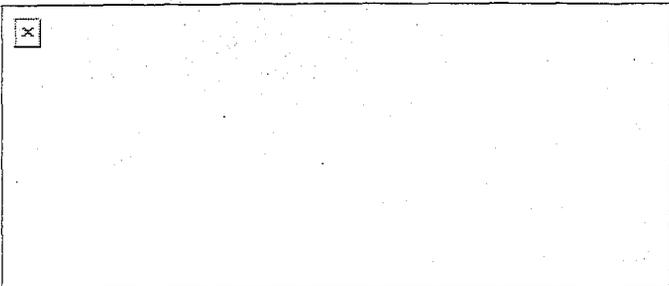
CSHP has concerns with the above underlined and bolded language as it pertains to IV medications and the urgent needs of some of these medications. **We have asked for an exemption of logging and pharmacy lot number assignment/labeling for those "immediate use" products as defined by USP. These products are needed urgently and there is a potential of delay with the additional record keeping requirements with no benefit to the patient. Any future recall of product would be moot as the IV would be already administered as an immediate-use.** Unfortunately, our concerns were not heard by the Board of Pharmacy and the proposed regulations have been posted without change. This means every STAT alteplase, epinephrine, diltiazem or other life-saving medication prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

In addition, for all products, whether STAT or non-urgent, extensive recordkeeping would be required for each product prepared and maintained for a minimum of 3 years. Considering the hundreds (or in some larger hospitals, thousands) of records daily that would be generated to meet the requirement, the proposed method for recordkeeping and maintaining records for 3 years is unrealistic.

This is just not necessary or practical???? Why would we want these fire hazards around so long, when we already generate enough flammable material in our storage areas????

David Elder, PharmD
Director of Pharmacy Services
Sierra Kings District Hospital
372 W. Cypress Ave.

Reedley, CA 93654
(559) 638-8155 Ext. **334**
(559) 637-7556 (FAX)
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delder@skdh.org



*12401 Washington Boulevard
Whittier, California 90602-1099
(562) 698-0811
Hearing Impaired TDD (562) 696-9267*

September 30, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, California 958834

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Herold:

I have commended and supported the California Board of Pharmacy for their previous and current efforts to strengthen the regulations surrounding pharmacists that compound medications. However, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to compounded IV medications in acute care hospitals.

In the past, there has always been a clear distinction between prescription compounding and manufacturing. Trying to apply manufacturing practices to an acute care setting can seriously jeopardize the hospital pharmacist's ability to respond to the acute needs of their patients. Clearly, the workflow process to manufacturer in bulk versus the compounding of sterile products for individual patient prescriptions are distinctly different in their response time and the need for timely administration to the patient.

I would highly recommend that the Board accept the recommended changes of the California Society of Health-System Pharmacists or create a working group of practicing hospital pharmacists and create a safe and workable process that will insure the ability of the hospital pharmacists to be responsive and responsible to safe guarding the protection of the patient. Creating regulations that mandate the same practice in all pharmacy practice arenas does not serve the specific needs of all of our patients.

If you have any questions, please do not hesitate to contact me at (562) 698-0811, Extension 2804.

Respectfully,

Alan Y. Endo, Pharm. D.
Pharmacy Director
RPh 27276



MNikuta <mnikuta@aol.com>

To karen_cates@dca.ca.gov

09/30/2008 08:03 AM

cc

bcc

Subject Proposed Requirements for Pharmacies that Compound Medication

I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*; such as alteplase, epinephrine, or diltiazem for treatment. I am concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I fail to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. Such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

Sincerely,

Mary Noud-Ikuta, PharmD

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Virginia
Herold/Pharmacy/DCANotes
09/30/2008 11:50 AM

To "Annie Sodergren" <anne_sodergren@dca.ca.gov>
cc
bcc
Subject Fw: BOP Compounding Reg Statement Letter - 9-15-08

Sent from Blackberry
Virginia Herold

"Harold Mathis"

----- Original Message -----

From: "Harold Mathis" [hmathis@tds.net]
Sent: 09/30/2008 11:47 AM
To: <Virginia_Herold@dca.ca.gov>
Subject: BOP Compounding Reg Statement Letter - 9-15-08

September 10, 2008

Virginia Herold

Executive Officer

California Board of Pharmacy

1625 N. Market Blvd N219

Sacramento, California 95834

Virginia_Herold@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

The following message accurately outlines a vital error / misunderstanding of the emergency practice of pharmacy in the acute hospital. Delays mandated under the proposed legislation WILL CAUSE LOSS OF LIVES!

Harold Mathis, Consultant Pharmacist, former Director of Pharmacies – Mercy Hospital, Denver, Colorado, Former Chairman of the Committee to Revise Pharmacy Regulations, Colorado.

Dear Ms. Herold:

The California Society of Health-System Pharmacists (CSHP) commends and supports the California Board of Pharmacy (board) for their previous and current efforts to strengthen the regulations surrounding pharmacies that compound medications. However, CSHP has concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direst of patients.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. CSHP members are concerned that the added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

CSHP fails to see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. CSHP believes that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done

before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products as the immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, *CSHP requests all proposed additional pharmacy record requirements be exempted from the pharmacy records. CSHP also requests an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.* CSHP believes that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. CSHP hopes the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

Founded in 1962, CSHP is a professional society representing more than 4,000 pharmacists, pharmacy technicians, and associates who serve patients and the public by promoting wellness and the best use of medications. CSHP members practice in a variety of organized health care settings including, but not limited to hospitals, integrated healthcare systems, clinics, home health care and ambulatory settings.

If you have any questions, please do not hesitate to contact me at (916) 447-1033 or CSHP's Legislative Advocate Bryce Docherty at (916) 446-4343.

Respectfully,

[IMAGE]

Dawn Benton

Executive Vice President, CEO

cc. Bryce Docherty

David Green



- header.htm



"Bryan Carlson"
<BCARLSON@childrenscentr
alcal.org>

10/01/2008 06:55 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject : Title 16. Board of Pharmacy Comments

To the California Board of Pharmacy,

Concerning the proposed changes beginning with Section: 1716 Requirements for Pharmacies that Compound Medications, Children's Hospital of Central California Pharmacy Department would like to make the following comments. In order to accommodate the changes being made to the pharmacy law, we feel that a phase in period of 12 months be considered. This time would allow for the necessary budget and process changes to be made. Although the Board of Pharmacy feels that these changes will have little fiscal impact on pharmacy practice, we feel differently. With all of the regulations that we are currently facing from the DEA, DHS, JCAHO, USP797, and the Board of Pharmacy, simply reviewing and coordinating them can be a costly venture both on time and finances.

Secondly, we suggest placing some of the burden back on the manufacturing community. Standardization of barcoding technology to include lot numbers and expiration dates along with the NDC would facilitate the record keeping process.

Lastly, we would like clarification on what is meant by "equipment" in Section 1735.3 subsection (a) (7). Are you asking that every lot number of every syringe and every needle used in the compounding process be documented and stored? Please clarify your intent on this item as we feel that this would be very difficult to comply with.

We, as a Children's Hospital, already have a very complex system to manage. As regulations add to the complexity, risk for error increases. Although we agree that pharmacy practice needs to be monitored and regulated, please consider the comments of CSHP and others when making your decisions. We cannot delay or negatively impact patient care just to comply with a regulation that was not well thought out.

Thank you for your time and consideration.

Pharmacy Department
Children's Hospital Central California
9300 Valley Children's Place
Madera, California 93636-8762
(559) 353-5504

To: Karen Cates
California State Board Of Pharmacy

From: Margaret Bradshaw, R.Ph.
PO Box 836
Albion, Ca 95410
bradshaw@mcn.org

Re: Comments on Proposed Regulation: Requirement for Pharmacies that Compound Medications

I would like to take the opportunity to comment on the proposed regulations entitled Requirements for Pharmacies that Compound Medications. I am a pharmacist practicing in a small rural hospital. I have been a pharmacist for 35 years and I have practiced in both large and small hospitals and in retail settings. I am drawing on my experience as a pharmacist in these practice settings as well as my examination of the requirements of USP 797 to make the following comments and suggestions.

The stated purposes for the proposed regulations are to define certain terms when used in referring to compounding, and to establish parameters for general compounding including the requirement for a quality assurance program. The regulations as proposed attempt to set forth a single set of regulations that cover both general compounding and sterile compounding for use in a variety of settings. These products may be self administered by a patient, administered by an independent practitioner, or administered by personnel in an institution or under the control of an institution where the compounding pharmacy is located. Pharmacy practice has become so complex that these examples represent only a few of the possible sites where we provide pharmaceuticals. I question the feasibility of having one set of regulations to govern both general compounding and sterile preparations compounding. It is also not feasible to attempt to cover all types of compounding without making specific regulations that would account for the specific needs that one would encounter in a given practice site. The attempt to cover all practice sites with a single set of regulations, without recognizing the inherent differences in the services provided, or the populations served, will result in a set of regulations that is incomplete, ambiguous and unduly burdensome.

The highest priority of the Board of Pharmacy as stated at Section 4001.1, Article 1, Chapter 9 Div: 2 of the Business and Professions Code, is the protection of the public. This can be achieved by providing pharmacy practitioners with a clear, unambiguous statement of the regulations.

In order to comply with the regulations, practitioners must have notice of the requirements. The proposed regulations do not give practitioners notice of the requirements. It is stated in the Factual Basis in the Initial Statement of Reasons for the proposed regulations that: "An inspector conducting an inspection is frequently asked questions regarding aspects of the inspection as well as clarifications and requirements of pharmacy law." Obviously, there is confusion about the various provisions of the existing pharmacy law and regulations. The new regulations do not clarify any of the ambiguities. It is my understanding that the inspectors have the authority to inspect facilities, not to interpret the law (See 4008, Business and Professions Code, Art. 1, Ch. 9, Div. 2). A clear statement of the regulations would give for proper notice, simplify the self-assessment process and provide uniformity in the inspection process.

It is my understanding that all sterile compounding is subject to the provisions of USP 797. Is it the intent of the Board to exempt California pharmacies compounding sterile preparations from the provisions of USP 797 that differ from the proposed regulations? If not, would it serve the Board's purpose to adopt the provisions of USP 797 as the rules, which would govern sterile compounding in California? Although USP 797 is very detailed, it has been thoroughly vetted by sterile compounding experts in the pharmaceutical community. Adoption of USP 797 would serve the purpose of protecting the public, and providing a clear unambiguous statement of the law that would give practitioners notice of the expectations of the law. It would also provide a reasonable

alternative to the proposed regulations as written. Since pharmacies compounding sterile preparations are subject to USP 797, it would not result in an additional financial impact. The impact on patient care must be weighed against business impact. The regulations as proposed would have a significant impact on patient care in hospitals:

The underlying data referred to in the Initial Statement of Reasons was reported in workgroup meetings, the last of which occurred in January 2005. A significant amount of discussion has taken place in the pharmaceutical community about compounded sterile preparations since that last meeting. The current USP 797 regulations are a result of that discussion. Below, I have detailed specific sections of the proposed regulations that I believe are problematic.

Compounding Definitions

Many terms used throughout the body of the regulations have definitions that relate specifically to compounding. These terms should be defined. For example, the terms designated area, critical area and controlled area are all used when referring to sterile compounding.

Compounding Limitations and Requirements Sec. 1732.2

(a) The requirement that the prescriber approve use of a compounded drug either orally or in writing. Does this apply to chart orders? It is understood that most parenteral medications are compounded sterile products.

(h) Determining a beyond use date might also be determined by the nature of the compound. Evidence stronger than professional judgement of the pharmacist should be required. A requirement that the compounding provisions of USP 795 should apply could be added. The expiration or beyond use dating for compounded sterile preparations depends on both stability and sterility concerns. This should be stated.

(i) The pharmacist performing or supervising compounding, may not be the same pharmacist responsible for delivery of a compounded drug product. These activities may be performed by different individuals.

Records of Compounded Drug Products 1735.3

(a) Requiring the maintenance of these records for compounded sterile products administered in the hospital inpatient or outpatient setting would be unduly burdensome. These products are used if not immediately, then in a very short period of time thereafter. Except for batch prepared items, the detailed records this section would require offer little value.

(b) Would this require pharmacies compounding sterile products to maintain records of the acquisition of all sterile medications that are used to prepare sterile products, including IV solutions, and any medication that might be added to an IV solution? Would a hospital pharmacy performing minimal general compounding for an inpatient be required to keep records of items that might not have been purchased with the intent to use those items for compounding?

Labeling of Compounded Drug Products 1735.4

This section refers to Sec. 4076. Section 4076 (B) states that the paragraph applies to outpatient pharmacies only. Does Section 1735.4 refer to outpatient dispensing? Labeling requirements for sterile compounded preparations for administration in a hospital should have certain exemptions.

Training of Compounding Staff 1735.7

This section does not provide any guidelines about what is considered minimum skills, training or competency or competency assessment. As such, the determination of the sufficiency of the training or competency assessment would be left entirely to the inspector.

Article 7 Sterile Injectable Compounding

As stated before, I believe that adoption of USP 797 would provide the regulation of sterile compounding in California that the Board is attempting to achieve.

Compounding Area

The definition of a compounding aseptic barrier isolator should be added to Sec. 1751 concerning the compounding area.

USP 797 now requires certification of the ISO 5 compounding workstation twice a year in addition to other specified occasions. The proposed regulations require an annual certification with no requirement for recertification if the equipment is removed from service for repair or relocated.

Sterile Injectable Labeling Requirements 1751.2

(d) In addition to agents used in chemotherapy, NIOSH and OSHA have designated a group of agents as hazardous drugs. These agents are subject to special handling guidelines. The pharmacy regulations do not address hazardous drugs. Not all hazardous agents are used as chemotherapy. They can be used for a variety of other conditions. Proper handling, labeling, and disposal are important both for sterile compounding and general compounding. The regulations should address this topic.

Sterile Injectable Policies and Procedures 1751.3

Most of the requirements of (d) should apply to all sterile injectable compounding, not just to sterile compounding from one or more non-sterile ingredients.

Facility and Equipment Standards for Sterile Injectable Compounding 1751.4

The proper attire required in (b) should be specified.

(d) The weekly cleaning schedule specified conflicts with USP 797 in the pharmacies compounding only low and medium risk preparations are only required to clean monthly.

(e) The use of a compounding aseptic isolator for preparing parenteral cytotoxic agents should be allowed.

Sterile Injectable Compounding Attire 1751.5

This section specifies attire for personnel preparing cytotoxic and compounding from non-sterile ingredients. This section should be rewritten to cover all sterile compounding except for immediate use preparations.

The regulations do not adequately address the issue of protecting either compounding personnel or the public from unintended exposure to hazardous agents including chemotherapy. This should be included in the new regulations.

(5) The gloves used for sterile compounding should be more than gloves made from low shedding material. If not sterile gloves, then at least latex or nitrile gloves should be specified. Gloves that are ASTM rated for chemotherapy should be specified for personnel preparing cytotoxic agents.

Training of Sterile Injectable Compounding Staff

The requirements listed in (e) (1) A-H should be required of all personnel compounding sterile preparations.

These regulations will have a significant impact on the practice of pharmacy, especially in hospitals. This could be the opportunity for the Board to clarify some of the confusion with the existing regulations. This is the time to answer the questions and concerns of pharmacy practitioners. The vagueness and ambiguity of the regulations do not provide proper guidance to pharmacy practitioners.

I have only addressed some of the issues I find with the proposed regulations. I would be happy to discuss any of these with you.

Thankyou,

Margaret C. Bradshaw

October 2nd, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834
Karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates:

As an ED clinical pharmacist, I have concerns regarding sections of the proposed compounding regulations that pertain to new labeling and pharmacy record requirements with regard to certain compounded IV medications that would inevitably delay treatment to the direct of patient care.

It is common practice for a pharmacy in an acute care facility to prepare emergency compounded medications for the treatment of heart attack, stroke, and other life-threatening situations. Such patients require *one-time and immediate-use (STAT) medications*, such as alteplase, epinephrine, or diltiazem for treatment. Added documentation requirements for both the label and pharmacy log will delay the preparation and delivery of these one-time and immediate-use medications; therefore, placing the patient at risk without any additional benefit to patient safety and care.

I do not see the advantage in delaying treatment for patients with critical conditions to record the pharmacy reference number or lot number on the label of each dispensed IV and the additional information in the pharmacy log when such labeling and recordkeeping requirements are primarily intended to be used in the event of a medication recall. I believe that such information would be obsolete in situations where patients are in need of one-time and immediate-use compounded products as any future recall of these products would be moot as the IV would be already administered to the patient.

As the proposed regulations stand now, every STAT compounded medication with life-saving potential prepared by a pharmacist during cardiac resuscitation, in the emergency department, in the operating rooms, or in other critical care areas would be delayed a few minutes longer to assure logging, assignment, and labeling of the IV bag with a pharmacy lot number.

Exempting immediate-use and one-time sterile products from some regulations has been done before. The recently updated United States Pharmacopeial Convention (USP) Chapter 797 has a special section related to *Immediate-Use Compounded Sterile Products* as the immediate-use provision is intended only for those situations where there is a need

for emergency or immediate patient administration of a compounded product.

As it relates to the preparation of one-time and immediate-use injectable products in acute care facilities, *I request all proposed additional pharmacy record requirements be EXEMPTED from the pharmacy records. I also request an exemption of having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.* I believe that an exemption from additional record keeping requirements would be best to ensure that patients in acute care facilities with one-time and immediate-use needs are treated in a safe and appropriate timeframe.

These exemptions in STAT situations will certainly benefit and prolong patients' lives as they receive compounded medications urgently. I hope the following suggestions will help to meet our shared goal of better and safer patient care, and appreciate the board's willingness to consider our requests.

If you have any questions, please do not hesitate to contact me at (650) 724-2467.

Respectfully,

Carolyn Nguyen, Pharm. D.

ED Clinical Pharmacist, Stanford and Clinics Hospital, Stanford, CA

Phone: 650-724-2467

Fax: 650-725-5028

City and County of San Francisco
Department of Public Health
COMMUNITY BEHAVIORAL HEALTH SERVICES



Mayor Gavin Newsom

Pharmacy Services
1380 Howard Street, Rm 130
San Francisco, CA 94103
Phone: (415) 255-3659
FAX: (415) 252-3036

October 3, 2008

California State Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd, N219
Sacramento, CA 95834

RE: Proposed New Compounding Regulations

Dear Ms. Karen Cates:

As a licensed working California pharmacist, with over 28 years experience in IV medication compounding, I've implemented compliance to USP <797> in multiple pharmacy practice sites for performance improvement and as a quality management function.

The proposed regulations require a "pharmacy reference number or lot number with each dispensed IV". I have strong concerns with this new requirement.

I understand the underlying reason for this new requirement is for the pharmacy to be able to trace back each unit of IV medication to its specific compounding information. **I recommend the regulations state that a pharmacy will be able to trace-back the pedigree (the compounding information) for an IV admixed product rather than prescriptively specifying the method of the trace-back.**

For many pharmacies, information currently on the label would allow for this trace-back. The information includes prescription numbers, patient name, date and time of admixing. Adding the pharmacy reference number or lot number would be redundant information for identifying the pedigree of a compounded product.

Adding this new requirement would require significant amounts of extra work and time. Our pharmacy labor and expense resources are limited and should be used for what is best to ensure quality of services to our patients, not be put redundant extra information on the labels of our dispensed products.

From medication safety standpoint, information on the label should be limited to only what is required for safe dispensing and administering the medication. Adding the lot number or pharmacy reference numbers adds more information to an already busy IV label, increasing the risk of confusion by patients or nurses in administering the

medication. An overload of information on the medication label discourages patients and nurses to verify critical basic information such as patient name, medication name expiration dating and proper storage information.

The proposed regulations 1735.2(a) would require prescribers to specify "the prescriber has approved use of a compounded drug product either orally or in writing". Will this be required for all prescriptions to be compounded including the hospital setting? Would it include prescriptions which can only be dispensed compounded such as an individualized TPN? My understanding of this proposed regulation is that prescribers are required to specify compounding on the prescription, and if not specified, the pharmacist would be required to call to obtain a verbal order. Based on my experience, it would be near impossible for prescribers to be aware and then remember the need to add the compounding specifics to the prescription. I am concerned that this requirement does not add to patient safety but rather would require additional pharmacist time and resources, and cause delays in filling the prescription. I urge the Board to remove this proposed requirement.

Please feel free to contact me for further discussion.

Sincerely,

Gloria Lee Wilder, Pharm.D
CBHS Pharmacy Director
San Francisco Department of Public Health
1380 Howard Street, #130, San Francisco, CA 94103
Gloria.wilder@sfdph.org
415-255-3703

Maria D. Serpa, Pharm.D.
6744 Paseo Del Sol
Elk Grove, California 95758
serpam@sutterhealth.org

October 3, 2008

Board of Pharmacy
Attn: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Regulations - Article 4.5 General Compounding

Dear Ms Cates:

I am very concerned with the sweeping changes proposed to the compounding and documentation of **sterile injectable** products. As I understand it, the California Board of Pharmacy was originally tasked to strengthening compounding practice and safety for **"traditional"** compounding. This area of pharmacy practice lacks specific regulation to adequately protect patients. My concern is that now **sterile injectable** compounding is lumped together with the **"traditional"** form of compounding and this added a layer of regulation is not necessary at this time. Current regulations regarding **sterile injectable** compounding are very specific and detailed from both the United States Pharmacopeia (USP) Convention guidelines at the federal level and current state BOP regulations.

I suggest **sterile injectable** and **non-sterile** compounding be maintained in separate regulations. Current California regulations, Article 7 Section 1751 (Sterile Injectable Compounding) and Business & Professions Code Section 4127 (Injectable Sterile Drug Products) cover the issues related to **sterile injectable** compounding. These current regulations contain the required elements (e.g., facility and equipment standards, policies and procedures, labeling and recordkeeping requirements, training and quality assurance processes) to assure patient safety. In addition, the Board requires additional licensure or accreditation of pharmacies to perform the functions of **sterile injectable** compounding. Changes or additional regulations to these sections are NOT needed.

The requirements for the safe preparation of **sterile injectable** and **"traditional" non-sterile** products are distinctly different. The United States Pharmacopeia (USP) regulates these processes separately in 2 distinct chapters. USP 797 deals with Pharmaceutical Compounding – Sterile Preparations and USP 795 deals with Pharmaceutical Compounding – Nonsterile Preparations.

I am additionally concerned patient care may be jeopardized by the additional documentation requirements suggested for **sterile injectable** compounding if lumped together with **"traditional" non-sterile** compounding. It is common practice for a pharmacy in an acute care facility to prepare emergency medications for the treatment of heart attack, stroke and other life-threatening situations. Currently these STAT, one-time, immediate-use medications are prepared in the pharmacy and labeled with adequate information to assure patient safety and recall should a medication be recalled in the next few hours during administration. Additional record keeping or generation of a pharmacy specific lot number for each injectable product compounded does not serve the patient. It only delays STAT medication preparation and delivery and places an

additional burden on the pharmacy. If changes are planned for sterile injectable compounding, exempting immediate-use sterile products from some of the documentation requirements is prudent to assure patient safety. This has been done before. The recently updated USP Chapter 797 has a special section related to Immediate-Use Compounded Sterile Products.

Thank you for considering these issues. I ask that the Board address the patient safety needs of **"traditional" non-sterile** compounding and move forward on those regulations. This is urgently needed. There is no need to change the current status and regulations for **sterile injectable** compounding.

Respectfully,

Maria D. Serpa, PharmD

October 3, 2008

Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd N219
Sacramento, California 95834

**SUBJECT: PROPOSED REQUIREMENTS FOR PHARMACIES THAT
COMPOUND MEDICATIONS**

Dear Ms. Herold:

This letter is to support the California Society of Health-System Pharmacists position regarding labeling and record keeping exemptions for one-time and immediate-use medications.

I believe that the USP Chapter 797 section on Immediate Use Compounded Sterile Products allows exemptions for emergency or immediate use of a compounded product—in particular in an acute care setting.

As a long time hospital pharmacist, I urge the Board of Pharmacy to grant this exemption, which will be in the best interest of patient safety and quality of care.

Sincerely,

Larry W. Schallock
PO Box 428
San Luis Rey, CA 92068

RPh 25825

RECEIVED BY CALIF
BOARD OF PHARMACY

September 27, 2008

Board of Pharmacy
Attention: Karen Cates (Proposed compounding regulations)
1625 Market Blvd. N219
Sacramento, Ca 95834

2008 OCT -3 PM 4:20

Dear Board of Pharmacy,

I am writing as a pharmacist with a 27-year history in the practice of Hospital Pharmacy. I am writing to pass along my strong opposition to your proposed compounding regulations, which, if not edited or clarified would have a significant negative impact on established pharmacy practice.

The standard of practice in hospital pharmacy for preparing IV admixtures is one that has been refined and continually updated by the pharmacy profession. Most recently, the extensive changes of the USP 797 requirements have further defined and altered the hospital pharmacy practice of preparing IV admixtures. The major problem with the proposed regulations by the Board of Pharmacy is the definition and distinction of what is considered a compounded item. It is my strong belief, and one I believe is shared by anyone in the hospital pharmacy profession, that IV admixture preparation practice should be not bundled in with compounded prescriptions (topical, oral, injectables compounded from non-sterile product or intended for sale or distribution to a patient or provider).

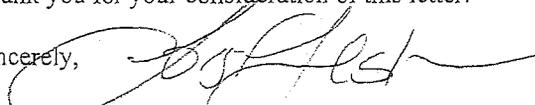
The most significant problem is with regulations 1735.3 and 1751.1 – the proposed recordkeeping regulations and they should NOT be passed. If the regulations are passed as proposed, and the intent is to apply it to all IV admixtures prepared in a hospital pharmacy environment, it would be a recordkeeping nightmare. The majority of IV admixtures prepared in the hospital setting fall within the low to medium risk category as well defined and described by USP 797. If for every IV admixture prepared the Board would expect to see LOT #, manufacturer, equipment used, personnel identity, pharmacist identity, pharmacy lot number, expiration dating, quantity, etc as described in 1735.3, the treatment of acutely ill patients would be at risk. Even in a small, rural critical access hospital we often mix over 100 IV admixtures in a day. In a larger institution, this number would be 10-20 times higher and the recordkeeping requirements, which the regulations imply, would be overwhelming and create an enormous burden on pharmacy professionals. Furthermore, I believe this extensive recordkeeping would not significantly improve medication or patient safety.

I strongly recommend that you **do not pass** the proposed regulations as they are currently written and you evaluate the intent of the regulations for all aspects of professional pharmacy practice. Specifically, please consider the recommendations and consultation of pharmacy professionals within hospital pharmacy practice and how the “sterile compound” regulations pertain to the practice of IV admixture services.

In addition to the above considerations, please reconsider the language of 1751.5, 1751.6 and 1751.7. It would seem prudent to follow the practice guidelines for USP 797 in the areas such as training, cleaning, garbing, and quality assurance as these standards have been reviewed by a group of nationally recognized individuals.

Thank you for your consideration of this letter.

Sincerely,


Lois F. Leister, RPh, M.S., M.B.A.
Practicing hospital pharmacist, Member of CSHP
29930 Sherwood Road
Fort Bragg, CA 95437
Email lfander@mcn.org



"Azama-Kihara, Karen - MSJ"
<Karen.Azama-Kihara@chw.edu>

10/05/2008 09:22 PM

To <karen_cates@dca.ca.gov>

cc

bcc

Subject Against Proposed IV Compounding Regulations

Dear Ms. Cates,

I am writing to let you know I am against the new proposed regulation to require pharmacists to record in a log each IV compounded. I feel there must be exemptions in life threatening and emergent situations. To require a delay in services to log a medication prepared during a cardiac arrest or other emergent situation could be detrimental to the patient. As a former ICU pharmacist who attended many code blues, this would have created unnecessary stress, and would not have provided any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted.

I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank you for taking my concerns for our profession and our patients' safety into consideration.

Karen Azama-Kihara, Pharm. D.
Pharmacy Supervisor
Mercy San Juan Medical Center



"Chan, Gary - MSJ"
<gary.chan001@chw.edu>
10/06/2008 12:33 AM

To <karen_cates@dca.ca.gov>
cc
bcc
Subject Proposed IV Compounding Regulations

October 6, 2008

Karen Cates
California Board of Pharmacy
1625 N. Market Blvd. N219
Sacramento, CA 95834
karen_cates@dca.ca.gov

Re: Proposed Requirements for Pharmacies that Compound Medications

Dear Ms. Cates,

I am writing to let you know that I am strongly opposed to the new proposed regulation to require pharmacists to record in a log each IV compounded. Being a clinical pharmacist working in the different units of a hospital, I am required to attend codes, rapid responses, and cardiac alerts. I do not see a benefit in the new regulation proposed. In fact, I see plenty of harm to the patient if this regulation were actually put in place. There are plenty of instances when these patients require "immediate" and "one time" STAT medications. The new proposed regulation would only hinder our ability to provide quick and safe care for these critical patients at their bedside. This would only create unnecessary stress, and would not provide any added safety benefit to the dying patient.

I am requesting that all proposed additional pharmacy record keeping requirements for the preparation of one-time and immediate use IV products in the acute care hospital be exempted. I am also requesting an exemption from having to record the pharmacy reference number or lot number on the label for one-time and immediate-use IV medications.

Thank for your time and consideration.

Gary W. Chan
Clinical Pharmacist
Mercy San Juan Medical Center



Sutter Lakeside Hospital

To: California Board of Pharmacy
Attention: Karen Cates (Proposed Compounding Regulation)
1625 N. Market Blvd. N219
Sacramento, CA 95834
Fax: (916) 574-8618

I would like to register my professional opinion regarding this proposed change. I am a 1972 graduate of U.C. San Francisco, also completing a clinical residency from U.S.C. School of Pharmacy in 1973. I have been a faculty member of the University of Michigan, U.S.C. and Western University Schools of Pharmacy; I have published articles pertaining to antibiotic therapy, pharmacokinetics, and pharmacy practice. For the last 30 years, my practice has been in acute care hospitals, primarily as a manager & clinical pharmacy practice promoter. During that time I have been either director or assistant director of 13 acute care facilities ranging from 25 beds to 530 beds.

I have seen many positive changes in our practice, witnessed the growth of our profession from a dispenser of medications to a true member of the health care team. I have also seen the barrage of regulations that have obvious good intentions come from various regulatory agencies including the Board of Pharmacy, but do not seem to "connect" in practice. Often the issues are related to inability to decipher the specific intent of the regulations - usually because they are written in legal language, and not in the language of the public nor healthcare. This confusion is reflected by various "interpretations" by individual inspectors of the same regulation. This regulation change is clear!

With respect to the proposed changes, my primary focus is on the requirement for one-time or administered immediately "compounded" preparations. I ask the question, "What is the purpose?" In the event of a recall, even that very day, the medication has been administered & can not be returned to the Pharmacy! To require additional labeling & maintenance of a log seems to be illogical and serves absolutely no useful purpose for the public with respect to safety, nor to the Board of Pharmacy.

I am aware that various official organizations, including CSHP and others, have made similar requests. As a practicing pharmacist, I ask that you strongly reconsider this aspect of the proposed regulatory change and grant an exemption for medications "compounded" for immediate or emergency use.

Thank you for your consideration,
Sincerely,

Ben J Devine, PharmD (RPh 27902)
Director of Pharmacy
Sutter Lakeside Hospital
5176 Hill Road East
Lakeport, CA 95453



American Society of
Health-System Pharmacists[®]
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-664-8892
www.ashp.org

October 6, 2008

Ms. Virginia Herold
Executive Officer
California Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Proposed Regulatory Changes Regarding Compounding

Dear Ms. Herold:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit the following comments regarding the proposed regulatory changes in Article 4.5, Compounding, of the California Code of Regulations. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

Compounding medications is a significant facet of the practice of pharmacy and we applaud the Board of Pharmacy's desire to ensure that patient safety is protected. ASHP also recognizes the importance of developing regulatory language that provides necessary parameters while avoiding potentially significant barriers to providing patient care. As such, having reviewed the proposed regulatory changes, ASHP does have some concerns regarding the labeling and documentation modifications within the proposed regulations.

The proposed regulatory change to labeling is of concern to ASHP. In the United State Pharmacopeial's revised *USP <797>, Guidebook to Pharmaceutical Compounding - Sterile Preparations*, it states that "unless immediately and completely administered...the [compounded sterile preparation (CSP)] shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour beyond-use date (BUD) and time."¹ This revision allows for less stringent labeling, as long as the compounded product meets all of the stated criteria.

Current ASHP practice guidelines recognize that states have the right to require specific labeling. Enclosed is a copy of the guideline's labeling requirements for sterile

¹ *USP <797> Pharmaceutical Compounding - Sterile Preparations*. Revised 2008. Pg. 13.

preparations. These labeling requirements are more detailed than the current USP revision; however, these guidelines specifically exclude the compounding of sterile preparations for emergency treatments from its scope, a vital distinction that we believe is necessary:

“These ASHP guidelines *do not* apply to the manufacture of sterile pharmaceuticals as defined in state and federal laws and regulations, *nor* do they apply to the preparation of medications by pharmacists, nurses, or physicians in emergency situations for *immediate* administration to patients (e.g., cardiopulmonary resuscitation)...It is recognized that, in certain emergency situations, a pharmacist may be requested to compound products under conditions that do not meet these guidelines. In such situations, it is incumbent upon the pharmacist to employ professional judgment in weighing the potential patient risks and benefits associated with the compounding procedure in question.”²

ASHP believes that the compounding of sterile preparations in emergency situations should be governed by the professional judgment of pharmacists and the policies of the institutions they practice in, as those situations demand that health care professionals have the utmost flexibility to decide what is best for the patient. We would, therefore, strongly encourage the Board to reconsider the current proposed language. While labeling requirements during normal events are beneficial to both the pharmacy and the patient, such strict requirements during emergency situations could negatively impact patient care and introduce delays in medication delivery. As currently proposed, the labeling requirement could in fact create the opposite effect than intended – delays in patient care that places patient health and safety in jeopardy.

In terms of the proposed changes to documentation, there may be some confusion as to whether the documentation requirement applies to every product that is prepared, including those for an individual patient, or if the new requirement will apply solely to those products that are prepared in batch for a yet-to-be determined patient. As pharmacies typically do not record such detailed information for patient-specific items, such a proposed regulation could create an extraordinary burden for pharmacies. Further, not only could this new requirement exist for emergency drugs, it could impact all products prepared for routine care. This added documentation requirement has the potential to delay the preparation and delivery of one-time and immediate-use medications. We would urge the Board to consider the potential implications of such a regulatory change.

We appreciate the opportunity to provide these comments and would be happy to work with you as you continue to develop appropriate guidelines and requirements that affect

² American Society of Health-System Pharmacists. ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products. *Am J Health-Syst Pharm.* 2000; 57:1150–69. pg. 54. (available at: <http://www.ashp.org/DocLibrary/BestPractices/QualityAssurance.aspx>)

California State Board of Pharmacy
Proposed Requirements on Compounding
October 6, 2008
Page 3

the pharmacy profession. If you have any questions or comments, please do not hesitate to contact me at 301-664-8687 or gtrujillo@ashp.org.

Sincerely,



Geralyn Trujillo, MPP
Director, State Government Affairs

cc: Philip Swanger, California Society of Health-System Pharmacists

Enclosure

ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products

RL 1.9: Labeling.

Sterile products should be labeled with at least the following information:

1. For patient-specific products: the patient's name and any other appropriate patient identification (e.g., location, identification number); for batch-prepared products: control or lot number,
2. All solution and ingredient names, amounts, strengths, and concentrations (when applicable),
3. Expiration date and time, when applicable,
4. Prescribed administration regimen, when appropriate (including rate and route of administration),
5. Appropriate auxiliary labeling (including precautions),
6. Storage requirements,
7. Identification (e.g., initials) of the responsible pharmacist (and technician),
8. Device-specific instructions (when appropriate), and
9. Any additional information, in accordance with state or federal requirements; for example, a prescription number for products dispensed to ambulatory care, long-term-care, and home care patients.

The label should be legible and affixed to the final container in a manner enabling it to be read while the sterile product is being administered (when possible). Written policies and procedures should address proper placement of labels on containers.

VIA EMAIL

California Board of Pharmacy
Attention: Karen Cates and Virginia Herold (Proposed Compounding Regulation)
1625 N. Market Blvd., N219
Sacramento, CA 95834
virginia_herold@dca.ca.gov
karen_cates@dca.ca.gov

October 6, 2008

RE: Title 16, Division 17 Proposed Changes

PETNET Solutions, Inc., a Siemens Company (DBA PETNET Pharmaceutical), operates specialty compounding nuclear pharmacies preparing solely radiopharmaceuticals for use in Positron Emission Tomography (PET) nuclear medicine diagnostic imaging studies. PETNET operates forty-five PET Nuclear Pharmacies in the US, with four locations in the state of California operating under both retail and sterile compounding pharmacy licenses.

The State of California does not provide unique regulations or significant special requirements for the operation and licensure of Nuclear Pharmacies (Radiopharmacies) in its statutes. Recently, the USP, in their revised Chapter <797>, *Pharmaceutical Compounding, Sterile Preparations*, recognized the significant differences in the nature of the products compounded for use in nuclear medicine and the nature by which such products are compounded. USP Chapter <797> further differentiates the relevant differences in radiopharmaceuticals used in PET from traditional radiopharmaceuticals by deferring most of the requirements in USP <797> to USP Chapter <823>, *Radiopharmaceuticals for Positron Emission Tomography-Compounding*.

The Food and Drug Administration Modernization Act of 1997 (public Law 105-115, FDAMA '97), Section 121, sets the legal requirements for the compounding of PET radiopharmaceuticals in the US. Producers of PET radiopharmaceuticals are legally bound by this law, and FDA currently inspects PET Nuclear Pharmacies for compliance to this law regardless of whether the PET compounding facility is registered as a drug establishment with FDA or not. Ultimately, as stipulated under FDAMA '97, FDA is required to regulate the compounding (production) of such drugs under a specific PET GMP regulation once the regulation is formally adapted into the Code of Federal Regulations in the future. Two years after FDA codifies the PET cGMP regulations in the CFR, FDA will require PET drug producers to register their drug establishments with FDA and to submit Human Drug Applications to the FDA.

Some unique differences between conventional drugs, conventional radiopharmaceuticals, and PET radiopharmaceuticals are:

- They cannot be purchased from a traditional commercial source.
- No radionuclide generators are employed

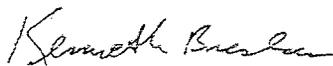
- No pre-manufactured radiopharmaceutical kits are employed.
- The physical half-life of the radionuclides used in PET radiopharmaceuticals ranges from 2 minutes to 110 minutes.
- The radioactive emissions are of very high energy compared with traditional radiopharmaceuticals thus requiring much more rigorous radiation shielding and remote physical handling.
- The radio-labeling of the ligand takes place in situ via an automated chemical synthesis unit utilizing a radionuclide extracted from a cyclotron target after the bombardment of a stable starting isotope. The synthesis module cannot be placed in an aseptic environment.
- Some non-sterile reagents and precursors are used.
- The final products are aseptically processed and sterilized by filtration into a sterile product vial.
- The quality control testing of each batch produced prior to release for patient use is extensive.
- The delivery of the finished radiopharmaceutical is highly time-critical because of the very short physical half-life of the isotopes employed.
- The expiration date is no greater than 12 hours after compounding
- Sterility testing is started when compounded, but the product must be used prior to the completion of the sterility test.

PETNET urges the California Board of Pharmacy to carefully consider the potential impact of their proposed revised regulations on Nuclear Pharmacies and PET Nuclear Pharmacies in light of the special nature of these drugs. PETNET further encourages the Board to avoid regulations that conflict with the requirements of those currently in place in the current revision of the USP Chapters <797> and <823> as applied to radiopharmaceuticals in general, and specifically to compounded PET radiopharmaceutical products.

PETNET suggests that it may be prudent for the Board to exempt the application of any revised sterile compounding regulations to PET drug compounding and stipulate the requirement to comply with the relevant USP chapters until such time the Board proposes and adopts its own regulations pertinent and applicable to radiopharmaceutical and PET radiopharmaceutical compounding

PETNET anticipates having a representative attend the October public hearings on this topic to offer expert input into the Boards rule making activities.

Sincerely,



Kenneth Breslow, MS, R.Ph., FAPhA

CC:

Michael Nazerias
Dwayne Mar
Josh Nutting
Jerry Kuhs

October 6, 2008

Board of Pharmacy
Attn: Karen Cates
1625 N. Market Blvd. N219
Sacramento, CA 95834
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karen_cates@dca.ca.gov

Re: Proposed Compounding Regulation

I am writing in regards to the proposed compounding regulations (starting with Section 1716), specifically the record keeping and labeling requirements.

I am very concerned that these requirements in acute care hospitals with large number of compounded IV medications would be very burdensome. The majority of these compounded IV medications are used within 24 hours, sometimes immediately, after being compounded.

In the acute care setting these compounded IV medications are used by very few patients, sometimes a single patient and for a very limited amount of time. Thus the typical batch compounding issues encountered in an chronic care setting (e.g., Home health or ambulatory care) do not apply.

I would respectfully request that the Board consider an exemption from the record keeping and labeling requirements in acute care facilities for IV compounded IV medications for immediate use.

Sincerely,

Robert Batman, Pharm.D.

Dear State Board of Pharmacy,

This letter is being written on behalf of the 3rd Year Community Pharmacy Management Elective at the University of Southern California School of Pharmacy. As a class project, our students were instructed to conduct a survey of community pharmacies to ascertain whether or not the proposed compounding regulation changes would affect community pharmacies. In contacting 12 random community pharmacies we were surprised that only 2 of the pharmacies were aware of the proposed regulation changes and the balance of pharmacies were unaware of the proposals. The conclusions that our class arrived at from our interview with these pharmacists are the following:

- 1) The regulation seems to hinder access in some unique situations. Particularly, community pharmacies that prepare compounded medications on a limited basis may completely halt their compounding activities due to the cost factors of having to meet the regulatory standards (end product testing, possible purchase of software, etc.). In our opinion, this may limit some pharmacies from changing dosing forms on a patient need basis. It will also make access to this service more limited for the general population. Furthermore, pharmacies that may stop preparing compounded medications have long standing relationships with certain patients that have been receiving their compounded prescriptions from the same pharmacy that prepares their non-compounded prescriptions. These regulations may cause these patients to switch pharmacies, and result in loss of revenue for the pharmacy and the loss of a long standing relationship between a pharmacist and a patient.
- 2) The regulations refer to end-product testing and quality assurance without clearly defining it. Pharmacists that were spoken to seemed to all agree that the proposed regulations do not clearly define issues regarding end-product testing, such as frequency of end-product testing, requirements for record keeping, and which products need to be tested.
- 3) The regulation did not make any distinction between the complexity of compounding and the amount of regulation needed. For example mixing two different products to create a cream or changing a tablet to a liquid dosing form for short term administration should not require as much oversight as complex compounding formula. We feel that this area needs to be further explored.

In conclusion we all agreed that regulations were needed in this area, but there needed to be some criteria for the amount of regulation needed vs. the difficulty of preparing a particular compounded medication. We want to thank you for the opportunity to present our opinion and those of community pharmacists in the Southern California community we interviewed.

Raffi Svadjian Pharm.D, MBA
Co-course Coordinator

Michael J. Rudolph Pharm.D
Co-course Coordinator