



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Enforcement Committee Report

Randy Kajioka, PharmD, Chair
Greg Lippe, Public Board Member
Neil Badlani, Pharmacist Member
Tappan Zee, Public Board Member

ENFORCEMENT COMMITTEE REPORT AND ACTION

The Enforcement Committee will meet July 25, 2011. Agendized items from this meeting will be discussed under subdivisions b and c (below).

- a. **FOR INFORMATION: Presentation by the National Association of Boards of Pharmacy NABP on:**
- 1. Prescription Monitoring Interconnect Program for Controlled Substances,**
 - 2. Pharmacist Assessment for Remediation and Evaluation, and**
 - 3. Update on Other NABP Activities**

ATTACHMENT 1

At this meeting, two NABP representatives will attend the meeting to provide an overview of two new programs and update the board on other NABP activities. Providing this presentation are:

- Josh Bolin, Government Affairs Director
- Scotti Russell, Government Affairs Manager

Copies of the PowerPoint presentation and other discussion materials that will be discussed are provided in **Attachment 1**.

Subdivisions b. and c. will be discussed at the Enforcement Committee Meeting scheduled for July 25, 2011. Action items will be brought to this meeting of the board for consideration and possible action.

- b. **FOR POSSIBLE ACTION: Request for Exemption from 16 California Code of Regulations Section 1707.5, Label Requirements for Prescription Drug Containers, as Authorized by California Business and Professions Code Section 4076.5**

Attachment 2

Status:

At the May Board Meeting, the board tabled the discussion of request from the California Pharmacists Association for an exemption from the requirements for patient-centered labels for

medications dispensed to patients in skilled nursing facilities. The board directed the committee to continue its discussion at the next Enforcement Committee Meeting. This discussion will occur the day before the July Board Meeting.

Background:

Effective January 1, 2011, the board's requirements for patient-centered labels went into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation is provided in **Attachment 2**.

Also effective January 1, 2011, amendments to Business and Professions Code section 4076.5, allow the board to exempt from the labeling requirements prescriptions dispensed to patients in certain environments. The exemptions are provided as subdivisions (d) and (e) below.

SEC. 25.1. Section 4076.5 of the Business and Professions Code is amended to read:

4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

(1) Medical literacy research that points to increased understandability of labels.

(2) Improved directions for use.

(3) Improved font types and sizes.

(4) Placement of information that is patient-centered.

(5) The needs of patients with limited English proficiency.

(6) The needs of senior citizens.

(7) Technology requirements necessary to implement the standards.

(d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

(e) (1) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:

- (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
- (B) The patient receives health-professional-directed education prior to the beginning of therapy by a nurse or pharmacist.
- (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.
- (D) Care is provided under a formal plan of care based upon a physician and surgeon's orders.
- (2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.
- (f) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report. (2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

This law directs that the board "may exempt," so to allow an exemption, the board would need to promulgate regulations.

At the December 2010, March and July 2011 Enforcement Committee Meetings, the committee heard presentations from groups seeking exemption from the labeling requirements for their specialized patient populations. The board has not yet approved a waiver request.

The committee has directed that any exemption request include at least: 1. an explanation as to why the company cannot comply with the new requirements and 2. information regarding policies or procedures in place that address the policy concerns behind the adopted regulations.

At this Meeting:

At this meeting, the board will continue its discussion with pharmacy representatives who serve skilled nursing facilities that seek an exemption to labeling requirements for medication dispensed to patients in skilled nursing facilities.

The specific issue before the board now focuses on: the skilled nursing facility will receive medication that is labeled for a specific patient, in the patient-centered format in 10 point font. However, the exemption sought is that the labeling would not be converted to 12 point font -- even upon patient request -- if the remaining medication is sent home with a discharged patient.

An excerpt from the minutes of the May Board Meeting is provided in **Attachment 2**.

c. DISCUSSION AND POSSIBLE ACTION:

Consider Recommendations by the Committee to Amend the Board's Disciplinary Guidelines at 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse

Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

Attachments 3 and 4

Background

The board has initiated a restructuring and updating of its Disciplinary Guidelines. To incorporate changes to the Disciplinary Guidelines, the board needs to initiate a rulemaking.

As part of this effort, the board has also determined to incorporate the recommendations of the DCA's Substance Abuse Coordination Committee into the Disciplinary Guidelines.

As you may remember, Senate Bill 1441 created the Substance Abuse Coordination Committee (SACC) and required that this committee, by January 1, 2010, formulate uniform and specific standards in specified areas that each healing arts board must use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program. To facilitate implementation of these standards, the DCA created a workgroup in 2009 consisting of staff from each of the healing arts boards to draft recommended standards for SACC consideration during public meetings. There are 16 standards that were developed.

The most recent version of the SACC standards was approved in April 2011. **Attachment 3** contains a copy of the standards in their current form.

In March 2011, a board subcommittee of Stan Weisser and Tappan Zee met in a first step toward incorporating these standards into the Disciplinary Guidelines.

At the May board meeting, the board directed staff to develop regulatory language to modify the disciplinary guidelines to incorporate the SB 1441 standards.

Attachment 4 contains the proposed changes that have been identified and drafted for board consideration for incorporation into the board's Disciplinary Guidelines. This will be the major discussion document for this section of the board meeting.

To ensure the relevance, integrity and value of the Disciplinary Guidelines, Deputy Attorney General Joshua Room has developed the draft of the Disciplinary Guidelines, incorporating three levels of changes (reorganization, Uniform Standards, Board Subcommittee).

It is important to note that several of the Uniform Standards do not fit within this framework and are more policy standards and/or standards of general application, rather than terms that must be negotiated as part of settlement.

The board needs to also discuss these items and determine how it wishes to proceed. Specifically:

- Uniform Standard # 6, which sets up factors the board should consider in deciding whether to send a respondent to inpatient, outpatient, or other type of treatment. The Disciplinary Guidelines do not currently have a term whereby the Board can send a respondent to treatment (PRP handles that, for those in PRP).
- Uniform Standard # 9, which defines a failed drug test as a major violation.

- Uniform Standard # 10, which defines major and minor violations.
- Uniform Standard # 11, which defines the criteria that must be met before a respondent can petition to return to full-time practice.
- Uniform Standard # 12, which defines the criteria that must be met before a respondent can "petition for reinstatement" to an unrestricted license (but is specifically defined as not the APA's petition for reinstatement in the Uniform Standards).
- Uniform Standard # 13 defines standards and specifications for contracts with and requirements of drug testing vendors/contractors.
- Uniform Standard # 14 defines what information about respondents/licensees who are in a diversion program (PRP) shall be publicly disclosed.
- Uniform Standard # 15 sets up auditing requirements for diversion services vendors.
- And Uniform Standard # 16 sets up board reporting requirements to the Legislature.

d. **INFORMATION: Selection of Enforcement Committee Meeting Dates for 2011**

September 15, 2011 -- Sacramento

December 6, 2011 – location to be arranged

e. **FOR INFORMATION: Meeting Planned of the Compounding Subcommittee**

The board has received a request from about 30 hospital pharmacies to discuss and clarify requirements of the board's compounding regulations that took effect January 1, 2010. A meeting for this discussion has been planned for August 23 in Sacramento. Board Members Kajioka and Badlani are members of this subcommittee.

f. **FOR INFORMATION: Review of Enforcement Statistics and Performance Standards of the Board**

ATTACHMENT 5

Attachment 5 contains the board's enforcement statistics as well as the Department's performance standards report for our board.

g. **FOR INFORMATION: Fourth Quarterly Report of the Committee's Goals for 2010/11**

ATTACHMENT 6

Attachment 6 contains the fourth quarter's update report on the committee's strategic plan.



NABP Update

Josh Bolin, Government Affairs Director
Scotti Russell, Government Affairs Manager



PARE

- “Pharmacist Assessment and Remediation Evaluation”
- The purpose of the PARE is to provide a multidimensional assessment that the boards of pharmacy may use as a contributory factor when making decisions regarding pharmacist practice deficiencies that result from disregarding pharmacy practice standards, non-compliance with laws and regulations, and/or threats to patient safety.





PARE (cont.)

- Designed to assess non-entry level competence
- Some possible uses for PARE
 - Pharmacists who may have been out of active practice for some time, either by choice or as a result of a suspension or revocation
 - Pharmacist whose competence is in question due to practice errors or other reasons
 - Pharmacists transferring a license from another state whose competency is in question for some reason
- This tool will continue to evolve depending on how boards want to use it
- Divided into 3 separate and distinct content areas





PARE (cont.) 3 content domains

1. The Practice of Pharmacy and Medication Safety (50%)
 - Safe and effective preparation and dispensing of medications
 - Prevention of medication errors
 - Continuous quality improvement
2. Pharmacist Care (25%)
 - Patient assessment, clinical pharmacology, therapeutics
 - Drug information
 - Promotion of wellness and public health
3. Professional Ethics/Pharmacist Judgment (25%)
 - Professional ethics
 - Decision/Actions affecting patient care
 - Code of ethics, professional behavior





PARE (cont.)

- Exam to consist of 210 items
- 70 questions for each area
- \$250 cost to take the test
- Time allowed to test is still being determined
- Available by 2012
- Volunteer board members needed to participate in the beta testing-beginning soon-we would welcome participation by California board members





Annual Meeting Update

- Executive Committee Elections
 - EC comprised of three officers, eight members, and a chairperson
- This year open officer and member positions: president-elect, treasurer, District 3, District 4, and District 8.
- District 4 and 8 contested
 - District 4: William J. Cover-IN and Sarah St. Angelo-IN (Cover elected)
 - District 8: Jeannine Dickerhofe-CO and Hal Wand-AZ-incumbent (Wand elected)





2011-2012 Executive Committee

William T. Winsley, Chairperson (OH)
Malcolm J. Broussard, President (LA)
Michael A. Burleson, President-Elect (KY)
Karen M. Ryle, Treasurer (MA)

District 1: James Devita (MA)

District 2: Edward McGinley (NJ)

District 3: Mark Conradi (AL)

District 4: William Cover (IN)

District 5: Lloyd Jessen (IA)

District 6: Joe Adams (LA)

District 7: Catherine Lew (OR)

District 8: Hal Wand (AZ)





5 Resolutions (full text on website)

- Full text on website
- New task force on technology, evaluate and recommend changes to the model act to support where appropriate
- New task force to recommend changes to the model act related to pharmacy/pharmacist responsibilities in the prevention, detection, and investigation of drug losses
- Encourage the exploration of new models of care for pharmacists to participate in primary health care
- Support for the development and implementation of the PMP interconnect
- Annual recognition resolution





2010-2011 Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act

- Charge:
 - Review selected provisions of the CSA and accompanying administrative regulations;
 - Identify those provisions that may require review and revision; and
 - Recommend legislative and regulatory changes to amend the CSA and accompanying administrative regulations.





Some CSA Task Force Recommendations

Full report on web site

- Definition changes to include separate definitions for “administer,” “dispense,” and “prescribe and pharmacists included in “practitioner”
- LTCF changes to include definition changes to “agent” and the inclusion of “medical record orders” in the definition of “prescription” to take care of some of the LTC issues with DEA rules and current practice
- Recommendations for changes to prescription elements and allowable changes that could be made by a pharmacist.
- Uniform time limit for validity of all CS prescriptions
- Changes to labeling requirements to allow for focus on patient centered labels
- Remove requirement for pharmacists to transfer prescriptions from database to database





Background on Government Affairs

- Directive of NABP Executive Committee
- Started activities in early 2010
- Launched officially in September 2010





Outreach and Education

- Gain understanding of board of pharmacy in each state
- Emerging pharmacy practice, legal, and regulatory issues
- Unique approaches to regulation
- Needs and challenges





Customized Level of Assistance

- Examination Programs
- Accreditation Programs
- Licensure
- Assessment
- Member Services





Assessment Services

- Operational Processes
 - Licensing
 - Discipline and Compliance
 - Policy
- NABP Programs and Services
- Training and Education
- Legislative and Regulatory Support
- Staffing Recommendation





Compliance-Related Services

- Compliance Officer Training
 - Classroom
 - Live
- Inspection Services
 - Wholesale Drug Distributors
 - Pharmacies
 - Controlled Substance Registrants





Legislative and Regulatory Support

- NABP Model Act
- Legislative/Regulation Tracking
- Written Comment
- Public Testimony





Goals for Government Affairs

- Programs and Services
- Education
- Relationship Building





Interactive Forums

- Executive Officer – September 21-22
- Compliance Officer – December 1-2
- NABP will cover travel costs for one participant from each Board





NABP Interconnect

- Since the mid 2000s, sponsored by the Bureau of Justice Assistance, PMPs and other interested parties have been working toward a solution
- Last year, some of our membership came to us and asked us to try to take their work to the next level and create a system that would facilitate data sharing from state to state





NABP Interconnect

- Does not house or store any Protected Health Information
- Enforces the unique rules of each state against the request
- Allows the states to maintain control over the systems they worked so hard to get enacted and operational





StatePMP

First Name

Last Name

Date of Birth / / 

Zip

States State 1 State 2 State 3





Sample Response Report

StatePMP

Patient Report

Patient

John Doe, DOB 1/11/1970; 123 Main Street, Columbus, OH 43201

Prescriptions

Fill Date	Product	Qty	Written	Rx #	Prescriber	Pharm
4/1/2011	Oxycodone 325 MG-5 Tab	60	4/1/2010	664356	RO SMI	P-5436
4/5/2011	Oxycodone 325 MG-5 Tab	60	4/5/2011	667890	MI THO	P-3489
4/23/2011	Oxycodone 325 MG-5 Tab	60	4/23/2011	661230	JA WRI	P-5467

Prescriber

Robert Smith, 3365 West Main Street, Columbus, OH 43201

Mike Thomas, 4201 Oak Street, New Albany, IN 47150

Jason Wright, 430 Brown Avenue, Cincinnati, OH 45201

Pharmacy

P-5436. Pharmacy 5436, Brooks Street, Columbus, OH 43201

P-5436. Pharmacy 5436, 120 East Market Street, New Albany, IN 47150

P-5467. Pharmacy 5467, 520 Brooks Street, Cincinnati, OH 45201





MOU/Contracting Process

- Programs will contract/enter into an agreement directly with NABP to participate in the NABP Interconnect
- Avoids multiple state-to-state contracts/memorandums of understanding (MOU)
- Allows the hub to handle the “rules reconciliation”
- NABP responsibilities vs. state responsibilities
- States agree to conduct investigations for misuse of information through the hub by their users
- Dispute resolution
- 30-day “out clause”





Cost to Participate

- NABP is absorbing **all costs** associated with the development and implementation of NABP Interconnect
- NABP will cover the costs of the annual base fee to participate in the system
- NABP will cover **annual participation fees for utilization of NABP Interconnect for five years**





Timeline for Implementation

- Development is complete
- NABP is now working with PMP software vendors to complete the relevant interface
- PMPs are beginning to configure their PMP on the PMP Interconnect Administrative Console
- PMPs will begin sharing data later this summer
- More PMPs will be brought online in Q3-Q4





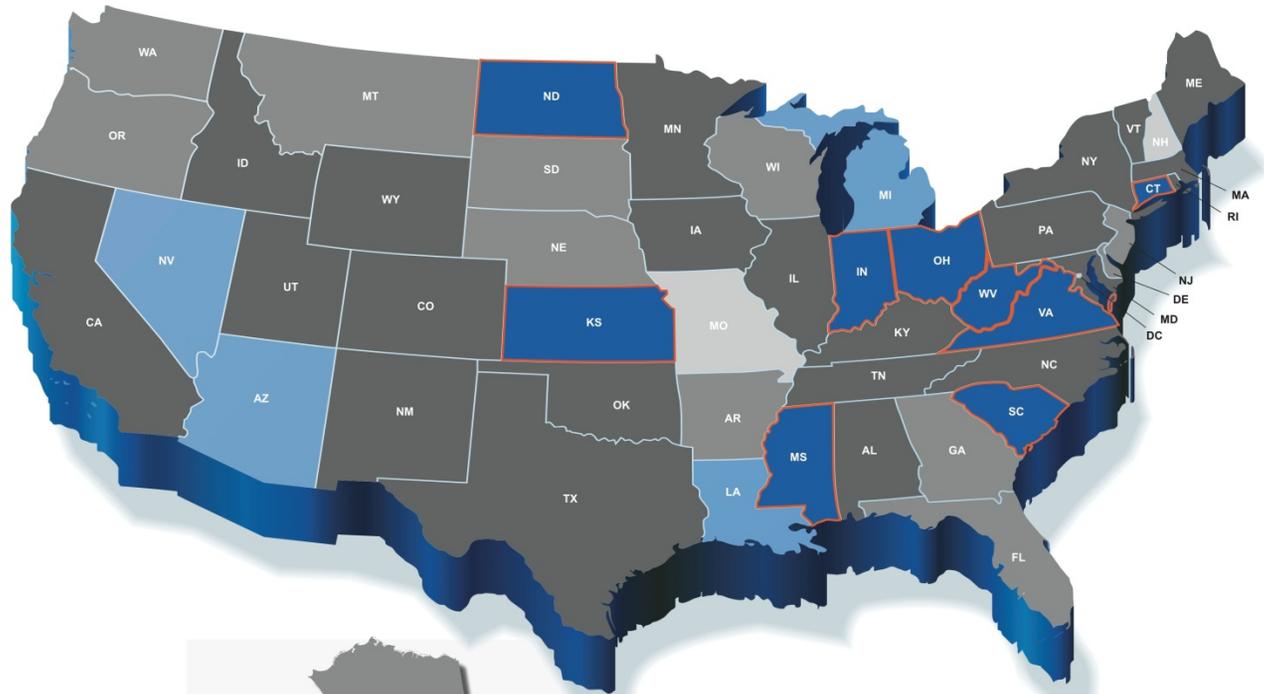
MOU Updates

- 9 MOUs Executed: CT, IN, KS, MS, ND, OH, SC, VA, WV
- 4 MOUs in final review stages: AZ, LA, MI, NV
- 15+ other PMPs have expressed an intent to sign on with PMP Interconnect





NABP PMP Interconnect™



Legend

- NABP PMP Interconnect Participant
- Pending NABP PMP Interconnect Participant
- Future Prospective NABP PMP Interconnect Participant
- PMP Legislation Enacted, No Program in Place
- PMP Legislation Pending





Questions?





Report of the Committee on Law Enforcement/Legislation

Members Present:

Patricia Donato (NY), *chair*; Buford Abeldt (TX); Wendy Anderson (CO); Lee Ann Bundrick (SC); Philip Burgess (IL); William Cover (IN); Susan DelMonico (RI); Charles Wetherbee (TX).

Others Present:

Hal Wand, *Executive Committee liaison*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Deborah Zak, *NABP staff*.

Introduction:

The Committee on Law Enforcement/Legislation met March 8-9, 2011, at NABP Headquarters.

Review of the Committee Charge

Committee members reviewed their charge and accepted it as follows:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Committee members then reviewed the report of the 2009-2010 Committee on Law Enforcement/Legislation for background information.

LE/L Recommendation 1: The committee recommends amending the terms “Drug Regimen Review” and “Drug Use Review” to “Drug Utilization Review” throughout the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*.

The recommended revisions by the Committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 104. Practice of Pharmacy.

The “Practice of Pharmacy” means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Use-Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care and Collaborative Pharmacy Practice; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

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Section 105. Definitions.

...

- (q) “Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Regimen Review (DURR), claims adjudication, refill authorizations, and therapeutic interventions.
- (r) “Certified Pharmacy Technician” means personnel registered with the Board who have completed a certification program approved by the Board and may, under the supervision of a Pharmacist, perform certain activities involved in the Practice of Pharmacy, such as:
- (1) receiving new Prescription Drug Orders;
 - (2) prescription transfer;
 - (3) Compounding; and
 - (4) assisting in the Dispensing process;
- but excluding:
- (1) Drug Utilization Regimen-Review (DUR);
 - (2) clinical conflict resolution;
 - (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
 - (4) Patient Counseling; and
 - (5) Dispensing process validation.

...

- (yy) “Drug Utilization Use Review” includes but is not limited to the following activities:
- (1) Evaluation of the Prescription Drug Order(s) and patient record(s) for:

- (i) known allergies;
- (ii) rational therapy contraindications;
- (iii) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
- (iv) reasonable directions for use;
- (v) potential or actual adverse Drug reactions;
- (vi) Drug-Drug interactions;
- (vii) Drug-food interactions;
- (viii) Drug-disease contraindications;
- (ix) therapeutic duplication;
- (x) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
- (xi) abuse/misuse.

...

(eeee) “Pharmacy Technician” means personnel registered with the Board who may, under the supervision of the pharmacist, assist in the pharmacy and perform such functions as:

- (1) assisting in the Dispensing process;
- (2) processing of medical coverage claims;
- (3) stocking of medications; and
- (4) cashiering

but excluding:

- (1) Drug Utilization Regimen Review (DUR);
- (2) clinical conflict resolution;
- (3) prescriber contact concerning Prescription Drug Order clarification or therapy modification;
- (4) Patient Counseling;
- (5) Dispensing process validation;
- (6) prescription transfer; and
- (7) receipt of new Prescription Drug Orders.

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(tttt) “Prospective Drug Utilization Use Review (DUR)” means a review of the patient’s Drug therapy and Prescription Drug Order as part of a Drug Utilization Use Review, as defined in the rules of the Board, prior to Dispensing the Drug.

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Section 104. Comment.

The definition of the “Practice of Pharmacy” is one of the most important, and perhaps one of the most discussed, clauses in the NABP Model Act. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Additionally, the definition limits certain activities to performance by Pharmacists only, while allowing qualified personnel to assist Pharmacists in practice. That distinction is noted by listing activities that must be performed by the Pharmacist, such as the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; Drug and Device selection; Drug Administration; Drug Utilization Use-Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; Patient Counseling; Pharmacist Care; and other tasks that the Pharmacist has responsibility for, such as Compounding

and Labeling of Drugs and Devices; the proper and safe storage of Drugs and Devices, and maintenance of proper records. The deliberate distinction between the terms “must perform” and “is responsible for” intends to allow delegation of tasks to Certified Pharmacy Technicians or Pharmacy Technicians.

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Section 105(yy). Comment.

A “reasonable” dose, duration of use, and route of administration under “Drug Utilization Use Review (DUR)” would be determined by taking into consideration patient-specific factors, including but not limited to, age, gender, and other patient factors, but dependent upon the information about the patient known to the pharmacist.

DUR is also known to mean “Drug Use Review”; however, “Drug Utilization Review” is the preferred term.

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Section 105(bbbbb) (and [cccc]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management intervention
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Use Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management
- Maintenance of confidential patient information

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National Association of Boards of Pharmacy Model Rules

Model Rules for the Practice of Pharmacy

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Section 3. Pharmacy Practice.

...

- (h) Prospective Drug Utilization Use Review (DUR)
A Pharmacist shall review the patient record and each Prescription Drug Order for:
- (1) known allergies;
 - (2) rational therapy contraindications;
 - (3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
 - (4) reasonable directions for use;
 - (5) potential or actual adverse Drug reactions;
 - (6) Drug-Drug interactions;
 - (7) Drug-food interactions;
 - (8) Drug-disease contraindications;
 - (9) therapeutic duplication;
 - (10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
 - (11) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

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- (o) Remote Pharmacy Services

...

- (5) Operations
- (i) Remote Pharmacies:
...
(B) may receive Prescription Drug Orders or refill requests by the patient or the patient's agent in accordance with the policies and procedures designated by the Pharmacist-in-Charge. The Certified Pharmacy Technician or Pharmacy Intern shall either transmit the Prescription Drug Order or refill request to the Coordinating Pharmacy or process the Prescription Drug Order or refill request so that the Pharmacist at the Coordinating Pharmacy may perform a Prospective Drug Utilization Use Review (DUR) prior to Dispensing;

...

(E) may contain an Automated Pharmacy System or a limited Drug inventory for the purposes of preparing medications for Dispensing. The Pharmacist at the Coordinating Pharmacy shall have access to the Remote Pharmacy's automated data processing system to perform a Prospective Drug Utilization Use Review (DUR) prior to Dispensing. The Pharmacist shall ensure, through the use of the video/auditory communication system, that the Certified Pharmacy Technician or Pharmacy Intern has accurately and correctly prepared the Drug for Dispensing according to the Prescription Drug Order.

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(ii) Remote Dispensing Sites:

(A) that are located within an Institutional Facility shall utilize an Automated Pharmacy System for the purposes of Dispensing. The Pharmacist at the Coordinating Pharmacy shall have the necessary patient information to perform a Prospective Drug Utilization Use Review (DUR) prior to Dispensing; and

...

Model Rules for Public Health Emergencies

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Section 3. Emergency Prescription Drug Order.

- (a) For the duration of a State of Emergency issued due to a Public Health Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Prescription Drug Order if the Pharmacist:
- (1) performs, to the extent possible, a Prospective Drug Utilization Use Review (DUR) and Patient Counseling in accordance with these rules;

...

Model Rules for Sterile Pharmaceuticals

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Section 12. Pharmacist Care Outcomes.

There shall be a documented, ongoing quality assurance control program that monitors patient care and Pharmacist Care outcomes, including but not limited to, the following:

- (a) routine performance of Prospective Drug Utilization Use Review (DUR) and patient monitoring functions by a Pharmacist, as defined in the Rules of the Board;

...

Model Rules for the Licensure of Wholesale Distributors

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Definitions.

...

- (d) “Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as Dispensing, Drug Utilization Use Review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

Background:

The Committee on Law Enforcement/Legislation discussed the provided background information and initially determined that “drug regimen review” should be amended to “drug use review” as was recommended. Upon further discussion there was consensus among the members that “drug use review” should be replaced throughout the *Model Act* with “drug utilization review” as it is the most appropriate term of art and is what is taught to pharmacy students. The committee also recommended adding a comment explaining that “drug utilization review” is the preferred term.

LE/L Recommendation 2: The committee recommends amending the *Model Act* in regard to developing the standards for the community pharmacy accreditation program’s medication adherence monitoring services to encompass the broader definition of compliance in relation to adherence.

The revisions recommended by the Committee are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 105. Definitions.

...

(~~pppp~~) (gggg) “~~Patient Compliance Program~~” “Medication Adherence Monitoring Service” is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, in order to improve patient compliance with and adherence to prescribed medication therapy and that involves the collection and analysis of data related to patient medication use. ~~Patient Compliance Programs~~ Medication Adherence Monitoring Services may incorporate such efforts as refill reminder and patient education programs.

...

Section 3. Pharmacy Practice.

...

- (s) ~~Patient Compliance~~ Medication Adherence Monitoring Services and Intervention Programs
Medication Adherence Monitoring Services ~~Patient Compliance~~ and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs. (See Appendix E for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs.)

Section 105(gggg). Comment.

Compliance is intended to mean the initial filling of a prescription and encompasses adherence, which is the continuation of therapy.

Appendix E

Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs

Section 1: Purpose

The purpose of these Guidelines is to provide Pharmacists and patients with appropriate direction and information for the design, implementation, and participation in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs. Such Guidelines are needed in the interest of public health to protect the confidentiality of patient health care information and prohibit inappropriate and potentially detrimental contact with the patient.

Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs are those that promote improved medication use behaviors, such as medication regimen adherence ~~compliance~~ and appropriate self monitoring and self reporting, through such efforts as refill reminder programs and patient medication, disease state, and Drug therapy option education.

It shall be contrary to these Guidelines for any Person (including, but not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises) to attempt to or cause a switch of a patient’s medication, or direct a patient away from a course of therapy, solely for economic or financial gains or incentives.

Nothing in these Guidelines supersedes existing State Drug product selection laws or procedures for Drug recalls, nor prevents access to Nonconfidential Health Care Information for research purposes.

The privacy standards found in the NABP’s Model Rules for the Privacy of Individually Identifiable Patient Information should be carefully considered when conducting adherence ~~compliance~~ and patient intervention programs.

Section 2: Definitions

- (a) “Affiliated Entity” means legally separate covered entities that are affiliated and that designate themselves as a single covered entity for the purposes of this section.

- (b) “De-identified Health Information” means Health Information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. De-identified health information must meet the specifications of the de-identified health information described in the Health Insurance Portability and Accountability Act (HIPAA) privacy rules (45 CFR §164.514(b)).
- (c) “External Entities” means those organizations that exist outside of the pharmacist-patient relationship and that participate in the implementation of Patient Compliance and Patient Intervention Programs. External Entities include, but are not limited to, health insurance carriers, health benefit management companies, and health care marketing enterprises.¹
- (d) “Health Information” means any information, whether oral or recorded in any form or medium, that:
- (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse.
 - (2) relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual.
- (e) “HIPAA” is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof.
- (f) “Individually Identifiable Health Information” is information that is a subset of health information, including demographic information collected from an individual and
- (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
 - (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
 - (i) that identifies the individual; or
 - (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- (g) Medication Adherence Monitoring Service ~~“Patient Compliance Program”~~ is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the patient or caregiver via phone, print, electronic media, or other means of communication, in order to improve patient adherence to and compliance with prescribed medication therapy and that involves the collection and analysis of data related to patient medication use. Medication Adherence Monitory Services ~~Patient Compliance Programs~~ may incorporate such efforts as refill reminder and patient education programs.
- (h) “Patient Intervention Program” is defined as any structured activity that complements or supplements the existing responsibilities regarding the Dispensing of prescriptions and associated Patient Counseling, and that uses Protected Health Information to contact the

¹ Depending on the activities conducted by External Entities, they may be construed as “business associates” as defined under HIPAA and its related privacy rules (45 CFR Part 160). If so, HIPAA and its privacy rules that apply to those External Entities acting as business associates shall take precedence over contrary state law. In addition, “business associate agreements,” as defined under HIPAA and its privacy rules, shall be required between a Pharmacist or Pharmacy and the External Entity acting as a business associate so as to prevent the unauthorized use or disclosure of Protected Health Information.

patient or caregiver via phone, print, electronic media, or other means of communication, to discuss, inform, and/or affect patient therapy or choice of medications.

- (i) “Protected Health Information” means individually identifiable health information:
 - (1) Except as provided in paragraph (2) of this definition, that is
 - (i) transmitted by electronic media;
 - (ii) maintained in any medium described in the definition of electronic media at §162.103 of the HIPAA privacy rules (45 CFR Part 160);
 - (iii) transmitted or maintained in any other form or medium.
 - (2) Protected health information excludes individually identifiable health information in
 - (i) education records covered by the Family Educational Right and Privacy Act, as amended 20 USC 1232(g);
 - (ii) records described at 20 USC 1232(g)(4)(B)(iv); and
 - (iii) employment records held by a licensee in its role as an employer.

Section 3: Protection Against Illegal Use or Disclosure of Protected Health Information

Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs shall be conducted in a manner to protect against the illegal use or disclosure of Protected Health Information. The illegal use or disclosure of Protected Health Information constitutes a violation of HIPAA and its related privacy rules (45 CFR Part 160) and may constitute a violation of state pharmacy practice acts or rules or other State laws or rules.

The following minimal safeguards shall be in place for Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs:

- (a) Appropriate notice shall be given to patients regarding participation in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs;
- (b) Protected Health Information shall be maintained in a manner to protect against the illegal use or disclosure of such information;
- (c) Protected Health Information shall be accessed only by the pharmacist or by individuals under the direct supervision of the pharmacist, or by an affiliated entity of that pharmacist and may be released or disclosed to an External Entity pursuant to the notice of privacy practices required by 45 CFR §164.520 and the Model Rules for the Privacy of Individually Identifiable Patient Information of this Model Act;
- (d) Protected Health Information used to implement a Medication Adherence Monitoring Service ~~Patient Compliance~~ or Patient Intervention Program shall not be released or disclosed to any External Entity other than the External Entity implementing the program with, or on behalf of, the pharmacy;
- (e) All personnel with access to Protected Health Information shall sign and their employer shall retain on file current confidentiality and non-disclosure agreements;
- (f) If the Medication Adherence Monitoring Service ~~Patient Compliance~~ or Patient Intervention Program information is mailed, delivery systems that (1) ensure the information will be delivered to the designated patient or caregiver and will remain confidential; and (2) allow for the return of the information if not deliverable, shall be utilized. For example, if the contact is via the US Postal Service, the information should be mailed first class in a sealed security envelope;

- (g) Methods to access, transmit, store, analyze, or purge Protected Health Information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience;
- (h) External Entities maintaining Protected Health Information outside the pharmacy's internal system shall adhere to the same security requirements adhered to by the pharmacy in regard to its internal system, including but not limited to, those requirements addressing information access, storage, auditability, and release;
- (i) Procedures shall be in place to ensure that purged Protected Health Information cannot be misused or placed into active operation without appropriate authorization; and
- (j) Internet connectivity or remote access tied directly to systems containing Protected Health Information must be secure.

Section 4: Patient Participation

Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention

Programs shall be conducted in the best interest of the patient and shall inform patients about the program's purpose and use of Protected Health Information. The patient shall have the option to withdraw from any such program at any time. Patients shall be provided with a notice of privacy practices, which includes a description of the Medication Adherence Monitoring Service ~~Patient Compliance~~ or Patient Intervention Program;

Programs designed to change a patient's medication or medication therapy solely for economic or financial gains or incentives without the consent of the patient and prescribing practitioner are contrary to these Guidelines and may violate state pharmacy practice acts and rules and/or other state and federal laws or regulations.

Nothing in these Guidelines supersedes existing State Drug product selection laws or procedures for Drug recalls, nor prevents access to De-identified Health Information for research purposes.

Section 5: Pharmacist Participation

A pharmacist shall oversee and approve all Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs and shall be responsible for: (1) the accuracy of the list of participating patients; and (2) the accuracy and appropriateness of the information being presented to the patients during the life of the program. Pharmacists involved in Medication Adherence Monitoring Services ~~Patient Compliance~~ and Patient Intervention Programs, whether through contact with patients or caregivers or through the design, implementation, management, and analysis of the programs, shall be educated about such programs and their objectives. Results of the programs shall be communicated to all participating pharmacists.

Section 6: Utilization of De-identified and Protected Health Information for Research Purposes

Notwithstanding any other provision of law, nothing in these Guidelines shall be interpreted to prohibit the release of:

- (a) Protected Health Information for research that is subject to the requirements of federal laws and regulations protecting the rights and welfare of research participants;
- (b) De-identified Health Information; or
- (c) A limited data set for purposes of research, public health, or health care operations.

Section 7: Measurement and Analysis of Program

Medication Adherence Monitoring Services Patient Compliance and Patient Intervention Programs may include methodologies to measure the outcomes of the program in relation to patient care and the performance of the pharmacy/pharmacist. The following minimum guidelines shall be observed when measuring and analyzing the program outcomes:

- (a) Analysis and aggregate data reports shall not contain Protected Health Information;
- (b) Study design, measurement, and analysis shall adhere to accepted research and study designs; and
- (c) Reports prepared or published shall provide accurate and statistically correct information.

Background:

The committee discussed the issue at length and agreed that compliance is the broader of the two terms in that it encompasses adherence. Members determined that compliance occurs when the patient initially fills a prescription and adherence constitutes a long-term focus, whereby the patient continues to fill the prescription. The committee also agreed that a comment should be added to explain that the intent is that compliance includes adherence.

LE/L Recommendation 3: The committee recommends not to approve the recommendation of the Task Force to Review and Recommend Revisions to the Controlled Substances Act to add a definition of “Abuse of Medication” to the Model Act.

Background:

The committee reviewed the recommendation of the task force and determined that a definition of “abuse of medication” was unnecessary in light of the fact that abuse includes a multitude of behaviors that would be difficult to list.

LE/L Recommendation 4: The committee recommends approval of the amendments to the Model Act suggested by the National Alliance of State Pharmacy Associations (NASPA), with revisions.

The revisions recommended by the NASPA are denoted by underlines and ~~striketroughs~~. The recommended revisions by the committee are denoted by double underlines and ~~double striketroughs~~.

**National Association of Boards of Pharmacy
Model State Pharmacy Act**

Article I

Title, Purpose, and Definitions

...

Section 104. Practice of Pharmacy.

The “Practice of Pharmacy” means the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Use Review; the Practice of Telepharmacy within and

across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to provide Pharmacist Care in all areas of patient care, including Primary Care, ~~and Medication Therapy Management,~~ Collaborative Pharmacy Practice, ~~the ordering, conducting, and interpretation of appropriate laboratory tests, and the recommendation and administration selecting and administering~~ of immunizations; and the responsibility for Compounding and Labeling of Drugs and Devices (except Labeling by a Manufacturer, Repackager, or Distributor of Non-Prescription Drugs and commercially packaged Legend Drugs and Devices), proper and safe storage of Drugs and Devices, and maintenance of required records. The practice of pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

Section 105. Definitions.

...

~~(w)~~ “Collaborative Pharmacy Practice” is that Practice of Pharmacy whereby one or more Pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more Practitioners under protocol and in collaboration with Practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes. ~~whereby the Pharmacist may perform certain patient care functions authorized by the Practitioner or Practitioners under certain specified conditions and/or limitations.~~

(x) “Collaborative Pharmacy Practice Agreement” is a written and signed agreement between one or more Pharmacists and one or more Practitioners that provides for Collaborative Pharmacy Practice ~~for the purpose of conducting Medication Therapy Management activities,~~ as defined by law and the Rules of the Board.

...

~~(www)~~ “Pharmacist Care” is the provision by a Pharmacist of patient care services activities, as defined by the rules of the board Medication Therapy Management Services, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process, ~~as defined in the Rules of the Board.~~

...

Model Rules for Pharmacy Interns

Section 3. Supervision.

A Pharmacy Intern shall be allowed to engage in the Practice of Pharmacy provided that such activities are under the supervision of a Pharmacist. A Pharmacist shall be in ~~continuous~~ contact with, and actually giving instructions to, the Pharmacy Intern during all professional activities throughout the entire Pharmacy practice experience period. ~~The Whenever a Pharmacy Intern engages in Dispensing, a Pharmacist shall physically review the Prescription Drug Order and the Dispensed product before the product is Delivered to the patient or the patient’s agent. The supervising~~ Pharmacist is responsible for supervising all the work of Practice of Pharmacy

activities performed by the Pharmacy Intern, including but not limited to the accurate Dispensing of the Drug.

...

Section 3. Comment.

Supervision includes an actual review of the Prescription Drug Order and the dispensed Drug or product to ensure public protection.

...

Model Rules for the Practice of Pharmacy

...

Section 3. Pharmacy Practice.

...

(k) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct ~~Medication Therapy Management~~ activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

- (i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;
- (ii) the types of ~~Medication Therapy Management~~ decisions that the Pharmacist is allowed to make, which may include:
 - (A) a detailed description of the types of diseases, Drugs, or Drug categories involved, and the activities allowed in each case;
 - (B) a detailed description of the methods, procedures, decision Criteria, and plan the Pharmacist is to follow when conducting allowed activities; and
 - (C) a detailed description of the activities the Pharmacist is to follow, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the Practitioner concerning specific decisions made. In addition to the

- Agreement, documentation shall occur on the prescription record, patient profile, a separate log book, or in some other appropriate system.
- (iii) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;
 - (iv) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;
 - (v) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;
 - (vi) a provision that allows either party to cancel the Agreement by written notification;
 - (vii) an effective date; and
 - (viii) signatures of all collaborating Pharmacists and Practitioners who are party to the agreement, as well as dates of signing.
- Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

...

Section 4. Independent Practice of Pharmacists Pharmacy Provision of Pharmacist Care Outside of a Licensed Pharmacy.

- (a) A Pharmacist may provide Pharmacist Care services outside of a licensed Pharmacy if ~~all the following conditions are met:~~
- ~~(1) the Pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of Pharmacist Care services and appropriately reviews such information before performing any such functions; and~~
 - ~~(2) access to the information described in paragraph (1) of this section is secure from unauthorized access and use, and all access by Pharmacists is documented; and~~
 - ~~(3)~~ a Pharmacist providing Pharmacist Care services outside the premises of a licensed Pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall:
 - ~~(i)~~ (1) provide accountability and an audit trail;
 - ~~(ii)~~ (2) be provided to the Board upon request; ~~and~~
 - ~~(iii)~~ (3) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and
 - (4) secure from unauthorized access and use.

Background:

The committee reviewed in-depth the suggested amendments to the *Model Act* proposed by NASPA. Members largely agreed with NASPA's suggestions, particularly the suggestion that adds Medication Therapy Management (MTM), laboratory tests, and immunizations in the definition of the "Practice of Pharmacy." The committee further recommended that the language be revised to provide for the pharmacist to recommend immunizations, as well as changing "laboratory tests" to "appropriate tests" to elucidate that pharmacists also seek information from and should have access to other non-laboratory tests.

Members also agreed that the term “Medication Therapy Management” should be removed from the definition of “Collaborative Practice Agreement” as MTM is now a commonly accepted scope of pharmacist care and the previous definition made it appear that MTM services could only be provided within a collaborative practice agreement. Along these lines, members agreed with NASPA to remove the term “Medication Therapy Management” from the definition of “Pharmacist Care,” but decided that to revise “patient care services” to “patient care activities” as they believed it was a better reflection of what pharmacists actually do.

Regarding the suggested amendments to the section pertaining to pharmacy interns, the committee agreed with NASPA regarding the concept that the previous language gave the impression that only dispensing is considered to be the practice of pharmacy, thus members agreed to revise the section for clarity and add a comment specifying that supervising, in the interest of protecting the public health, included the actual review of the prescription drug order and the dispensed drug or product.

The committee also agreed with amending the title of Section 4 of the *Model Rules for the Practice of Pharmacy*. Members decided to slightly revise NASPA’s suggestion of “Practice of Pharmacy Outside of a Licensed Pharmacy” to “Provision of Pharmacist Care Outside of a Licensed Pharmacy” to more succinctly label this type of practice. Members also determined that subsection (a)(2) should be revised and more suitably be placed under the existing subsection (3).



Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act

Please note that NABP will be convening a subsequent task force with Drug Enforcement Administration (DEA) and other stakeholders to continue to review and revise the Controlled Substances Act, including those areas not addressed in this report.

Members Present:

Jack “Jay” Campbell (NC), *chairperson*; Ross Brinkley (American Society of Consultant Pharmacists); Patricia “Trish” D’Antonio (District of Columbia); Kristi R. Dover (Purdue Pharma L.P.); Danna Droz (OH); Virginia “Giny” Herold (CA); Suzan Kedron (TX), Susan Ksiazek (NY); Lawrence “Larry” Mokhiber (NY); Suzanne Neuber (OH); Jeanne Waggener (TX); Brenda Warren (TN).

Others Present:

Lloyd Jessen, Cathryn J. Lew, *Executive Committee liaisons*; Carmen A. Catizone, Melissa Madigan, Eileen Lewalski, Chris Siwik, Deborah Zak, *NABP staff*.

Introduction:

The Task Force to Review and Recommend Revisions to the Controlled Substances Act met January 25-26, 2011, at NABP Headquarters. This task force was established in response to Resolution 106-6-10, Task Force to Review and Recommend Revisions to the Controlled Substances Act, which was approved by the NABP membership at the Association’s 106th Annual Meeting in May 2010.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review selected provisions of the CSA and accompanying administrative regulations;
2. Identify those provisions that may require review and revision; and
3. Recommend legislative and regulatory changes to amend the CSA and accompanying administrative regulations.

Background:

The Task Force to Review and Recommend Revisions to the Controlled Substances Act initially convened on October 5-6, 2010. The purpose of the task force’s initial meeting was to determine which sections of the Controlled Substances Act (CSA) and the federal regulations should be reviewed for recommending possible revisions. Members and guests reviewed all relevant sections and discussed those that appeared problematic,

antiquated, or in general need of revision. On the task force's second day the members reviewed the previously selected sections and determined which of the four subgroups – community, hospital, long-term care, and/or miscellaneous provisions – would be most appropriate to further review and make recommendations. The four subgroup teleconferences took place on November 1-2, 2010, to discuss the issues that the task force had assigned to them. Below is a summary of the main issues and the subgroups' and task force's recommendations.

Recommendation 1: Amend 21 U.S.C.A. § 802 to Include Separate Definitions for “Administer,” “Dispense,” and “Prescribe”

The task force discussed this issue and agreed that there should be three separate definitions for “administer,” “dispense,” and “prescribe” that are functional in nature and broad enough to encompass future practices. The members cautioned that there may be unintended consequences with these definitions regarding the term “practitioner” and to keep this in mind when developing the definitions. Members also looked at several existing definitions and agreed that the definition for “prescribe” utilized by the New York State Board of Pharmacy was logical and practical and should be recommended. The task force recommends the following definitions and revisions denoted by underlines and ~~striketroughs~~.

§ 802. Definitions

...

The term “administer” means the direct application of a Drug to the body of a patient or research subject by injection, inhalation, ingestion, or by any other means.

...

(10) The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner, including the ~~prescribing and administering of a controlled substance and the~~ packaging, labeling, or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

...

The term “prescribe” means a direction or authorization, by prescription, permitting an ultimate user lawfully to obtain controlled substances from any person authorized by law to dispense such substances.

Issue: Should a definition of “prescribe” be added to the CSA?

- The members discussed carving the term “prescribe” out of the current definition of “dispense.”
- Members thought that the *Model State Pharmacy Act and the Model Rules of the National Association of Boards of Pharmacy* definition of “dispense” would be helpful in considering this issue: “Dispense” or “Dispensing” means the interpretation, evaluation, and implementation of a prescription drug order,

including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

21 U.S.C.A. § 802

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part A. Introductory Provisions 15

§ 802. Definitions

...

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

Subgroup Recommendations:

Community Subgroup - The subgroup recommended adding a definition of "prescribe" to the CSA. The subgroup also recommended amending the definition of the term "administer" to include the term "pharmacist." The subgroup believed that prescribe, dispense, and administer should each be defined separately and should delineate which practitioners may perform each function.

Hospital Subgroup - The subgroup agreed with the task force's recommendation to add a definition of "prescribe" to the CSA, particularly in light of the fact that more health care practitioners have been granted prescribing authority.

Long-term Care Subgroup - The subgroup also recommended adding a definition of "prescribe."

Recommendation 2: Revision of the term “Manufacturer” is Unnecessary

The task force recommends leaving the term “manufacturer” as defined. Members discussed the subgroups’ recommendations, specifically the Community Subgroup’s recommendation to remove the first mention of the term “compounding” and agreed that taking it out could possibly allow for a broader interpretation of the term, which could result in ambiguity.

Issue: Should the definition of “manufacture” be updated?

- Members suggested that this definition be reviewed for relevance and to determine if it should be updated.

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance.

Subgroup Recommendations:

Community Subgroup - The subgroup recommended removing the first mention of the term “compounding” from the definition.

Hospital Subgroup - The subgroup determined the definition was adequate, comprehensible, and does not require revising.

Recommendation 3: Amend the term “Practitioner” to Include Pharmacists

The task force agreed with the subgroups and recommends that pharmacists should be included in the definition of “practitioner.” The revision is denoted by underlines.

§ 802. Definitions

...

(21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Issue: Consider including “pharmacist” in the definition of “practitioner.”

- Members would like to include “pharmacist” in the definition of “practitioner.” Drug Enforcement Administration (DEA) now registers pharmacists as mid-level practitioners pursuant to DEA regulations. (Please review the language found in the statute and in the regulations.)

(21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

Subgroup Recommendations:

Community Subgroup - The subgroup agreed with the task force’s recommendation to include “pharmacist” in the definition of “practitioner.”

Hospital Subgroup - The subgroup agreed with the task force’s recommendation to include “pharmacist” in the definition of “practitioner.”

Long-term Care Subgroup - The subgroup agreed with the task force’s recommendation to include “pharmacist” in the definition of “practitioner.”

Recommendation 4: Amend the Definitions of “Individual Practitioner” and “Mid-Level Practitioner” to Conform with the Definitions of “Dispense” and “Prescribe”

The task force recommends the following revisions denoted by underlines and ~~strikethroughs~~.

§ 1300.01 Definitions relating to controlled substances.

...

(17) The term individual practitioner means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to prescribe, administer, and dispense a controlled substances in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

...

(28) The term mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to prescribe, administer, and dispense a controlled substances in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, ~~and~~ physician assistants, and pharmacists who are authorized to prescribe, administer, and dispense controlled substances by the state in which they practice.

Issue: Review the following definitions found in the CFR for consistency with the definitions found in the CSA.

- DEA currently registers pharmacists as mid-level practitioners under the regulations.

21 C.F.R. § 1300.01

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1300. Definitions (Refs & Annos)

§ 1300.01 Definitions relating to controlled substances.

...

(17) The term individual practitioner means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

...

(28) The term mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

...

(33) The term pharmacist means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

Subgroup Recommendations:

Community Subgroup - The subgroup recommended defining “dispense,” “administer,” and “prescribe” and clarify which practitioners may perform each.

Hospital Subgroup - The subgroup determined the definitions were consistent with the definitions found in the CSA, however, reiterated that “pharmacists” should be added to the definition of “practitioner.”

Long-term Care Subgroup - The subgroup recommended the following changes to the definition of “individual practitioner.” The revisions recommended by the subgroup are denoted by underlines and strikethroughs.

§ 1300.01 Definitions relating to controlled substances.

...

(17) The term individual practitioner means a physician, pharmacist, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to prescribe or dispense a controlled substance in the course of professional practice, but does not include ~~a pharmacist~~, a pharmacy, or an institutional practitioner.

Recommendation 5: Amend the Definition of the Term “Long Term Care Facility”

The task force recommends that the term “long term care facility” be defined broadly to allow for flexibility particularly at the state level. Revisions are denoted by underlines and ~~strikethroughs~~.

§ 1300.01 Definitions relating to controlled substances.

...

(25) The term Long Term Care Facility (LTCF) means an institution, ~~nursing home, retirement care, mental care or other facility or institution~~ which provides extended health care to resident patients.

Issue: Should the term “Long Term Care Facility” be revised?

§ 1300.01 Definitions relating to controlled substances.

...

(25) The term Long Term Care Facility (LTCF) means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

Subgroup Recommendation:

Long-term care Subgroup - The subgroup recommended revising the term “Long Term Care Facility (LTCF).” The subgroup recommended that “facility” be replaced with “institution” and that the definition should reflect the definition in the Model State Pharmacy Act and the Model Rules of the National Association of Boards of Pharmacy (Model Act). Members cautioned though, not to inadvertently include institutions without board of pharmacy oversight.

Recommendation 6: Add a New Definition for the Term “Agent” to the Code of Federal Regulations While Maintaining the Definition of “Agent” in 21 U.S.C.A. § 802

The task force believes that the term “agent” as defined in the CSA fails to describe the typical agency relationship that exists between practitioners and those individuals that assist them with the day-to-day activities. Members recommend the following new definition to be added to the Code of Federal Regulations to address this relationship.

The term “agent” means a person authorized to act on behalf of a practitioner as provided by state law or written agency agreement.

Issue: Review and, if necessary, suggest edits to the definition of “agent.”

21 U.S.C.A. § 802

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part A. Introductory Provisions

§ 802. Definitions

...

(3) The term “agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

Subgroup Recommendation:

Long-term Care Subgroup - The subgroup agreed that edits to the definition of “agent” are necessary. The subgroup recommended expanding the definition to include “nurses,” “pharmacists,” and “medication aides.” They also recommended that the definition of “agent” be expanded and that a written agency agreement should not always be necessary when the agent is not an employee of the prescriber.

Recommendation 7: Amend the term “Prescription” to Include Medical Record Orders and Provide for a Default Maximum of Seven Days When No Quantity or Diagnosis is Indicated

The task force recommends medical record orders should be included in the definition of the term “prescription” to allow for what have historically been called “chart orders.” Members discussed open-ended medication record orders, which could potentially allow for an unlimited days supply and agreed that a default maximum must be established. The task force debated whether to allow individual facilities to dictate default maximums in their policies and procedures but ultimately decided to recommend that this be addressed in the federal regulations. The members recommend to add verbiage, specifically in §§1301.01(b)(35), 1306.05(a), 1306.11(a), 1306.21(a) to address medical record orders as denoted below by underlines.

§ 1300.01 Definitions relating to controlled substances.

...

(35) The term prescription means an order, including a medical record order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

§1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. A medical record order without a discernable quantity will be limited to a seven-day supply.

§1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner or a medical record order, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with §1304.04(h) of this chapter.

§1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a medical record order, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Sec. 1306.05, except for the signature of the practitioner.

Issue: Determine whether “chart order” be included in the definition of “prescription.”

- Determine whether the definition should include chart orders or whether a new definition should be created specifically for chart orders.
- Include direction for hospice care.

(35) The term prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.)

Subgroup Recommendation:

Long-term care Subgroup - The subgroup recommended including “chart order” in the definition of “prescription.” The subgroup would like DEA to accept chart orders as valid prescriptions and recommended referencing the definition of “chart order” from the Model Act.

Recommendation 8: Further Amend 21 C.F.R. § 1306.05(a) to Revise Prescription and Medical Record Order Requirements

The task force discussed which prescription drug order elements should actually be required on a prescription at the time it is presented at the pharmacy versus the elements that should not necessarily be required on the face of the prescription if they are made readily available to pharmacy staff by the pharmacy. The task force also believed that this was the best place to include the *Model Act* language pertaining to medical record orders. Members also agreed that the elements that the pharmacist may change should also be included to clarify the existing policy regarding allowable changes to CII-CV prescriptions. The revisions are denoted by underlines and ~~strikethroughs~~.

§1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name ~~and address of~~ the patient, the drug name, strength, ~~dosage form,~~ quantity prescribed, directions for use, and the name, ~~address and registration number of the practitioner.~~ The address and date of birth of the patient and the address and registration number of the practitioner are not necessary on the face of the prescription if made readily available to pharmacy staff by the pharmacy and attached to the electronic record of the prescription. The pharmacist may add or change the drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. The pharmacist shall note such consultation on the prescription. A medical record order entered on the chart or a medical record of an inpatient or resident of a LTCF by a practitioner or his or her designated agent shall contain the full name of the patient, date of issuance, name and strength of the drug prescribed, directions for use, and if written, the prescribing practitioner's signature or the signature of the practitioner's agent (including the name of the prescribing practitioner). Only a seven day supply of medication may be dispensed pursuant to a medical record order without a discernable quantity.

Issue: Should the text of the following sections be updated? Consider adding text addressing oral prescriptions.

Review “agency” text.

- Members suggested a general review to update wording may be in order.

21 C.F.R. § 1306.03

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

General Information

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

- (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and
- (2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

21 C.F.R. § 1306.05

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

General Information

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e) of this chapter.

(c) Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.

(d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

(e) Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the

hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.

(h) An official exempted from registration under § 1301.23(a) of this chapter must include on all prescriptions issued by him his branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each paper prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

21 C.F.R. § 1306.21

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or **the practitioner's agent** to the pharmacy, an electronic prescription that meets the requirements

of this part and part 1311 of this chapter, **or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.**

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a paper prescription signed by an individual practitioner, a facsimile of a paper prescription or order for medication transmitted by the practitioner or the **practitioner's agent** to the institutional practitioner-pharmacist, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

Subgroup Recommendations:

Community Subgroup - The subgroup agreed with the task force's recommendation to update the wording in the text of 1306.05 and to add text to that section to address oral orders.

Long-term Care Subgroup - The subgroup suggested that some of the difficulties may be alleviated if chart orders are accepted as valid prescriptions and nurses are allowed to provide prescriptions to the pharmacy either verbally or via facsimile. The subgroup recommended that the following language be added to subsection 1306.21 (a) "A chart order in an institutional facility is recognized as a prescription drug order and can be transmitted orally, electronically, or via facsimile by the practitioner's agent to the pharmacy."

Recommendation 9: Remove the Phrase “by the Secretary or Agent” from § 1306.05(f) and throughout the Code of Federal Regulations Pertaining to Controlled Substances

The task force agreed that removing this phrase would allow for broad interpretation to alleviate the issue outlined below and to make it sound more contemporary. The revision is denoted below by ~~strikethroughs~~.

§ 1306.05 Manner of issuance of prescriptions.

...

(f) A prescription may be prepared ~~by the secretary or agent~~ for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

Issue: It has been reported to NABP that a DEA field agent has interpreted a pharmacist submitting a faxed refill request to the prescriber as acting as the prescriber’s agent in “preparing the prescription for signature.” See subsection (f) and consider creating an exception for pharmacists.

- Members suggested the need to ensure that a faxed refill request is not interpreted as a prescription order prepared for signature.

21 C.F.R. § 1306.05

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

General Information

§ 1306.05 Manner of issuance of prescriptions.

...

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription

shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.

...

Subgroup Recommendation:

Community Subgroup - The subgroup agreed with the task force's recommendation to clarify subsection (f) of 21 C.F.R. § 1306.05 by adding the text "does not include a request sent by a pharmacist via facsimile for a refill authorization."

Recommendation 10: Amend the Definition of “Addict” to Mirror the Definition Utilized by the Federation of State Medical Boards (FSMB)

The task force agreed that the FSMB definition of “addiction” was more suitable and has been modified to the term “addict. It is denoted below by underlines and ~~strikethroughs~~.

§ 802. Definitions

The term “addict” means an individual who suffers from addiction, which is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction. ~~any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.~~

Issue: Should the definition of addict be revised?

- Members discussed the need to revise the definition to reflect modern understanding of and values relating to addictions.

21 U.S.C.A. § 802

United States Code Annotated
Title 21. Food and Drugs
Chapter 13. Drug Abuse Prevention and Control
Subchapter I. Control and Enforcement
Part A. Introductory Provisions

§ 802. Definitions

As used in this subchapter:

(1) The term “addict” means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup agreed with the task force’s recommendation to revise the definition of “addict” and recommended that NABP staff craft a definition from various sources, such as the American Pain Society, to modernize the definition and reflect addiction as a disease state.

The following definition was crafted through combining definitions recognized by the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine.

(1) The term “addict” refers to an individual having a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors that causes an individual’s behavior to be characterized by one or more of the following: impaired control over drug use, compulsive use of the drug, continued use of the drug despite harm and or craving of the drug.

Recommendation 11: Define “Abuse of Medication” in the *Model Act*

The task force discussed the fact that the term “abuse of medication” does not appear in the CSA therefore making a definition unnecessary. The members however, agreed that the issue should be addressed and believed that the *Model Act* may be the best vehicle to do so.

Issue: Should a definition of “abuse of medication” be added to the CSA?

- Members believed that abuse and addiction should be defined separately according to what has been discovered regarding addiction to controlled substances.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended adding a definition for “abuse of medication” to the CSA and requested for NABP staff to craft the definition for the task force to review.

The following definition was crafted through combining numerous definitions found on the Internet. The term “abuse of medication” means the compulsive, excessive, and self-damaging use of habit forming drugs or substances by taking medications that were prescribed to someone else or taken in a manner or dosage other than what was prescribed and leading to addiction or dependence, serious physiological injury (such as damage to kidneys, liver, heart) and/or psychological harm (such as dysfunctional behavior patterns, hallucinations, memory loss), or death.

Recommendation 12: Revision of the Term “Serial Number” is Unnecessary

The task force agreed that it was unnecessary to revise the term “serial number,” particularly in light of the fact that this provision is not in the CSA or corresponding Code of Federal Regulations.

Issue: Should the term “serial number” be updated?

- Note this wording is found in the Food, Drug and Cosmetic Act (21 USC 353(b)(2) see below)

21 U.S.C.A. § 353

United States Code Annotated Currentness

Title 21. Food and Drugs (Refs & Annos)

Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)

Subchapter V. Drugs and Devices

Part A. Drugs and Devices (Refs & Annos)

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which--

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

(C) Redesignated (B)

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the

requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, **the serial number** and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended that no revision is necessary.

Recommendation 13: Await Pending DEA Action Regarding the Standardization of DEA suffixes.

Members felt it necessary to review upcoming proposed rules on this issue before making recommendations.

Issue: Discuss how DEA number suffixes might be standardized.

- Members discussed the need to standardize DEA suffixes – DEA informed the task force that there will be new DEA regulations to address this.

Subgroup Recommendation:

Community Subgroup - The subgroup agreed with the task force that the DEA number suffixes should be standardized but decided to await DEA's rulemaking.

Issue: Discuss how to standardize internal codes lists and locations for such lists within an institution.

- Also discussed was the need to clarify the internal codes list locations and standards.

21 C.F.R. § 1301.22

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Exceptions to Registration and Fees

§ 1301.22 Exemption of agents and employees; affiliated practitioners.

...

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

...

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a **specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12);** and

(6) **A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.**

Subgroup Recommendations:

Community Subgroup - The subgroup supported the concept of standardizing internal code lists and locations for such lists within institutions. A discussion ensued regarding the basis of the problem: that hospital interns and residents, in many cases, cannot be issued their own DEA numbers. The subgroup suggested further investigation into the matter and solutions that perhaps included an intern registration system through DEA.

Hospital Subgroup - The subgroup discussed this issue at length. They felt it was a complicated issue, involving not only standardizing codes but also allowing access to such codes to a variety of persons, which could actually increase the risk of diversion. With this in mind, the group felt it would need much additional information to make any kind of recommendation. It was determined that the primary task force should review this issue in depth and consider making a recommendation at that time.

Recommendation 14: Revise 21 CFR § 1301.23 by Replacing the Utilization of a Social Security Number as the Service Identification Number for a Public Health Service Employee to His or Her Assigned Serial Number

The task force agreed that an individual's Social Security number should not be utilized for identification purposes and provides that 28 CFR § 700.25 as shown below explicitly prohibits this practice.

28 C.F.R. § 700.25

Code of Federal Regulations

Title 28. Judicial Administration

Chapter VII. Office of Independent Counsel

Part 700. Production or Disclosure of Material or Information of the Office of Independent Counsel (Refs & Annos)

Subpart A. Protection of Privacy and Access to Individual Records Under the Privacy Act of 1974

§ 700.25 Use and collection of social security numbers.

(a) Each system manager of a system of records that utilizes Social Security numbers as a method of identification without statutory authorization, or authorization by regulation adopted prior to January 1, 1975, shall take steps to revise the system to avoid future collection and use of the Social Security numbers.

(b) The Office shall take such measures as are necessary to ensure that employees authorized to collect information from individuals are advised that individuals may not be required to furnish Social Security numbers without statutory or regulatory authorization and that individuals who are requested to provide Social Security numbers voluntarily must be advised that furnishing the number is not required and that no penalty or denial of benefits will flow from the refusal to provide it.

Issue: Should the requirement that a Public Health Service individual use his or her social security number as a service identification number be changed?

- FDA informed us that the Public Health Service issues a "serial number" that is assigned to each officer upon commissioning that is used for personnel and/or administrative purposes.

21 C.F.R. § 1301.23

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Exceptions to Registration and Fees

§ 1301.23 Exemption of certain military and other personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and the service identification number of the issuing official in lieu of the registration number required on prescription forms. **The service identification number for a Public Health Service employee is his/her Social Security identification number.**

(b) The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his/her official duties.

(c) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended changing the provision and utilizing the assigned serial number as a service identification number instead of the social security number.

Recommendation 15: Revision of the Waiver Process is Unnecessary but Request that DEA Look to Mitigating Circumstances Regarding Individual Waivers Requests Submitted by Registrants for Employees Who Have Been Convicted of a Felony Offense Relating to Controlled Substances

The task force discussed the issue and the fact that DEA has specifically placed the onus on the registrant in order to exert control over these types of matters. The members agreed that the waiver process should remain as is, but that DEA should take into consideration any mitigating circumstances when determining whether a waiver should be granted.

Issue: Consider adding language related to hiring persons whose convictions having been discharged, taking into consideration the time since the conviction and the seriousness of the offense.

- Members discussed how this affects employment and registration for individuals who may have been convicted but whose convictions were later discharged due to satisfying probationary provisions.

21 U.S.C.A. § 824

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 824. Denial, revocation, or suspension of registration

(a) Grounds

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant--

(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of Title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

(b) Limits of revocation or suspension

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

21 C.F.R. § 1301.76

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Security Requirements

§ 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term “for cause” means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- (5) Whether the specific controlled substances are likely candidates for diversion;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(c) Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted in § 1301.13(e) (1) and/or §§ 1307.11-1307.12) he/she shall comply with the requirements imposed on nonpractitioners in § 1301.74(a), (b), and (e).

(d) Central fill pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for

delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106. Retail pharmacies must comply with § 1301.74(e) when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106.

21 C.F.R. § 1309.72

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1309. Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals (Refs & Annos)

Security Requirements

§ 1309.72 Felony conviction; employer responsibilities.

(a) The registrant shall exercise caution in the consideration of employment of persons who will have access to listed chemicals, who have been convicted of a felony offense relating to controlled substances or listed chemicals, or who have, at any time, had an application for registration with the DEA denied, had a DEA registration revoked, or surrendered a DEA registration for cause. (For purposes of this subsection, the term “for cause” means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances or listed chemicals.) The registrant should be aware of the circumstances regarding the action against the potential employee and the rehabilitative efforts following the action. The registrant shall assess the risks involved in employing such persons, including the potential for action against the registrant pursuant to § 1309.43. If such person is found to have diverted listed chemicals, and, in the event of employment, shall institute procedures to limit the potential for diversion of List I chemicals.

(b) It is the position of DEA that employees who possess, sell, use or divert listed chemicals or controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended that the entire waiver process be revised by placing the onus on the individual seeking a waiver instead of the registrant. The subgroup also recommended that DEA strongly defer to the boards of pharmacy and that certain mitigating criteria such as a non-trafficking crime, type of

treatment received, whether the conviction was expunged, and the type of board action should be considered.

Recommendation 16: Revision of 21 CFR § 1301.12 as it Pertains to the Registration of Automated Dispensing Systems and Emergency Kits is Unnecessary

The task force discussed the issue and determined that it appears to involve practical versus legal confusion of the DEA registration provisions. Members agreed to an informal recommendation to identify the issue and educate the states regarding the legal issues.

Issue: Discuss the requirement that automated dispensing machines be registered under a pharmacy DEA number, as opposed to emergency kits, which do not need to be associated with a pharmacy DEA number. Does this inconsistency need to be remedied?

21 C.F.R. § 1301.12

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Registration

§ 1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location in the same State or jurisdiction of the United States) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(4) A freight forwarding facility, as defined in § 1300.01 of this part, provided that the distributing registrant operating the facility has submitted written notice of intent to operate the facility by registered mail, return receipt requested (or other suitable means of documented delivery) and such notice has been approved. The notice shall be submitted

to the Special Agent in Charge of the Administration's offices in both the area in which the facility is located and each area in which the distributing registrant maintains a registered location that will transfer controlled substances through the facility. The notice shall detail the registered locations that will utilize the facility, the location of the facility, the hours of operation, the individual(s) responsible for the controlled substances, the security and recordkeeping procedures that will be employed, and whether controlled substances returns will be processed through the facility. The notice must also detail what state licensing requirements apply to the facility and the registrant's actions to comply with any such requirements. The Special Agent in Charge of the DEA Office in the area where the freight forwarding facility will be operated will provide written notice of approval or disapproval to the person within thirty days after confirmed receipt of the notice. Registrants that are currently operating freight forwarding facilities under a memorandum of understanding with the Administration must provide notice as required by this section no later than September 18, 2000 and receive written approval from the Special Agent in Charge of the DEA Office in the area in which the freight forwarding facility is operated in order to continue operation of the facility.

21 C.F.R. § 1301.27

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Exceptions to Registration and Fees

§ 1301.27 Separate registration by retail pharmacies for installation and operation of automated dispensing systems at long term care facilities.

(a) A retail pharmacy may install and operate automated dispensing systems, as defined in § 1300.01 of this chapter, at long term care facilities, under the requirements of § 1301.17. No person other than a registered retail pharmacy may install and operate an automated dispensing system at a long term care facility.

(b) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one registered retail pharmacy operates automated dispensing systems at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility.

(c) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

Subgroup Recommendation:

Long-term Care Subgroup - The subgroup recommended that if the definition of "chart order" were to be revised according to the Model Act, then patient specific dispensing devices would be supported (as opposed to emergency kit dispensing), at which point a review of these provisions should take place.

Recommendation 17: Revise 21 CFR § 1301.28 to Allow for Detoxification of Maintenance Treatment of LTCF Patients

The task force recommends the following revisions denoted by underlines.

§ 1306.07 Administering or dispensing of narcotic drugs.

...

(c) This section is not intended to impose any limitations on a physician or authorized hospital or LTCF staff to administer or dispense narcotic drugs in a hospital or LTCF to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

Issue: Review issues related to detoxification treatment using methadone and buprenorphine.

- Members discussed the increasing need to dispense detoxification medications in LTCFs to patients being treated for other conditions. This is specifically allowed in hospitals.

21 C.F.R. § 1301.28

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Exceptions to Registration and Fees

§ 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(a) An individual practitioner may dispense or prescribe Schedule III, IV, or V narcotic controlled drugs or combinations of narcotic controlled drugs which have been approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment without obtaining the separate registration required by § 1301.13(e) if all of the following conditions are met:

(1) The individual practitioner meets the conditions specified in paragraph (b) of this section.

(2) The narcotic drugs or combination of narcotic drugs meet the conditions specified in paragraph (c) of this section.

(3) The individual practitioner is in compliance with either paragraph (d) or paragraph (e) of this section.

(b)(1) The individual practitioner must submit notification to the Secretary of Health and Human Services stating the individual practitioner's intent to dispense or prescribe

narcotic drugs under paragraph (a) of this section. The notice must contain all of the following certifications:

(i) The individual practitioner is registered under § 1301.13 as an individual practitioner and is a “qualifying physician” as defined in section 303(g)(2)(G) of the Act (21 U.S.C. 823(g)(2)(G)).

(ii) The individual practitioner has the capacity to refer the patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs for appropriate counseling and other appropriate ancillary services.

(iii) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section will not exceed 30 at any one time unless, not sooner than 1 year after the date on which the practitioner submitted the initial

notification to the Secretary of Health and Human Services, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this subparagraph shall contain the certifications required by subparagraphs (i) and (ii) of this paragraph. The Secretary of Health and Human Services may promulgate regulations to change the total number of patients.

(iv) [Reserved by 73 FR 29688]

(2) If an individual practitioner wishes to prescribe or dispense narcotic drugs pursuant to paragraph (e) of this section, the individual practitioner must provide the Secretary of Health and Human Services the following:

(i) Notification as required under paragraph (b)(1) of this section in writing, stating the individual practitioner's name and DEA registration number issued under § 1301.13.

(ii) If the individual practitioner is a member of a group practice, the names of the other individual practitioners in the group and the DEA registration numbers issued to the other individual practitioners under § 1301.13.

(c) The narcotic drugs or combination of narcotic drugs to be dispensed or prescribed under this section must meet all of the following conditions:

(1) The drugs or combination of drugs have been approved for use in “maintenance treatment” or “detoxification treatment” under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.

(2) The drugs or combination of drugs have not been the subject of an adverse determination by the Secretary of Health and Human Services, after consultation with the Attorney General, that the use of the drugs or combination of drugs requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

(d)(1) After receiving the notification submitted under paragraph (b) of this section, the Secretary of Health and Human Services will forward a copy of the notification to the Administrator. The Secretary of Health and Human Services will have 45 days from the date of receipt of the notification to make a determination of whether the individual practitioner involved meets all requirements for a waiver under section 303(g)(2)(B) of the Act (21 U.S.C. 823(g)(2)(B)). Health and Human Services will notify DEA of its determination regarding the individual practitioner. If the individual practitioner has the appropriate registration under § 1301.13, then the Administrator will issue the practitioner an identification number as soon as one of the following conditions occurs:

- (i) The Administrator receives a positive determination from the Secretary of Health and Human Services before the conclusion of the 45-day review period, or
 - (ii) The 45-day review period has concluded and no determination by the Secretary of Health and Human Services has been made.
- (2) If the Secretary denies certification to an individual practitioner or withdraws such certification once it is issued, then DEA will not issue the individual practitioner an identification number, or will withdraw the identification number if one has been issued.
- (3) The individual practitioner must include the identification number on all records when dispensing and on all prescriptions when prescribing narcotic drugs under this section.
- (e) An individual practitioner may begin to prescribe or dispense narcotic drugs to a specific individual patient under this section before receiving an identification number from the Administrator if the following conditions are met:
- (1) The individual practitioner has submitted a written notification under paragraph (b) of this section in good faith to the Secretary of Health and Human Services.
 - (2) The individual practitioner reasonably believes that the conditions specified in paragraphs (b) and (c) of this section have been met.
 - (3) The individual practitioner reasonably believes that the treatment of an individual patient would be facilitated if narcotic drugs are prescribed or dispensed under this section before the sooner of:
 - (i) Receipt of an identification number from the Administrator, or
 - (ii) Expiration of the 45-day period.
 - (4) The individual practitioner has notified both the Secretary of Health and Human Services and the Administrator of his or her intent to begin prescribing or dispensing the narcotic drugs before expiration of the 45-day period.
 - (5) The Secretary has not notified the registrant that he/she is not qualified under paragraph (d) of this section.
 - (6) The individual practitioner has the appropriate registration under § 1301.13.
- (f) If an individual practitioner dispenses or prescribes Schedule III, IV, or V narcotic drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment in violation of any of the conditions specified in paragraphs (b), (c) or (e) of this section, the Administrator may revoke the individual practitioner's registration in accordance with § 1301.36.

21 C.F.R. § 1306.07

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

General Information

§ 1306.07 Administering or dispensing of narcotic drugs.

- (a) A practitioner may administer or dispense directly (but not prescribe) a narcotic drug listed in any schedule to a narcotic dependant person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:
 - (1) The practitioner is separately registered with DEA as a narcotic treatment program.

- (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to the Act.
- (b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.
- (c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.
- (d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of § 1301.28 of this chapter.

Subgroup Recommendation:

Long-term Care Subgroup - The subgroup discussed the issues related to treatment using methadone and buprenorphine in LTCFs and agreed that this was a complicated issue that needed to be addressed. The subgroup related that patients come into LTCFs who are being treated with maintenance narcotics for addiction. Currently, LTCF physicians cannot legally prescribe these medications as they do not possess the proper DEA registration. LTCF patients are viewed as outpatients and accordingly must either obtain such medications from a narcotic detoxification treatment center or have a physician with the proper DEA registration prescribe the medication. The subgroup recommended that LTCFs be allowed to provide such medications to their patients, as hospitals or acute care settings are currently allowed to do.

Recommendation 18: A Separate DEA Registration is Not Necessary to Document REMS Training but Consider Addressing Hospices Separately

The task force discussed this issue and agreed that documentation of REMS training should not be tied to DEA registration. Members were informed that NABP is reviewing REMS in a separate context with the possibility that REMS may be incorporated into the community pharmacy accreditation program standards.

Issue: Would it be feasible to document opioid (Risk Evaluation and Mitigation Strategies) REMS training through Drug Enforcement Administration (DEA) registration (similar to authority to prescribe and/or dispense buprenorphine)?

21 U.S.C.A. § 823

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 823. Registration requirements

...

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

- (i) The practitioner is a qualifying physician (as defined in subparagraph (G)).
- (ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.
- (iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.

...

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup discussed the feasibility of documenting opioid REMS training through DEA registration. The subgroup recommended that there should be standardized training that utilizes a centralized database but did not agree that there should be a separate DEA registration for REMS.

Recommendation 19: Allow for a Six-Month Time Limit for the Validity of CII and CV Prescriptions

The task force discussed the issue and determined that there should be a uniform time limit for the validity of all controlled substance prescriptions. Members were reluctant to recommend a 30-day time limit for CII prescriptions due to a conflict with the existing provision in 21 CFR § 1306.12 that allows for multiple prescriptions for up to a 90-day supply.

Issue: Should there be a time limit on the validity of CII and CV prescriptions?

- Members suggested that a time limit may be appropriate.

Subgroup Recommendations:

Community Subgroup - The subgroup agreed with the task force's suggestion and recommended a time limit of 30 days for CII prescriptions and 180 days for CV prescriptions, reflecting the time limit for CIII and CIV prescriptions.

Hospital Subgroup - The subgroup agreed with the task force's recommendation that a time limit on the validity of CII prescriptions should be implemented and recommended a six-month limit on CV prescriptions.

Long-term care Subgroup - The subgroup recommended a time limit of six months for CII and CV prescriptions for consistency with CIII and CIV prescriptions.

Recommendation 20: Revision of the No-Refill Provision for CII Controlled Substances is Unnecessary

The task force discussed the issue and agreed not to recommend that refills be allowed for CII prescriptions particularly in light of the fact that DEA addressed this with the multiple prescription provision previously mentioned.

Issue: Should refills be allowed on CII prescriptions?

- Members suggested that refills for certain CII prescriptions may be appropriate (perhaps if the prescriber included the indication for use). Consider how this would alleviate the need for issuance of multiple prescriptions (21 CFR 1306.12) and the ambiguity created by the policy statements regarding what can be changed on a CII prescription.

21 U.S.C.A. § 829

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C.A. § 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. **No prescription for a controlled substance in schedule II may be refilled.**

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C.A. § 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

21 C.F.R. § 1306.12

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

63

Controlled Substances Listed in Schedule II

§ 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

- (i) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
- (ii) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;
- (iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
- (iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and
- (v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Subgroup Recommendations:

Community Subgroup - The subgroup, with a vote of three to two, disagreed with the task force's recommendation to allow refills on CII prescriptions. The subgroup members who voted against the recommendation were concerned with diversion and accountability, whereas those members who were in agreement with the recommendation were inclined to allow refills with the stipulation of allowing only one refill with a time limit and only for specific drugs.

Hospital Subgroup - The subgroup discussed this issue at length and members voiced a variety of opinions. The subgroup ultimately decided that additional information was necessary for making a recommendation and believed that the primary task force should discuss this issue further.

Long-term care Subgroup - The subgroup declined to make a recommendation, but agreed this issue was worth exploring.

Recommendation 21: Revision of the Definition of “Emergency Situation” is Unnecessary

Members agreed with the subgroups’ discussions and determined that a revision of this term is not necessary.

Issue: Review the definition of “emergency situation.”

- American Society of Consultant Pharmacists noted it has worked with FDA. Definition is incorporated by reference to the FDC Act (see 21 CFR §290.10 below).
- FDA has indicated that it is open to updating this definition.

21 C.F.R. § 1306.11

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedule II

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in § 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 1306.05, except for the signature of the prescribing individual practitioner;

(3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual

practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face “Authorization for Emergency Dispensing,” and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

...

21 C.F.R. § 290.10

Code of Federal Regulations

Title 21. Food and Drugs

Chapter I. Food and Drug Administration, Department of Health and Human Services

(Refs & Annos)

Subchapter C. Drugs: General

Part 290. Controlled Drugs (Refs & Annos)

Subpart A. General Provisions

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term **emergency situation** means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subgroup Recommendations:

Community Subgroup - The subgroup believed that the current definition is appropriate and recommended not revising.

Long-term Care Subgroup - The subgroup agreed that the immediate needs of the patient should be taken into consideration but determined that the definition of “emergency situation” should not be addressed until the definitions of “chart order” and “agent” were added and/or revised.

Recommendation 22: Amend 21 C.F.R. § 1306.13 by Removing the “Unable to Supply” Provision and Increase the Time Limit for the Partial Filling of a Prescriptions from 72 Hours to 30 Days

The task force discussed the two issues listed below concurrently and agreed that removing the term “unable to supply” and increasing the time frame allowable for partially filling a CII prescription addressed patient care issues such as expense, tolerability of a drug, and patient choice. The revision is denoted below by underlines and ~~strikethroughs~~.

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist does not ~~is unable to~~ supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 30 days ~~72 hours~~ of the first partial filling; however, if the remaining portion is not or cannot be filled within the 30-day ~~72-hour~~ period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 30 days ~~72 hours~~ without a new prescription.

Issue: Consider defining “unable to supply.”

- Members discussed instances where patient initially may not want full amount or the pharmacist has to bill twice due to insurance restrictions (see DEA letter on partial fills).

Subgroup Recommendation:

Community Subgroup - The subgroup discussed how the patient’s best interests need to be taken into consideration and that “unable to supply” should be construed more liberally. The subgroup recommended that text should be added after “unable to supply” to clarify its meaning, such as “per patient request, inventory shortage, or insurance limitations.”

Issue: Consider repealing the requirement that the remainder of partially filled prescriptions be provided to patients within 72 hours.

21 C.F.R. § 1306.13

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedule II

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is **unable to supply** the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. **The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.**

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is “terminally ill” or an “LTCF patient.” A prescription that is partially filled and does not contain the notation “terminally ill” or “LTCF patient” shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

(c) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

(1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the

LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription and the information required in § 1306.13(b).

(2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(3) Retrieval of partially filled Schedule II prescription information is the same as required by § 1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

Subgroup Recommendation:

Community Subgroup - The subgroup recommended changing the requirement that the remainder of a partially filled prescription be filled within 72 hours to within 30 days.

Recommendation 23: Revise 21 C.F.R. § 290.5 by Removing the Warning Statement from the Labeling Requirements or, in the Alternative, Revise to Make it More Understandable

The task force realized that the spirit of the warning statement is to decrease rampant drug abuse and addiction, but believed that the label should only contain important patient information. If it is determined that the statement should remain, members would urge that the statement be reworded and agreed with the Community Subgroup’s recommendation of “It is unlawful to share this medication.”

Issue: Should the “warning” statement referenced in paragraphs 825(c) and 290.5 below be reworded to improve its ability to be understood by patients?

- Members suggested rewording the warning statement, keeping in mind its potential relevance to controlled substance take-back programs.

21 U.S.C.A. § 825

United States Code Annotated Currentness

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 825. Labeling and packaging

(a) Symbol

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a) of this section.

(c) Warning on label

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

21 C.F.R. § 290.5

Code of Federal Regulations

Title 21. Food and Drugs

Chapter I. Food and Drug Administration, Department of Health and Human Services
(Refs & Annos)

Subchapter C. Drugs: General

Part 290. Controlled Drugs (Refs & Annos)

Subpart A. General Provisions

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a “controlled substance” in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: **“Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”** This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are “blind.”

Subgroup Recommendations:

Community Subgroup - The subgroup recommended revising the warning statement in a way that ensures that patients understand that they can return medications to take-back programs. The subgroup also recommended replacing the phrase “Federal law prohibits the transfer...” with “It is unlawful to share this medication.”

Miscellaneous Provisions Subgroup - The subgroup agreed to vote on the issue. Six members voted in favor of removing the warning statement altogether, two voted in favor of revising the term “transfer” to “give” or “sell” to increase patients’ understanding, and one voted to leave the statement as is.

Recommendation 24: Amend 21 C.F.R. § 1306.14 to No Longer Require Central Fill Pharmacy Identification Information on the Label

The task force discussed the issue and agreed that this information should not be required on the prescription label as it is not vital information for patients. Members recognized that this information is important in that it maintains an audit trail of the prescription filling process, and that this information should be recorded in the pharmacy systems. Members also discussed that patients have the right to know where their prescriptions are being filled, but that this can be addressed at state level. The task force ultimately agreed upon the following revisions denoted by underlines and ~~strikethroughs~~.

§ 1306.14 Labeling of substances and filling of prescriptions.

- (a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.
- (b) If the prescription is filled at a central fill pharmacy, the ~~central fill~~ retail pharmacy shall maintain an audit trail that contains documentation as to where the prescription was centrally filled ~~affix to the package a label showing the retail pharmacy name and address and a unique identifier,~~ (i.e. the central fill pharmacy's DEA registration number) ~~indicating that the prescription was filled at the central fill pharmacy,~~ in addition to the information required under paragraph (a) of this section.

Issue: Consider repealing the requirement that central fill pharmacy identification information be included on the label.

21 C.F.R. § 1306.14

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedule II

§ 1306.14 Labeling of substances and filling of prescriptions.

(a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(b) If the prescription is filled at a central fill pharmacy, the central fill pharmacy shall affix to the package a label showing the retail pharmacy name and address and a unique identifier, (i.e. the central fill pharmacy's DEA registration number)

indicating that the prescription was filled at the central fill pharmacy, in addition to the information required under paragraph (a) of this section.

(c) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: Provided, That:

...

Subgroup Recommendations:

Community Subgroup - The subgroup recommended repealing the requirement that the central fill pharmacy's identification information be included on the label. The subgroup believed that this information was unnecessary, especially in light of space limitations, but agreed that there should be an alternate method of informing patients of the central fill pharmacy location such as on the receipt or posted in the pharmacy.

Miscellaneous Provisions Subgroup - The subgroup recommended removing the identification of the central fill pharmacy from the label provided that an audit trail is maintained.

Recommendation 25: Revision of 21 C.F.R. § 1306.04 is Unnecessary

Members felt this was not an issue that needed to be addressed at this time.

Issue: Consider agency issues related to purchase of controlled substances for office use.

- Members discussed whether a prescription could be used as an “invoice.”

21 C.F.R. § 1306.04

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

General Information

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for “detoxification treatment” or “maintenance treatment,” unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended that it was unnecessary to revise this provision.

Recommendation 26: Revision for the Purpose of Allowing the Delivery of Controlled Substances to the Location of the Patient's Choice is Unnecessary

Members felt this was not an issue that needed to be addressed at this time.

Issue: Consider agency issues related to delivery of a controlled substance to a prescriber for administration to a specific patient.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended allowing a prescription for a controlled substance to be delivered to the location of the patient's choice.

Recommendation 27: Revision of 21 C.F.R. § 1306.15 is Unnecessary

Members felt this was not an issue that needed to be addressed at this time.

Issue: Discuss whether to recommend that central fill pharmacies be allowed to ship medication directly to patients.

21 C.F.R. § 1306.15

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedule II

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall also apply:

(a) Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile.

The retail pharmacy transmitting the prescription information must:

(1) Write the words "CENTRAL FILL" on the face of the original paper prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal. For electronic prescriptions the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

(2) Ensure that all information required to be on a prescription pursuant to Section 1306.05 of this part is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);

(3) Maintain the original prescription for a period of two years from the date the prescription was filled;

(4) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

(1) Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and DEA registration number of the retail pharmacy transmitting the prescription;

(2) Keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist filling the prescription, and the date of filling of the prescription;

(3) Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common or contract carrier).

Subgroup Recommendation:

Community Subgroup - The subgroup supported this activity although concerns were voiced that this activity may constitute “mail order” in some states. The subgroup recommended that this issue requires clarification at the state level regarding “central fill” versus “mail order.”

Recommendation 28: Revise 21 C.F.R. § 1306.25 to Allow for Electronic Transfers

The task force agreed that direct communication for transfers was unnecessary if pharmacies share an electronic, real-time, online database. The task force recommends the following revision denoted by underlines.

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) Unless the pharmacies share an electronic, real-time, online database, ~~the~~ transfer must be communicated directly between two licensed pharmacists.

Issue: Review “between two pharmacists” wording in light of available technology. Also, review online database wording.

21 C.F.R. § 1306.25

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. **However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.**

(b) Transfers are subject to the following requirements:

(1) The transfer must be communicated directly between two licensed pharmacists.

(2) The transferring pharmacist must do the following:

(i) Write the word “VOID” on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(ii) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

- (iii) Record the date of the transfer and the name of the pharmacist transferring the information.
- (3) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to § 1306.21(a), the pharmacist receiving the transferred prescription information must write the word “transfer” on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to § 1306.05 and include:
- (i) Date of issuance of original prescription.
 - (ii) Original number of refills authorized on original prescription.
 - (iii) Date of original dispensing.
 - (iv) Number of valid refills remaining and date(s) and locations of previous refill(s).
 - (v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
 - (vi) Name of pharmacist who transferred the prescription.
 - (vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.
- (4) For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:
- (i) The date of the original dispensing.
 - (ii) The number of refills remaining and the date(s) and locations of previous refills.
 - (iii) The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
 - (iv) The name of the pharmacist transferring the prescription.
 - (v) The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.
- (5) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under paragraph (b)(4) of this section.
- (c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.
- (d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.
- (e) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

Subgroup Recommendation:

Community Subgroup - The subgroup reviewed the wording in subsection (b) (1) and recommended adding “unless the pharmacies share an electronic, real-time, online database.”

Recommendation 29: Recommend Revising 21 C.F.R. § 1301.74 to Require Reporting of Suspicious Orders Only for Direct Customers

The task force discussed this issue at length, particularly noting that the requirements are rather stringent for registrants in light of the fact that DEA limits access to the data, which makes it difficult to determine what to report. Members also acknowledged that the Automation of Reports and Consolidated orders System (ARCOS) database is only for CII and CIII narcotics so therefore not all of the data may be available. The task force recommends the following revisions denoted by underlines and ~~strikethroughs~~.

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose a direct customer's ~~to the registrant~~ suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Issue: Review suspicious order requirements.

Issue: Should manufacturers be allowed to collaborate with other groups to obtain information required to determine suspicious orders?

21 C.F.R. § 1301.74

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Security Requirements

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field

Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

89

- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- (5) Whether the specific controlled substances are likely candidates for diversion;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup discussed issues 34 and 35 collectively and recommended that DEA allow distributors, wholesalers, and manufacturers access to the Automation of Reports and Consolidated Orders System database. The subgroup also recommended establishing a program similar to prescription monitoring programs, which would proactively assist in preventing diversion.

Recommendation 30: Revision of the Power of Attorney Provisions is Unnecessary

Issue: To whom should a registrant be able to assign power of attorney to order CI or CII controlled substances?

- Members would like to clarify who can obtain the power of attorney.

21 C.F.R. § 1305.04

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart A. General Requirements

§ 1305.04 Persons entitled to order Schedule I and II controlled substances.

(a) Only persons who are registered with DEA under section 303 of the Act (21 U.S.C. 823) to handle Schedule I or II controlled substances, and persons who are registered with DEA under section 1008 of the Act (21 U.S.C. 958) to export these substances may obtain and use DEA Form 222 (order forms) or issue electronic orders for these substances. Persons not registered to handle Schedule I or II controlled substances and persons registered only to import controlled substances are not entitled to obtain Form 222 or issue electronic orders for these substances.

(b) An order for Schedule I or II controlled substances may be executed only on behalf of the registrant named on the order and only if his or her registration for the substances being purchased has not expired or been revoked or suspended.

21 C.F.R. § 1305.05

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart A. General Requirements

§ 1305.05 Power of attorney.

(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the

same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

(c) The power of attorney and notice of revocation must be similar to the following format:

Power of Attorney for DEA Forms 222 and Electronic Orders

(Name of registrant)

(Address of registrant)

(DEA registration number)

I, _____ (name of person granting power), the undersigned, who am authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for Forms 222 and to sign orders for Schedule I and II controlled substances, whether these orders be on Form 222 or electronic, in accordance with 21 U.S.C. 828 and Part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney must lawfully do or cause to be done by virtue hereof.

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

(signature of attorney-in-fact)

Witnesses:

1. _____
2. _____

Signed and dated on the ___ day of ___, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled

Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact ____ this same day.

(Signature of person revoking power)

Witnesses:

1. _____
2. _____

Signed and dated on the ____ day of ____, (year), at ____.

(d) A power of attorney must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the power of attorney is being granted; and two witnesses.

(e) A power of attorney must be revoked by the person who signed the most recent application for DEA registration or reregistration, and two witnesses.

Subgroup Recommendations:

Community Subgroup - The subgroup recommended that the individual who received the power of attorney should be a licensee for disciplinary purposes and to decrease the risk of diversion. Three members of the subgroup voiced that the power of attorney must be granted to a licensed pharmacist, while two members of the subgroup thought it would be appropriate to grant the power to a technician.

Hospital Subgroup - The subgroup recommends that only pharmacists should receive power of attorney.

Miscellaneous Provisions Subgroup - The subgroup recommended not revising this provision due to the fact that many wholesale distributors do not employ licensed pharmacists.

Recommendation 31: Encourage Interested Stakeholders to Provide Specific Recommendations to DEA

The task force discussed the issue and agreed that ARCOS could be streamlined but believed that industry stakeholders were better qualified to provide specific recommendations to DEA.

Issue: Review 21 CFR 1305.21 – 1305.29 (the provisions addressing the Controlled Substance Ordering System (CSOS)) to determine whether the procedures involved can be streamlined and/or clarified.

21 C.F.R. § 1305.21

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart C. Electronic Orders

§ 1305.21 Requirements for electronic orders.

- (a) To be valid, the purchaser must sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided in part 1311 of this chapter.
- (b) The following data fields must be included on an electronic order for Schedule I and II controlled substances:
- (1) A unique number the purchaser assigns to track the order. The number must be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.
 - (2) The purchaser's DEA registration number.
 - (3) The name of the supplier.
 - (4) The complete address of the supplier (may be completed by either the purchaser or the supplier).
 - (5) The supplier's DEA registration number (may be completed by either the purchaser or the supplier).
 - (6) The date the order is signed.
 - (7) The name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).
 - (8) The quantity in a single package or container.
 - (9) The number of packages or containers of each item ordered.
- (c) An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.

21 C.F.R. § 1305.22

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)
Subpart C. Electronic Orders

§ 1305.22 Procedure for filling electronic orders.

(a) A purchaser must submit the order to a specific supplier. The supplier may initially process the order (e.g., entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The registrant must maintain control of the processing of the order at all times.

(b) A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under § 1305.06.

(c) A supplier must do the following before filling the order:

(1) Verify the integrity of the signature and the order by using software that complies with Part 1311 of this chapter to validate the order.

(2) Verify that the digital certificate has not expired.

(3) Check the validity of the certificate holder's certificate by checking the Certificate Revocation List. The supplier may cache the Certificate Revocation List until it expires.

(4) Verify the registrant's eligibility to order the controlled substances by checking the certificate extension data.

(d) The supplier must retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record must also include any data on the original order that the supplier completes. Software used to handle digitally signed orders must comply with part 1311 of this chapter.

(e) If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (h) of this section.

(f) A supplier must ship the controlled substances to the registered location associated with the digital certificate used to sign the order, except as specified in paragraph (h) of this section.

(g) When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived.

(h) Registered procurement officers of the Defense Supply Center of the Defense Logistics Agency may order controlled substances for delivery to armed services establishments within the United States. These orders may be shipped to locations other than the registered location, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

21 C.F.R. § 1305.23

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice
Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)
Subpart C. Electronic Orders

§ 1305.23 Endorsing electronic orders.

A supplier may not endorse an electronic order to another supplier to fill.

21 C.F.R. § 1305.24

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart C. Electronic Orders

§ 1305.24 Central processing of orders.

(a) A supplier that has one or more registered locations and maintains a central processing computer system in which orders are stored may have one or more of the supplier's registered locations fill an electronic order if the supplier does the following:

- (1) Assigns each item on the order to a specific registered location for filling.
- (2) Creates a record linked to the central file noting both which items a location filled and the location identity.
- (3) Ensures that no item is filled by more than one location.
- (4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

21 C.F.R. § 1305.25

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart C. Electronic Orders

§ 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

- (1) The required data fields have not been completed.
- (2) The order is not signed using a digital certificate issued by DEA.
- (3) The digital certificate used had expired or had been revoked prior to signature.
- (4) The purchaser's public key will not validate the digital signature.
- (5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier

refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

21 C.F.R. § 1305.26

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart C. Electronic Orders

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is “Not Accepted” and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

21 C.F.R. § 1305.27

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)

Subpart C. Electronic Orders

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

21 C.F.R. § 1305.28

Code of Federal Regulations
Title 21. Food and Drugs
Chapter II. Drug Enforcement Administration, Department of Justice
Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)
Subpart C. Electronic Orders

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy “Void,” and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

21 C.F.R. § 1305.29

Code of Federal Regulations
Title 21. Food and Drugs
Chapter II. Drug Enforcement Administration, Department of Justice
Part 1305. Orders for Schedule I and II Controlled Substances (Refs & Annos)
Subpart C. Electronic Orders

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

Subgroup Recommendation:

Community Subgroup - The subgroup agreed with the task force recommendation to streamline and/or clarify the provisions addressing the CSOS.

Recommendation 32: The Record Retention Requirement Should Remain at Two Years

The task force discussed the issue and the fact that DEA reviewed this requirement while promulgating the regulations for electronic prescriptions for controlled substances and left it intact. Members agreed that this issue should be addressed at the state level in jurisdictions where it is problematic.

Issue: Consider increasing record retention requirement to three years to accommodate requirement that inventories be performed every two years.

21 U.S.C.A. § 827

United States Code Annotated Currentness

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 827. Records and reports of registrants

...

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

...

21 C.F.R. § 1304.04

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1304. Records and Reports of Registrants (Refs & Annos)

General Information

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the

Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

- (i) The nature of the records to be kept centrally.
- (ii) The exact location where the records will be kept.
- (iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.
- (iv) Whether central records will be maintained in a manual, or computer readable, form.

(2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances.

However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law

enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

Subgroup Recommendations:

Community Subgroup - The subgroup recommended increasing the record retention requirement to three years to accommodate the biennial inventory requirement.

Miscellaneous Provisions Subgroup - The subgroup with a vote of five to three recommended not increasing the record retention requirement from two to three years.

Recommendation 33: Revise 21 C.F.R. § 1304.11 to Allow for Electronic Maintenance of Inventories

The task force discussed this issue at length. Although members agreed that the wording in the statute and the regulation could be more consistent, they decided that a revision of the statute was unnecessary. Members did agree however, to recommend revising the regulation to allow for electronic maintenance of inventories, which is denoted below by underlines.

§ 1304.11 Inventory requirements.

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in electronic, written, typewritten, or printed form at the registered location.

...

Issue: Review the following wording in Subsection (a) (1) for consistency with the regulations found in 1304.11.

21 U.S.C.A. § 827

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section--

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) **which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;**

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured,

received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

...

21 C.F.R. § 1304.11

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1304. Records and Reports of Registrants (Refs & Annos)

Inventory Requirements

§ 1304.11 Inventory requirements.

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in

written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

...

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup recommended revising the language in 1304.11(a) by adding “electronic” to the terms “written,” “typewritten,” or “printed.”

Recommendation 34: Revise 21 C.F.R. § 1304.04 to Allow for All Records to Be Stored Electronically at a Central Location

The task force briefly discussed the issue and unanimously agreed that in light of today's technology, electronic storage of all controlled substances records and inventories at a central location should be allowed. Members recommend the following changes as denoted by underlines and ~~striketroughs~~.

Section 1304.04 Maintenance of records and inventories.

...

(1) ~~Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter)~~ Records and inventories may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records.

...

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

~~(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.~~

~~(1)~~(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records.

...

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows. Records may be scanned and stored electronically. If maintained electronically, the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location.

...

Issue: Should registrants be allowed to store all records electronically?

Subgroup Recommendations:

Hospital Subgroup - The subgroup recommended that registrants be allowed to store all records electronically.

Miscellaneous Provisions Subgroup - The subgroup unanimously recommended allowing registrants to store all records electronically.

Issue: Should language be added to allow electronic records and/or images to be stored electronically in a central location?

21 C.F.R. § 1304.04

Code of Federal Regulations

Title 21. Food and Drugs
Chapter II. Drug Enforcement Administration, Department of Justice
Part 1304. Records and Reports of Registrants (Refs & Annos)
General Information

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, every inventory and other records required to be kept under this part must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration.

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§ 1305.17 and 1305.27 of this chapter) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration of his intention to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the Administration in the area in which the registrant is located. Unless the registrant is informed by the Special Agent in Charge that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge. All notifications must include the following:

- (i) The nature of the records to be kept centrally.
 - (ii) The exact location where the records will be kept.
 - (iii) The name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally.
 - (iv) Whether central records will be maintained in a manual, or computer readable, form.
- (2) A registered retail pharmacy that possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this part for those additional registered sites at the retail pharmacy or other approved central location.

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

(2) If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.

(3) The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the Administration for such records, and if the Administration chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration to inspect such records at the central location upon request by such employees without a warrant of any kind.

(4) In the event that a registrant fails to comply with these conditions, the Special Agent in Charge may cancel such central recordkeeping authorization, and all other central

recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this paragraph the registrant shall, within the time specified by the Special Agent in Charge, comply with the requirements of this section that all records be kept at the registered location.

(c) Registrants need not notify the Special Agent in Charge or obtain central recordkeeping approval in order to maintain records on an in-house computer system.

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

(f) Each registered manufacturer, distributor, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

(g) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in paragraph (f) of this section.

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances.

However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

Subgroup Recommendations:

Hospital Subgroup - The subgroup recommended adding language to allow electronic records and/or images to be stored in a central location.

Miscellaneous Provisions Subgroup - The subgroup recommended adding language to allow electronic records and/or images to be stored in a central location.

Recommendation 35: Revision of 21 C.F.R. § 1304.11 is Unnecessary

The task force discussed this issue at length. Members agreed that issues of overfill and wastage conceivably could facilitate substance abuse by health care practitioners. Nonetheless, the members agreed that the sheer amount of work necessary to completely document overfill or wastage would be burdensome and contribute slightly, if at all, to preventing substance abuse or diversion.

Issue: Should registrants be required to keep complete records and/or documentation related to wastage, specifically for compounding and surgical center pharmacies?

- Clarify needs for record keeping in general, particularly for wastage and/or overage in compounding and for overfill from manufacturers.

21 C.F.R. § 1304.11

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1304. Records and Reports of Registrants (Refs & Annos)

Inventory Requirements

§ 1304.11 Inventory requirements.

(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed.

Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) Initial inventory date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) Inventory date for newly controlled substances. On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts. Each person registered or authorized (by § 1301.13 or §§ 1307.11-1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) Inventories of manufacturers. Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held

for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

- (A) The name of the substance;
- (B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
- (C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) Inventories of distributors. Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) Inventories of dispensers, researchers, and reverse distributors. Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

- (i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or
- (ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) Inventories of importers and exporters. Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) Inventories of chemical analysts. Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

Subgroup Recommendation:

Hospital Subgroup - The subgroup agreed that registrants should be required to keep complete records and/or documentation related to wastage, specifically for compounding

and surgical center pharmacies. In addition, the subgroup, in reference to the wording addressing inventories, recommended replacing the term “estimated” with “exact.” The revisions recommended by the subgroup are denoted by underlines and strikethroughs.

(ii) If the substance is listed in Schedule III, IV or V, make an ~~estimated~~ exact count or measure of the contents, ~~unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.~~

Recommendation 36: Revision of 21 U.S.C.A. § 827 is Unnecessary

The task force discussed this issue and agreed that it was “over and above” the purview of the task force in that it addressed the practice of medicine.

Issue: Review 827 (c) (1) (B) to determine if the wording refers to samples and, if so, suggest edits to clarify and possibly modernize.

21 U.S.C.A. § 827

United States Code Annotated

Title 21. Food and Drugs

Chapter 13. Drug Abuse Prevention and Control

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

§ 827. Records and reports of registrants

(c) Nonapplicability

The foregoing provisions of this section shall not apply--

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances **and charges his patients**, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

...

21 C.F.R. § 1304.03

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1304. Records and Reports of Registrants (Refs & Annos)

General Information

§ 1304.03 Persons required to keep records and file reports.

...

(d) A registered individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances **and charges patients**, either separately or together with charges for other professional services, for substances so dispensed or

administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.

(e) Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he/she practices which describe the conditions and extent of his/her authorization to dispense controlled substances and shall make such

documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines or practice agreements.

(f) Registered persons using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections, are not required to keep records if he/she notifies the Administration of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(g) A distributing registrant who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records must contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing registrant may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location must be submitted in accordance with § 1304.04 of this part. These records must be maintained for a period of two years.

(h) A person is required to keep the records and file the reports specified in § 1304.06 and part 1311 of this chapter if they are either of the following:

- (1) An electronic prescription application provider.
- (2) An electronic pharmacy application provider.

Subgroup Recommendations:

Hospital Subgroup - The subgroup discussed the provision and determined that there should be no exceptions to record keeping to ensure compliance with good practices and address concerns over public safety, and that physicians should be required to keep all records. Members also voiced concern over the ambiguity in the term “regularly engages.”

Miscellaneous Provisions Subgroup - The subgroup recommended revising these provisions to provide for the record keeping of all drugs that are dispensed or administered and specifically recommended deleting the term “charges patients.” The subgroup also recommended that manufacturers of controlled substances not distribute samples and instead issue vouchers that prescribers can give to patients so the patients may obtain the product from pharmacies at no charge.

Recommendation 37: Revision of DEA Form 106 is Unnecessary

Members agreed with the subgroup recommendation that the amount of space for text on DEA Form 106 was adequate.

Issue: Should DEA Form 106 be revised to increase the space provided for explanation of loss?

- Is there a character limit on the electronic DEA Form 106?

21 C.F.R. § 1301.74

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Security Requirements

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. **The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss.** Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) The specific controlled substances lost;
- (3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

- (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- (5) Whether the specific controlled substances are likely candidates for diversion;
- (6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term “customer” includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

Subgroup Recommendation:

Hospital Subgroup - The subgroup reviewed the space provided for explanation of loss on a DEA Form 106 and determined the space is adequate and does not require revising.

Recommendation 38: Revise 21 C.F.R. § 1306.22 by Removing Subsection (f)(3) that Contains the Requirement that the Pharmacist Date and Sign the Printed Refill Log

The task force agreed with the subgroups' recommendations in that this requirement is a quaint remnant of a long by-gone era and is completely unnecessary providing that the electronic log is readily available.

Issue: Consider whether the requirement of having the pharmacist date and sign the printed refill log is necessary.

21 C.F.R. § 1306.22

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

- (1) The name and dosage form of the controlled substance.
- (2) The date filled or refilled.
- (3) The quantity dispensed.
- (4) The initials of the dispensing pharmacist for each refill.
- (5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

- (1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.
- (2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of

refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be

maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

Subgroup Recommendations:

Community Subgroup - The subgroup agreed that the requirement of having the pharmacist date and sign the printed refill log is unnecessary due to the fact that these records are kept electronically; however, they recommended that the records must be readily available.

Hospital Subgroup - The subgroup determined that signing and dating the printed refill log was unnecessary because an electronic log is maintained that contains the required information.

Recommendation 39: Revise 21 C.F.R. § 1306.26 To Allow for an Electronic Record Log for the Dispensing of Nonprescription Controlled Substances

The task force agreed that registrants should be allowed to retain records for nonprescription controlled substances transactions electronically. The revision is denoted by underlines.

§ 1306.26 Dispensing without prescription.

...

(e) An electronic record or bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

...

Issue: Consider adding an electronic record keeping option for the dispensing of nonprescription controlled substances.

21 C.F.R. § 1306.26

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1306. Prescriptions (Refs & Annos)

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

- (a) Such dispensing is made only by a pharmacist (as defined in part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);
- (b) Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
- (c) The purchaser is at least 18 years of age;
- (d) The pharmacist requires every purchaser of a controlled substance under this section not known to him to furnish suitable identification (including proof of age where appropriate);
- (e) **A bound record book for dispensing of controlled substances under this section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of**

each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of § 1304.04 of this chapter); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law.

(g) Central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this section.

Subgroup Recommendation:

Community Subgroup - The subgroup recommended allowing an electronic log providing that the pharmacist verifies and adds the patient's identification or license number in the log at the time of purchase.

Recommendation 40: Reinstatement of 21 U.S.C.A. § 886a is Unnecessary

Members discussed the issue and concluded that this was an issue that need not be addressed at this time.

Issue: Congressional oversight of this account was struck from the law in 1998. Should it be reinstated?

21 U.S.C.A. § 886a

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part E. Administrative and Enforcement Provisions

§ 886a. Diversion Control Fee Account

(1) In general

There is established in the general fund of the Treasury a separate account which shall be known as the Diversion Control Fee Account. For fiscal year 1993 and thereafter:

(A) There shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of \$15,000,000, for the operation of its diversion control program.

(B) Such amounts as are deposited into the Diversion Control Fee Account shall remain available until expended and shall be refunded out of that account by the Secretary of the Treasury, at least on a quarterly basis, to reimburse the Drug Enforcement Administration for expenses incurred in the operation of the diversion control program. Such reimbursements shall be made without distinguishing between expenses related to controlled substance activities and expenses related to chemical activities.

(C) Fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.

(D) The amount required to be refunded from the Diversion Control Fee Account for fiscal year 1994 and thereafter shall be refunded in accordance with estimates made in the budget request of the Attorney General for those fiscal years. Any proposed changes in the amounts designated in said budget requests shall only be made after notification to the Committees on Appropriations of the House of Representatives and the Senate fifteen days in advance.

(2) Definitions

In this section:

(A) Diversion control program

The term “diversion control program” means the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.

(B) Controlled substance and chemical diversion control activities

The term “controlled substance and chemical diversion control activities” means those activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals.

CREDIT(S) (Pub.L. 102-395, Title I, § 111(b), Oct. 6, 1992, 106 Stat. 1843; Pub.L. 105-362, Title X, § 1001(b), Nov. 10, 1998, 112 Stat. 3291; Pub.L. 108-447, Div. B, Title VI, § 633(a), Dec. 8, 2004, 118 Stat. 2921.)

HISTORICAL AND STATUTORY NOTES

...

1998 Amendments. Par. (5). Pub.L. 105-362, § 1001(b), struck out par. (5), which read: “The Attorney General shall prepare and submit annually to the Congress, statements of financial condition of the account, including the beginning balance, receipts, refunds to appropriations, transfers to the general fund, and the ending balance.”

Subgroup Recommendation:

Miscellaneous Provisions Subgroup - The subgroup agreed with the task force’s recommendation to reinstate paragraph five above.

Recommendation 41: NABP Should Comment on Proposed Rules to the Secure and Responsible Drug Disposal Act of 2010 when Posted

The task force agreed that NABP should continue to wait for a DEA Notice Of Rulemaking and comment appropriately.

Issue: Consider commenting in the future on drug disposal issues.

- DEA has indicated that two separate rules are pending for community pharmacy and LTCF.

21 C.F.R. § 1307.21

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1307. Miscellaneous (Refs & Annos)

Disposal of Controlled Substances

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

(b) The Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substance;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By destruction in the presence of an agent of the Administration or other authorized person; or

(4) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

(c) In the event that a registrant is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the registrant to dispose of such substances, in accordance with paragraph (b) of this section, without prior approval of the Administration in each instance, on the condition that the registrant keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting such authority, the Special Agent in Charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.

(d) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any State.

Subgroup Recommendation:

Long-term Care Subgroup - The subgroup recommended that the task force should comment on the rules once proposed.

Resolutions passed at 107th Annual Meeting, San Antonio, TX

Resolution No. 107-1-11

Title: Task Force on Pharmacy Practice Technology Systems

Action: Pass

Whereas, significant advances in technologies, including the use of automated pharmacy systems, remote dispensing systems, electronic prescribing systems, and other methodologies have rapidly emerged to support the preparation (including storage and packaging), delivery or distribution, dispensing, and administration of medication to patients in the pharmacy and other health care settings; and

Whereas, the national use of such systems requires greater uniformity to define terms found in the laws and regulations of individual states and avoid disparity and confusion when assessing, authorizing, and applying the use of such systems; and

Whereas, the boards of pharmacy are uniquely positioned to create or influence greater specificity and uniformity of federal and state laws and regulations addressing the use of such systems so as to facilitate optimal patient care and safety in pharmacy and other health care settings; and

Whereas, security and accuracy related to the use of these systems are primary concerns of the state boards of pharmacy in protecting the public health and safety; and

Whereas, there is a need for NABP to review and possibly revise the sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* that address this important subject;

THEREFORE BE IT RESOLVED that NABP commission a task force of interested stakeholders to review existing current state laws and regulations addressing the use of technology systems and relevant *Model Act* language in accordance with the protection of public health and safety as determined by the state boards of pharmacy and to propose recommendations to update *Model Act* language to accommodate advances in technology systems.

Resolution No. 107-2-11

Title: Information Exchange for Prescription Monitoring Programs

Action: Pass

Whereas, the development and implementation of prescription monitoring programs (PMP) provide a valuable resource for state boards of pharmacy, state boards of medicine, pharmacists, prescribers, and law enforcement agencies to assist patients and manage the prescribing and use of controlled substances and other drugs of concern; and

Whereas, the operability of PMPs between states is critical; and

Whereas, NABP has assisted states and serves as a means to facilitate and manage communications and data exchange among the states for a variety of programs and resources;

THEREFORE BE IT RESOLVED that state boards of pharmacy continue to support NABP developing and implementing a centralized interconnect hub to facilitate the interoperability and data sharing among state PMPs.

Resolution No. 107-3-11

Title: Control and Accountability of Prescription Medications

Action: Pass

Whereas, state boards of pharmacy are aware that prescription medications, including controlled substances, that are diverted from licensed pharmacies contribute to drug abuse, including abuse by children, adolescents, and teens; and

Whereas, the diversion of prescription drugs compromises patient safety; and

Whereas, preventing and detecting diversion is an important responsibility of state boards; and

Whereas, state boards use different methods and include in state practice acts and regulations provisions to encourage pharmacists and pharmacies to proactively maintain the security of controlled drugs;

THEREFORE BE IT RESOLVED that NABP commission a task force of interested stakeholders to review existing state laws and regulations addressing the control and accountability of prescription drugs, the Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act, as well as relevant sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to identify potential language for incorporation into the *Model Act* that will reflect the responsibility of licensed pharmacies and pharmacists to maintain control over prescription medications and provide workable examples of controls and monitoring measures that pharmacies and pharmacists can utilize to prevent, detect, and investigate losses of prescription drugs.

Resolution No. 107-4-11

Title: Pharmacists and Pharmacy Care

Action: Pass

Whereas, population demographics are leading the United States health care delivery system toward an inadequate supply of physicians and other practitioners that provide primary health care to the burgeoning population of aging and underserved Americans; and

Whereas, pharmacists in many US states currently possess limited prescribing authority and authority to dispense medications pursuant to collaborative protocols and procedures agreed upon by the pharmacist and the practitioner; and

Whereas, pharmacists in many US states are caring for patients by performing medication therapy management (MTM) and other collaborative drug therapy management arrangements with practitioners;

THEREFORE BE IT RESOLVED that NABP encourage and support efforts by the profession to study the primary health care activities in which pharmacists can be engaged and methods by which pharmacists could be incorporated into the medical home model to address the impending paucity of primary health care providers and the abyss between the availability of primary health care providers and the growing demand for primary health care services; and

BE IT FURTHER RESOLVED that NABP work with the Federation of State Medical Boards, National Council of State Boards of Nursing, the state boards of pharmacy, and other stakeholders to facilitate a

broader understanding of the potential for pharmacists, as providers, to engage in primary health care activities and ensure appropriate availability of primary health care services for all citizens.

Resolution No. 107-5-11

Title: Recognition Resolution

Whereas, the individuals listed here have made significant contributions to NABP, the protection of the public health, and the profession of pharmacy:

Thomas Dudley (OK)
Thomas Foster (KY)
Francis H. Hicks (ID)
Joseph Hodge (SC)
Steven C. Judy (WV)
Thomas C. Lynch, Jr (SC)
Barbara McAndrew (TN)
Fred Shiel, Jr (LA)
Barbara Wells (ON)
Joseph F. Zastera, Jr (MN)

Whereas, NABP and its member boards of pharmacy are saddened by the death of these individuals;

THEREFORE BE IT RESOLVED that NABP and its members formally acknowledge the leadership and contributions made by these individuals; and

BE IT FURTHER RESOLVED that NABP and the boards of pharmacy extend their sincere sympathies to the family and friends of these members.

PATIENT-CENTERED LABEL REQUIREMENTS:

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

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

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

(A) Name of the patient

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Enforcement Committee Attachment 2

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

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

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

(c) Beginning in October 2011 the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

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

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

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

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

Excerpt of Board of Pharmacy Meeting Minutes, May 3, 2011:

Request 3: From CPhA's Long-Term Care Academy for Skilled Nursing Facilities

Dr. Kajioka provided that the committee had a detailed discussion with CPhA long-term care members about the method of drug distribution within skilled nursing facilities (SNFs), continuing discussions started at the prior Enforcement Committee and February 2011 Board Meeting. He stated that of particular concern to the committee was that if the exemption were provided to pharmacies dispensing drugs to skilled nursing facilities, how will the pharmacies, particularly those dispensing medications in the bingo cards that are often used in SNFs, be able to ensure that these discharged patients can readily read the labels when they leave the facility.

Dr. Kajioka provided that the labels must adhere to the labeling requirements if there is any opportunity for the medication to go home with the patient.

Dr. Kajioka provided that when reviewing the bingo-type cards in use in SNFs, the committee generally concluded that these cards should be labeled according to the patient-centered requirement because they are potentially likely to be taken home with patients because they may contain a seven or 30 day supply of drugs. He stated that the committee noted that there appears to be adequate space on the bingo cards to label the product according to the patient-centered requirements.

Dr. Kajioka provided that the committee agreed that unit-dose medications dispensed via an automated dispensing machine in SNFs could be exempt from the patient-centered labeling requirements.

Dr. Kajioka reviewed the motion from the committee to recommend an exemption to the patient-centered label requirements for unit dose medications dispensed via an automated dispensing machine in SNFs pursuant to Business and Professions Code section 4076.5(d).

Discussion

Ms. Shellans clarified that the exemption is being sought for unit-dose medications that are administered to the patient by a licensed healthcare professional.

The board discussed the committee's recommendation in light of the request. Concern was expressed that the recommendation does not specify that the exemption is specifically for medication that will not go home with the patient. The board asked for clarification on CPhA's request.

Mr. Room clarified that CPhA's initial request was for an exemption for all medications dispensed by a pharmacy to a SNF. He indicated that the committee felt that the request was only appropriate for unit-dose medication that would not go home with the patient.

Stan Goldenberg, representing CPhA, and Scott Hahn, representing Omnicare, provided an overview of emergency medications dispensed in SNFs. He discussed that this medication, usually a unit-dose, can come from an automated system or an e-kit. Mr. Goldenberg clarified that in both cases, no medication will go home with the patient. He also provided comment regarding new technology that pre-pours medications, as programmed by the contracting pharmacy, into an envelope to be administered by nursing staff to patients. Mr. Goldenberg stated that the envelopes are labeled to the patient according to the labeling laws previous to the patient-centered label regulation.

Mr. Goldenberg provided that the labels on bingo cards will be in a 10-point font, in compliance with the regulation. He discussed that the committee indicated that the patient can request a 12-point font at the time of the next refill post discharge from a SNF. He requested that, in the event the exemption is granted, the next issue of *The Script* include an article to clarify the exemption for the industry.

Mr. Room discussed two legally defensible possibilities regarding dispensing: (1) dispensing to the patient happens only once during the initial dispensing or (2) dispensing to the patient happens when the patient has an opportunity to comment on the dispensing transaction. He recommended that the board clarify what it considers a dispensing transaction to be by way of regulation.

Mr. Goldenberg discussed additional challenges with the overlay of new federal and insurance requirements that require dispensing in smaller doses. He also discussed the need for uniformity in labeling for licensed staff and the challenges faced with the relabeling of medication prior to discharge.

Board Member Deborah Veale cautioned the board from overanalyzing this issue. She reiterated that bingo cards will be dispensed with a label in a 10-point font and the patient will have the opportunity to request a 12-point font at the time of the next refill.

Board Member Ramón Castellblanch discussed that the population being discharged from SNFs are at a greater need for understanding and reading the information on the label. He provided that any medication that could go home with the patient, including bingo cards, should comply with the requirements of the regulation.

Mr. Goldenberg provided comment regarding patient discharge from SNFs and indicated that requiring relabeling of medication in a 12-point font prior to

discharge will result in significant delays. He discussed that requiring a 12-point label for all medications would result in larger, costly packaging and would disrupt the established systems inside SNFs to ensure that patients receive the appropriate medication.

Dr. Castellblanch provided that the pharmacy industry has expressed similar concern; yet, is complying with the requirements. He expressed concern regarding the board's jurisdiction with regards to discharge in nursing homes and suggested that the board hear input from nursing home advocates on this issue.

Mr. Room discussed the board's limited authority under section 4076.5(d) which states that the board may not exempt prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility. He stated that the only way the requirement for 12-point font upon request will not be required is if the board determines that dispensing only occurs at the time of the initial dispensing and the request for 12-point font can be ignored. Mr. Room indicated that this is an interpretation, not an exemption.

President Weisser encouraged the board to consider what interpretation is in the best interest of the patient. He discussed that patient protection could be compromised if it is determined that no medications can go home at discharge.

Discussion continued. Concern was expressed regarding ownership of the medication while the patient is in a SNF and possible unintended consequences in the event the medication is withheld.

Ms. Shellans provided that regulations will need to be promulgated before any exemption can be granted. She stated that this discussion will be used for development of such regulations.

Dr. Kajioka suggested that this issue be returned to the Enforcement Committee for further review.

MOTION: Table action on the recommendation from the Enforcement Committee.

M/S: Schell/Lippe

Support: 10

Oppose: 0

Abstain: 0

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee



Brian J. Stiger, Director
April 2011



Substance Abuse Coordination Committee

Brian Stiger, Chair
Director, Department of Consumer Affairs

Elinore F. McCance-Katz, M.D., Ph. D.
CA Department of Alcohol & Drug Programs

Janelle Wedge
Acupuncture Board

Kim Madsen
California Board of Behavioral Sciences

Robert Puleo
Board of Chiropractic Examiners

Lori Hubble
Dental Hygiene Committee of California

Richard De Cuir
Dental Board of California

Linda Whitney
Medical Board of California

Heather Martin
California Board of Occupational Therapy

Mona Maggio
California State Board of Optometry

Teresa Bello-Jones
**Board of Vocational Nursing and
Psychiatric Technicians**

Donald Krpan, D.O.
Osteopathic Medical Board of California

Francine Davies
Naturopathic Medicine Committee

Virginia Herold
California State Board of Pharmacy

Steve Hartzell
Physical Therapy Board of California

Elberta Portman
Physician Assistant Committee

Jim Rathlesberger
Board of Podiatric Medicine

Robert Kahane
Board of Psychology

Louise Bailey
Board of Registered Nursing

Stephanie Nunez
Respiratory Care Board of California

Annemarie Del Mugnaio
**Speech-Language Pathology & Audiology &
Hearing Aid Dispenser Board**

Susan Geranen
Veterinary Medical Board

Table of Contents

Uniform Standard #1 4

Uniform Standard #2 6

Uniform Standard #3 7

Uniform Standard #4 8

Uniform Standard #5 12

Uniform Standard #6 13

Uniform Standard #7 14

Uniform Standard #8 16

Uniform Standard #9 17

Uniform Standard #10 18

Uniform Standard #11 20

Uniform Standard #12 21

Uniform Standard #13 22

Uniform Standard #14 26

Uniform Standard #15 27

Uniform Standard #16 28

#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:
 - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;
 - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,
 - is approved by the board.
2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
3. The clinical diagnostic evaluation report shall:
 - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
 - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
 - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.
2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

TESTING FREQUENCY SCHEDULE

A board may order a licensee to drug test at any time. Additionally, each licensee shall be tested RANDOMLY in accordance with the schedule below:

Level	Segments of Probation/Diversion	Minimum Range of Number of Random Tests
I	Year 1	52-104 per year
II*	Year 2+	36-104 per year

*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program or who has committed a Major Violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued.

EXCEPTIONS TO TESTING FREQUENCY SCHEDULE

I. PREVIOUS TESTING/SOBRIETY

In cases where a board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing, prior to being subject to testing by the board, the board may give consideration to that testing in altering the testing

frequency schedule so that it is equivalent to this standard.

II. VIOLATION(S) OUTSIDE OF EMPLOYMENT

An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule.

III. NOT EMPLOYED IN HEALTH CARE FIELD

A board may reduce testing frequency to a minimum of 12 times per year for any person who is not practicing OR working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the licensee's board. Prior to returning to any health care employment, the licensee shall be subject to level I testing frequency for at least 60 days. At such time the person returns to employment (in a health care field), if the licensee has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

IV. TOLLING

A board may postpone all testing for any person whose probation or diversion is placed in a tolling status if the overall length of the probationary or diversion period is also tolled. A licensee shall notify the board upon the licensee's return to California and shall be subject to testing as provided in this standard. If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

V. SUBSTANCE USE DISORDER NOT DIAGNOSED

In cases where no current substance use disorder diagnosis is made, a lesser period of monitoring and toxicology screening may be adopted by the board, but not to be less than 24 times per year.

OTHER DRUG STANDARDS

Drug testing may be required on any day, including weekends and holidays.

The scheduling of drug tests shall be done on a random basis, preferably by a computer program, so that a licensee can make no reasonable assumption of when he/she will be tested again. Boards should be prepared to report data to support back-to-back testing as well as, numerous different intervals of testing.

Licensees shall be required to make daily contact to determine if drug testing is required.

Licensees shall be drug tested on the date of notification as directed by the board.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.

Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.

Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.

Collection of specimens shall be observed.

Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.

Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

A board may use other testing methods in place of, or to supplement biological fluid testing, if the alternate testing method is appropriate.

PETITIONS FOR REINSTATEMENT

Nothing herein shall limit a board's authority to reduce or eliminate the standards specified herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522 or statutes applicable to the board that contains different provisions for reinstatement or reduction of penalty.

OUTCOMES AND AMENDMENTS

For purposes of measuring outcomes and effectiveness, each board shall collect and report historical and post implementation data as follows:

Historical Data - Two Years Prior to Implementation of Standard

Each board should collect the following historical data (as available), for a period of two years, prior to implementation of this standard, for each person subject to testing for banned substances, who has 1) tested positive for a banned substance, 2) failed to

appear or call in, for testing on more than three occasions, 3) failed to pay testing costs, or 4) a person who has given a dilute or invalid specimen.

Post Implementation Data- Three Years

Each board should collect the following data annually, for a period of three years, for every probationer and diversion participant subject to testing for banned substances, following the implementation of this standard.

Data Collection

The data to be collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

Probationer/Diversion Participant Unique Identifier
License Type
Probation/Diversion Effective Date
General Range of Testing Frequency by/for Each Probationer/Diversion Participant
Dates Testing Requested
Dates Tested
Identify the Entity that Performed Each Test
Dates Tested Positive
Dates Contractor (if applicable) was informed of Positive Test
Dates Board was informed of Positive Test
Dates of Questionable Tests (e.g. dilute, high levels)
Date Contractor Notified Board of Questionable Test
Identify Substances Detected or Questionably Detected
Dates Failed to Appear
Date Contractor Notified Board of Failed to Appear
Dates Failed to Call In for Testing
Date Contractor Notified Board of Failed to Call In for Testing
Dates Failed to Pay for Testing
Date(s) Removed/Suspended from Practice (identify which)
Final Outcome and Effective Date (if applicable)

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year.
3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.
3. If the worksite monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance:

1. The board shall order the licensee to cease practice;
2. The board shall contact the licensee and instruct the licensee to leave work; and
3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;
2. Communicate with the licensee and/or any physician who is treating the licensee; and
3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a “deferred prosecution” stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Licensee will be ordered to cease practice.
 - a) the licensee must undergo a new clinical diagnostic evaluation, and
 - b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee’s substance abuse.
3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.
5. Continuous sobriety for three (3) to five (5) years.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

(a) Specimen Collectors:

- (1) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.
- (2) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.
- (3) The provider or subcontractor must provide collection sites that are located in areas throughout California.
- (4) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.
- (5) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.
- (6) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

- (7) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.
- (8) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- (9) Must undergo training as specified in Uniform Standard #4 (6).

(b) Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- (1) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- (2) must be licensed or certified by the state or other nationally certified organization;
- (3) must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year;
- (4) shall report any unexcused absence within 24 hours to the board, and,
- (5) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

(c) Work Site Monitors:

The worksite monitor must meet the following qualifications:

- (1) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
- (2) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no

monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

- (3) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
 - (4) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
2. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.
 3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
 4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;

- any indicators that can lead to suspected substance abuse.

(d) Treatment Providers

Treatment facility staff and services must have:

- (1) Licensure and/or accreditation by appropriate regulatory agencies;
- (2) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
- (3) Professional staff who are competent and experienced members of the clinical staff;
- (4) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
- (5) Means to provide treatment/progress documentation to the provider.

(e) General Vendor Requirements

The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

- (1) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.
- (2) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
- (3) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.
2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.
- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

Potential Revisions to Disciplinary Guidelines to Incorporate SB 1441 Uniform Standards and Staff Proposals¹

Changes in blue reflect the Uniform Standards (green is used for subcommittee edits)

Changes in red reflect staff proposals that may have predated the Uniform Standards

18. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation² (Appropriate for those cases where evidence demonstrates that mental illness, substance abuse, or disability was a contributing cause of ~~the~~ a violation or violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [pharmacist, pharmacy technician, or designated representative] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee. If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to other terms and conditions listed in these guidelines (e.g., required psychotherapy, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt these restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.~~

~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

¹ This document is limited to those terms and conditions in the Disciplinary Guidelines that would be affected by the SB 1441 Uniform Standards. For those, it shows both the proposed changes necessary to conform to the SB 1441 Uniform Standards and the changes separately proposed by staff. There are other terms and conditions where staff have proposed changes that are not included here, because this discussion is focused on the Uniform Standards.

² The changes to this term are those necessary to make it consistent with Uniform Standards # 1 and # 2.

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

~~If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.~~

Option #1 (mandatory in all cases involving alcohol or substance abuse): The evaluation(s) shall be conducted in accordance with acceptable professional standards for alcohol or substance abuse clinical diagnostic evaluations. The written report(s) shall set forth, at least, the opinions of the evaluator as to: whether respondent has an alcohol or substance abuse problem; whether respondent is a threat to him/herself or others; and recommendations for alcohol or substance abuse treatment, practice restrictions, or other steps related to respondent's rehabilitation and safe practice. If the evaluator determines during the evaluation process that respondent is a threat to him/herself or others, the evaluator shall notify the board within twenty-four (24) hours.

Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [pharmacist, pharmacy technician, or designated representative] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [pharmacist, pharmacy technician, or designated representative];
- Respondent has submitted to observed bodily fluid testing for the presence of alcohol, dangerous drugs, or controlled substances [pursuant to Term and Condition ??] ~~at least twice per week~~ for at least thirty (30) days;
- During the testing period, respondent has not had a confirmed positive test result for alcohol, or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment, ~~for at least thirty (30) days;~~

- The board or its designee has determined that respondent is safe to return to either full-time or part-time practice as a [pharmacist, pharmacy technician, or designated representative], after considering the evaluation report(s), the results of the fluid testing, and criteria including the license type, respondent's history, respondent's documented period of sobriety or documented time since last use, respondent's scope and pattern of use, respondent's treatment history, respondent's medical history and current medical condition, the nature, duration, and severity of respondent's alcohol or substance abuse, and whether respondent is a threat to him/herself or others; and
- Respondent receives written notice that practice may resume.

[Staff propose moving this paragraph from the guidelines to the form used to select evaluators:]

The board or its designee shall select or approve evaluator(s) holding a valid, unrestricted license to practice, with a scope of practice that includes the conduct of clinical diagnostic evaluations and at least three (3) years experience conducting such evaluations of health professionals with alcohol or substance abuse problems. The evaluator(s) shall not have a financial relationship, personal relationship, or business relationship with respondent within the last five (5) years. The evaluator(s) shall provide an objective/ unbiased, and independent evaluation of respondent.

For all such evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator ~~is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.~~ completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices.

Option #2 (optional in all other cases): Commencing on the effective date of this decision, respondent ~~is suspended from practice and~~ shall not ~~engage in the practice of pharmacy practice as a [pharmacist, pharmacy technician, or designated representative] until notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The final written report of the evaluation shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days. completes the evaluation.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

Option #3 (optional in all other cases): If recommended by the ~~evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [pharmacist, pharmacy technician, or designated representative] by providing written notice of suspension. Upon suspension, respondent shall not resume practice as a [pharmacist, pharmacy technician, or designated representative] until another evaluation done at respondent's expense by a licensed practitioner selected or approved by the board or its designee recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days. completes the evaluation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs

~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During ~~any such~~ suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, ~~pharmacy technician, or designated representative~~. Respondent shall not direct or control any aspect of the practice of pharmacy, ~~or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices~~. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ ~~any such~~ suspension shall be considered a violation of probation.

NEW TERM & CONDITION (applicable in cases involving alcohol or substance abuse):
??. **Reporting of Employment; Consent.**³ Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her] direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, or other compliance supervisor(s). Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

22. ~~Random Drug Screening~~ Drug and Alcohol Testing⁴ (If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required Mandatory in all cases involving alcohol or substance abuse; may be combined with PRP.)

Respondent, at ~~his or her~~ ~~[his/her]~~ own expense, shall participate in random testing, ~~including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee. ~~Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the~~

³ This term would comply with Uniform Standard # 3.

⁴ This term would comply with Uniform Standard # 4.

~~board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, nareotics, hypnotiescontrolled substances, and dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing. Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee.~~

~~By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate in a timely fashion shall be considered a violation of probation.~~

~~Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day. Though the frequency of testing will be determined by the board or its designee, and shall be designed so as to prevent respondent from anticipating testing dates (either randomized testing or unpredictable dates), the frequency of testing shall be at least the following: at least fifty two (52) test dates during the first year of probation; at least thirty six (36) test dates during the second, third, fourth, and fifth years of probation; and at least one (1) test per month in each year of probation after the fifth so long as there have been no positive test results during the previous five (5) years. The board or its designee may require less frequent testing if any of the following applies:~~

- ~~• Where respondent has previously participated in a treatment or monitoring program requiring testing, the board or its designee may consider that prior testing record in applying the three tier testing frequency schedule described above;~~
- ~~• Where the basis for probation or discipline is a single incident or conviction involving alcohol or drugs, or two incidents or convictions involving alcohol or drugs that were at least seven (7) years apart, that did not occur at work or on the way to or from work, the board or its designee may skip the first year testing frequency requirement(s);~~

- Where respondent is not employed in any health care field, frequency of testing may be reduced to a minimum of twelve (12) tests per year. If respondent wishes to thereafter return to employment in a health care field, respondent shall be required to test at least once a week for a period of sixty (60) days before commencing such employment, and shall thereafter be required to test at least once a week for a full year, before [he/she] may be reduced to a testing frequency of at least thirty-six (36) tests per year, and so forth;
- Respondent's testing requirement may be suspended during any period of tolling of the period of probation;
- Where respondent has a demonstrated period of sobriety and/or non-use, the board or its designee may reduce the testing frequency to no less than twenty-four (24) tests per year.

Any detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, may cause the board or its designee to increase the frequency of testing, in addition to any other action including but not limited to further disciplinary action.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary for payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection through testing of a controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [pharmacist, pharmacy technician, or designated representative] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or

its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.⁵

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and or~~ devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist, pharmacy technician, or designated representative. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

[Staff propose including these elements of Uniform Standard # 4 in the testing vendor contract]:
The board may be required to report data to support testing on consecutive days as well as numerous different testing intervals, and shall require cooperation from the vendor to do so.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The

⁵ This blue text incorporates a modified form of Uniform Standard # 8, though it reverses the order of events. The Board's existing language permits a suspension only after a respondent fails to supply a prescription or some other documentation justifying a positive result. Uniform Standard # 8 calls for the suspension to be immediate upon the detection of a "banned substance," after which it can be lifted upon documentation of a legitimate prescription. The language included here also does not explicitly incorporate the language in Uniform Standard # 8 mandating that in investigating a positive test result, Board staff consult with the specimen collector and the laboratory, communicate with respondent and/or his/her physician, and speak with any treatment provider, including group facilitators.

appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

The board will be required to collect and report historical and post implementation data on testing as follows, and shall require cooperation from the vendor to do so:

For the two-year period prior to implementation of the Uniform Standards, the board shall collect and report data (as available) for each person subject to testing who has (1) tested positive for a banned substance, (2) failed to appear or call in for testing on more than three occasions, (3) failed to pay testing costs, or (4) given a dilute(d) or invalid specimen.

For a period of three years following implementation of the Uniform Standards, the board shall collect and report the data including but not limited to the following to the Department of Consumer Affairs and/ upon request, to the Legislature:

Probationer/Diversion Participant Unique Identifier

License Type

Probation/Diversion Effective Date

General Range of Testing Frequency by/for Each Probationer/Diversion Participant

Dates Testing Requested

Dates Tested

Identify the Entity that Performed Each Test

Dates Tested Positive

Dates Contractor (if applicable) was informed of Positive Test

Dates Board was informed of Positive Test

Dates of Questionable Tests (e.g. dilute, high levels)

Date Contractor Notified Board of Questionable Test

Identify Substances Detected or Questionably Detected

Dates Failed to Appear

Date Contractor Notified Board of Failed to Appear

Dates Failed to Call In for Testing

Date Contractor Notified Board of Failed to Call In for Testing

Dates Failed to Pay for Testing

Date(s) Removed/Suspended from Practice (identify which)

Final Outcome and Effective Date (if applicable)

NEW TERM & CONDITION (applicable in cases involving alcohol or substance abuse):

Facilitated Group Recovery and/or Support Meetings.⁶ Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is run by a trained facilitator approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee, after taking into consideration respondent's history, the documented length of the respondent's sobriety or time since last use, any recommendation(s) from any clinical diagnostic evaluation(s), the scope and pattern of respondent's use, respondent's treatment history, and the

⁶ This term would comply with Uniform Standard # 5.

nature, duration, and severity of respondent's prior or present substance abuse. Respondent shall continue regular attendance as directed at an approved facilitated group meeting until the board or its designee advises in writing that respondent may cease regular attendance.

The facilitator shall, upon request by the board or its designee, provide the board with a dated document signed by the facilitator that includes respondent's name, the group's name, if any, the date and time of its regular meeting(s), respondent's attendance record, and respondent's participation level and progress. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

The approved facilitator shall report any unexcused absence by respondent from a facilitated group meeting to the board within twenty four (24) hours of its occurrence.

[Again, this may be something that does not need to be in the probationary term itself]:

The board or its designee shall select or approve facilitators with at least three (3) years of experience in the treatment and rehabilitation of substance abuse, with a license or certificate from the state or other nationally certified organization. The facilitator(s) shall not have had a financial, personal, or business relationship with respondent within the last year.

18. Work Site Monitor (~~Appropriate for those cases with chemical dependency (alcohol, drugs)~~ applicable in cases involving alcohol or substance abuse)⁷

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board ~~quarterly~~ monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor ~~determine~~ suspect at any time during the probationary period that respondent has ~~not maintained sobriety~~ abused alcohol or drugs, he or she shall notify the board immediately, ~~either orally or in writing as directed~~. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within forty-eight (48) hours of the occurrence. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board or its designee, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board by the monitor, shall be considered a violation of probation.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the board; however, under no circumstances shall respondent's work site monitor be respondent's employee.

⁷ These modifications are intended to conform this term to Uniform Standard # 7. As written, this optional term in the Disciplinary Guidelines is currently only applicable to pharmacy technicians and designated representatives because, at least typically, pharmacists and pharmacy interns would be enrolled in PRP and PRP will require a work site monitor and control the selection and requirements of that monitor. To conform to Uniform Standard # 7, this term will need to be made more universally applicable and/or the criteria for selection of a work site monitor will need to be made applicable to those persons whose work site monitors are being selected by PRP/Maximus staff.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the board or its designee, shall be a person in a position of authority who is capable of monitoring respondent while at work.

~~If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~

Within thirty (30) days of being approved by the board or its designee, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within forty-eight (48) hours of the occurrence. Should respondent change employment, a new work site monitor must be designated, for prior approval by the PRP, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

The work site monitor shall not have a financial, personal, familial or other relationship with the respondent that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the PRP. If it is impractical for anyone but respondent's employer to serve as work site monitor, this requirement may be waived by the PRP; however, under no circumstances shall respondent's work site monitor be respondent's employee.

The work site monitor shall hold a license with a scope of practice including the scope of practice of the respondent's license, shall be another health care professional if no monitor with like practice is available, or, as approved by the PRP, shall be a person in a position of authority who is capable of monitoring respondent while at work.

~~If the work site monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.~~

Within thirty (30) days of being approved by the PRP, the work site monitor shall sign an affirmation that he or she has reviewed the terms and conditions of respondent's disciplinary order and agrees to monitor respondent. The work site monitor shall at least:

- 1) Have regular face-to-face contact with respondent in the work environment, at least once per week or with greater frequency if required by the board or its designee;
- 2) Interview other staff in the office regarding respondent's behavior, if applicable; and
- 3) Review respondent's work attendance.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2010/2011

Corrected

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Complaints/Investigations

Received	583	599	643	600	2425
Closed	733	635	595	629	2572
Pending (at the end of quarter)	1151	1229	1290	1324	1324

Cases Assigned & Pending (by Team) at end of quarter*

Compliance Team	394	324	233	450	450
Drug Diversion/Fraud	98	121	141	172	172
Probation/PRP	85	82	67	78	78
Mediation/Enforcement	74	14	8	28	28
Criminal Conviction	475	518	479	485	485

Application Investigations

Received	181	217	151	244	793
Closed					
Approved	85	147	177	129	538
Denied	24	32	31	49	136
Total**	150	251	392	228	1021
Pending (at the end of quarter)	448	432	205	223	223

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	65	36	46	39	186
Citations Issued	308	253	192	290	1043
Citations Closed	339	358	290	185	1172
Total Fines Collected***	\$336,840.00	\$328,645.00	\$298,395.00	\$209,672.00	\$1,173,552.00

* This figure does not include reports submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected (through 6/30/2011 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics

Fiscal Year 2010/2011

Corrected

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	90	105	90	90	375
Pleadings Filed	83	65	55	102	305
Pending					
Pre-accusation	182	202	223	188	188
Post Accusation	255	268	241	258	257
Total*	508	496	516	520	520
Closed**					
Revocation					
Pharmacist	1	1	2	5	9
Pharmacy	0	0	0	0	0
Other	18	28	40	43	129
Revocation, stayed; suspension/probation					
Pharmacist	6	3	9	5	23
Pharmacy	0	0	0	0	0
Other	0	0	2	2	4
Revocation, stayed; probation					
Pharmacist	3	5	2	6	16
Pharmacy	1	1	6	1	9
Other	1	3	8	10	22
Suspension, stayed; probation					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Surrender/Voluntary Surrender					
Pharmacist	2	1	2	1	6
Pharmacy	1	1	1	1	4
Other	12	8	6	9	35
Public Reproval/Reprimand					
Pharmacist	0	0	0	0	0
Pharmacy	0	0	0	0	0
Other	0	0	0	0	0
Cost Recovery Requested***	\$108,566.50	\$317,558.50	\$449,152.25	\$136,329.00	\$1,011,606.20
Cost Recovery Collected***	\$38,755.24	\$74,313.04	\$255,471.34	\$53,990.59	\$422,530.21

* This figure includes Citation Appeals

** This figure includes cases withdrawn

**Board of Pharmacy Enforcement Statistics
Fiscal Year 2010/2011
Corrected**

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

*** This figure includes administrative penalties

Board of Pharmacy Enforcement Statistics

Fiscal Year 2010/2011

Corrected

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 10/11**

Probation Statistics

Licenses on Probation

Pharmacist	99	103	100	109	109
Pharmacy	8	11	15	19	19
Other	27	30	33	39	39
Probation Office Conferences	51	26	64	36	177
Probation Site Inspections	36	53	55	64	208
Probationers Referred to AG for non-compliance	1	0	5	3	9

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 6/30/2011)

Program Statistics

In lieu of discipline	1	0	0	0	1
In addition to probation	3	3	0	4	10
Closed, successful	1	7	3	2	13
Closed, non-compliant	1	0	0	4	5
Closed, other	2	1	3	1	7
Total Board mandated Participants	45	55	45	56	56
Total Self-Referred Participants*	30	22	19	19	19
Treatment Contracts Reviewed	67	72	68	66	273

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of June 30, 2011

Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

Workload Statistics **Total 08/09** **Total 09/10** **Total 10/11**

Complaints/Investigations

Received	2545	2347	2425
Closed	1648	3909	2572
Pending (at the end of fiscal year)	2686	1033	1324

Cases Under Investigation (by Team) at end of fiscal year*

Compliance	491	574	450
Drug Diversion/Fraud	183	103	172
Probation/PRP	244	102	78
Mediation/Enforcement	176	77	75
Criminal Conviction	1644	590	524

Application Investigations

Received	372	847	798
Closed			
Approved	178	558	538
Denied	58	100	136
Total**	285	769	1021
Pending (at the end of quarter)	345	423	223

Letter of Admonishment (LOA) / Citation & Fine

LOAs Issued	100	362	186
Issued	965	1827	1043
Abated	1064	1466	1172
Total Fines Collected ***	\$115,152.50	\$1,330,140.00	\$1,173,552.00

* This figure does not include cases that have been submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

Workload Statistics **Total 08/09** **Total 09/10** **Total 10/11**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	207	354	375
Pleadings Filed	125	272	305
Pending			
Pre-accusation	137	185	188
Post Accusation	106	281	257
Total *	274	433	520
Closed**			
Revocation			
Pharmacist	6	15	9
Pharmacy	4	2	0
Other	21	69	129
Revocation, stayed; suspension/probation			
Pharmacist	9	11	23
Pharmacy	0	5	0
Other	0	1	4
Revocation, stayed; probation			
Pharmacist	14	9	16
Pharmacy	1	1	9
Other	4	7	22
Suspension, stayed; probation			
Pharmacist	0	0	0
Pharmacy	0	0	0
Other	0	0	0
Surrender/Voluntary Surrender			
Pharmacist	3	9	6
Pharmacy	1	5	4
Other	7	17	35
Public Reproval/Reprimand			
Pharmacist	0	1	0
Pharmacy	0	0	0
Other	0	1	0
Cost Recovery Requested	\$147,025.00	\$312,840.75	\$1,011,606.20
Cost Recovery Collected	\$128,230.64	\$335,420.58	\$422,530.21

* This figure includes citation appeals

** This figure includes cases withdrawn

*** This figure included administrative penalties

Board of Pharmacy Enforcement Statistics Three Year Comparison Corrected

Workload Statistics **Total 08/09** **Total 09/10** **Total 10/11**

Probation Statistics

Licenses on Probation

Pharmacist	110	101	109
Pharmacy	4	8	19
Other	12	29	39
Probation Office Conferences	48	98	177
Probation Site Inspections	153	110	208
Probationers Referred to AG for non-compliance	5	13	9

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program

Program Statistics

In lieu of discipline	3	1	2
In addition to probation	9	6	10
Closed, successful	15	11	5
Closed, non-compliant	2	4	3
Closed, other	6	14	1
Total Board mandated Participants	58	47	49
Total Self-Referred Participants*	21	29	23
Treatment Contracts Reviewed	206	201	126

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Complete all desk investigations within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	547	145 26%	45 8%	80 15%	277 51%	276
	Qtr 2	550	177 32%	59 11%	82 15%	232 42%	202
	Qtr 3	690	166 24%	80 12%	104 15%	340 49%	209
	Qtr 4	557	199 36%	68 12%	112 20%	178 32%	174
	2. Complete all field investigations within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	363	140 38%	93 26%	75 21%	55 15%	195
	Qtr 2	333	113 34%	77 23%	81 24%	62 19%	181
	Qtr 3	283	125 44%	35 12%	70 25%	53 19%	165
	Qtr 4	300	111 37%	53 18%	49 16%	87 29%	207
	Data is calculated from date received to the date the report was accepted by SI/Manager. Does not include split cases.						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	407	298	45	14	50
Closed 4301 letters, license denials, withdrawn by Board	169	81	23	38	27
Cite and/or fine letter of admonishment	248	99	63	28	57
Attorney General's Office	87	25	19	13	30
Qtr 2	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	424	300	59	41	24
Closed 4301 letters, license denials, withdrawn by Board	202	95	34	35	38
Cite and/or fine letter of admonishment	161	62	44	24	31
Attorney General's Office	96	25	31	14	26
Qtr 3	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	444	298	73	37	36
Closed 4301 letters, license denials, withdrawn by Board	286	108	70	54	54
Cite and/or fine letter of admonishment	158	70	53	21	14
Attorney General's Office	85	34	16	20	15
Qtr 4	N	< 180	< 270	< 365	> 365
Closed investigations, no additional action, license approvals	413	336	35	18	24
Closed 4301 letters, license denials, withdrawn by Board	150	89	30	17	14
Cite and/or fine letter of admonishment	208	60	47	38	63
Attorney General's Office	86	26	19	19	22

Data is calculated from date received to date closed or referred to the AG.
 One case may have multiple respondents. The actual number of citations and letters of admonishment issued are shown on the next page.

Objective 1.2	Manage enforcement activities for achievement of performance expectations.																																			
Measure:	Percentage compliance with program requirements.																																			
Tasks:	<p>1. Administer the Pharmacists Recovery Program.</p> <table border="1" data-bbox="367 254 1511 527"> <thead> <tr> <th></th> <th>Voluntary Participants</th> <th>Participants Mandated Into Program</th> <th>Noncompliant, Terminated From Program</th> <th>Successfully Completed Program</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>30</td> <td>45</td> <td>1</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>22</td> <td>55</td> <td>0</td> <td>6</td> </tr> <tr> <td>Qtr 3</td> <td>19</td> <td>55</td> <td>0</td> <td>3</td> </tr> <tr> <td>Qtr 4</td> <td>19</td> <td>56</td> <td>5</td> <td>2</td> </tr> </tbody> </table>		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program	Qtr 1	30	45	1	0	Qtr 2	22	55	0	6	Qtr 3	19	55	0	3	Qtr 4	19	56	5	2										
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	Qtr 4	19	56	5	2																															
	<p>2. Administer the Probation Monitoring Program.</p> <table border="1" data-bbox="367 604 1235 905"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Individuals</td> <td>122</td> <td>129</td> <td>132</td> <td>148</td> </tr> <tr> <td>Sites</td> <td>10</td> <td>14</td> <td>18</td> <td>19</td> </tr> <tr> <td>Tolled</td> <td>34</td> <td>29</td> <td>28</td> <td>29</td> </tr> <tr> <td>Inspections Conducted</td> <td>51</td> <td>53</td> <td>53</td> <td>64</td> </tr> <tr> <td>Successfully Completed</td> <td>8</td> <td>4</td> <td>4</td> <td>4</td> </tr> <tr> <td>Petitions to Revoke Filed</td> <td>2</td> <td>9</td> <td>1</td> <td>1</td> </tr> </tbody> </table>		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Individuals	122	129	132	148	Sites	10	14	18	19	Tolled	34	29	28	29	Inspections Conducted	51	53	53	64	Successfully Completed	8	4	4	4	Petitions to Revoke Filed	2	9	1	1
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<p>3. Issue all citations and fines within 30 days.</p> <table border="1" data-bbox="367 982 1417 1367"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>> 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>312</td> <td>200 64%</td> <td>107 34%</td> <td>5 2%</td> <td>0 0%</td> <td>26</td> </tr> <tr> <td>Qtr 2</td> <td>263</td> <td>230 87%</td> <td>11 4%</td> <td>20 8%</td> <td>2 1%</td> <td>20</td> </tr> <tr> <td>Qtr 3</td> <td>195</td> <td>94 48%</td> <td>58 30%</td> <td>42 22%</td> <td>1 1%</td> <td>39</td> </tr> <tr> <td>Qtr 4</td> <td>291</td> <td>258 89%</td> <td>16 6%</td> <td>0 0%</td> <td>17 6%</td> <td>31</td> </tr> </tbody> </table>		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	312	200 64%	107 34%	5 2%	0 0%	26	Qtr 2	263	230 87%	11 4%	20 8%	2 1%	20	Qtr 3	195	94 48%	58 30%	42 22%	1 1%	39	Qtr 4	291	258 89%	16 6%	0 0%	17 6%	31	
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<p>4. Issue letters of admonishment within 30 days.</p> <table border="1" data-bbox="367 1465 1417 1829"> <thead> <tr> <th></th> <th><u>N</u></th> <th>30 days</th> <th>60 days</th> <th>90 days</th> <th>> 90 days</th> <th><u>Average Days</u></th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>44</td> <td>35 80%</td> <td>9 20%</td> <td>0 0%</td> <td>0 0%</td> <td>21</td> </tr> <tr> <td>Qtr 2</td> <td>31</td> <td>29 94%</td> <td>2 6%</td> <td>0 0%</td> <td>0 0%</td> <td>20</td> </tr> <tr> <td>Qtr 3</td> <td>42</td> <td>12 29%</td> <td>27 64%</td> <td>3 7%</td> <td>0 0%</td> <td>39</td> </tr> <tr> <td>Qtr 4</td> <td>39</td> <td>38 97%</td> <td>1 3%</td> <td>0 0%</td> <td>0 0%</td> <td>12</td> </tr> </tbody> </table>		<u>N</u>	30 days	60 days	90 days	> 90 days	<u>Average Days</u>	Qtr 1	44	35 80%	9 20%	0 0%	0 0%	21	Qtr 2	31	29 94%	2 6%	0 0%	0 0%	20	Qtr 3	42	12 29%	27 64%	3 7%	0 0%	39	Qtr 4	39	38 97%	1 3%	0 0%	0 0%	12	
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<p>These data are actual number of citations and letters of admonishment (LOA) issued. One investigation may have multiple licensees that are issued a citation or LOA (split cases).</p>																																				

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	1	0	0
Qtr 2	0	0	0
Qtr 3	1	0	2
Qtr 4	0	0	1

6. Submit petitions to revoke probation within 30 days once noncompliance with terms of probation is substantiated.

	30 days	60 days	> 60 days	<u>N</u>
Qtr 1	1	1	7	9
Qtr 2	5	0	0	5
Qtr 3	2	1	0	3
Qtr 4	2	0	0	2

Objective 1.3	Achieve 100 percent closure on all administrative cases within 1 year.																																															
Measure:	Percentage of administrative cases closed within 1 year.																																															
Tasks:	1. File pleadings within 90 days of referral.																																															
	<table border="1" data-bbox="370 254 1430 464"> <thead> <tr> <th></th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Number of Cases Referred to Attorney General's Office</td> <td>88</td> <td>97</td> <td>89</td> <td>89</td> </tr> <tr> <td>Accusations Filed</td> <td>74</td> <td>46</td> <td>48</td> <td>82</td> </tr> <tr> <td>Statement of Issues Filed</td> <td>6</td> <td>10</td> <td>6</td> <td>18</td> </tr> <tr> <td>Petitions to Revoke Probation Filed</td> <td>2</td> <td>9</td> <td>1</td> <td>1</td> </tr> </tbody> </table>									Qtr 1	Qtr 2	Qtr 3	Qtr 4	Number of Cases Referred to Attorney General's Office	88	97	89	89	Accusations Filed	74	46	48	82	Statement of Issues Filed	6	10	6	18	Petitions to Revoke Probation Filed	2	9	1	1															
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Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/11.																				
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																				
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Aggregate Inspections This Cycle</th> <th>Percent Complete</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>43</td> <td>499</td> <td>6%</td> </tr> <tr> <td>Qtr 2</td> <td>37</td> <td>536</td> <td>6%</td> </tr> <tr> <td>Qtr 3</td> <td>31</td> <td>567</td> <td>6%</td> </tr> <tr> <td>Qtr 4</td> <td>137</td> <td>680</td> <td>8%</td> </tr> </tbody> </table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	43	499	6%	Qtr 2	37	536	6%	Qtr 3	31	567	6%	Qtr 4	137	680	8%
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	Qtr 3	31	567	6%																	
	Qtr 4	137	680	8%																	
	2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.																				
	<table border="1"> <thead> <tr> <th></th> <th>Number of Inspections</th> <th>Number Inspected Late</th> </tr> </thead> <tbody> <tr> <td>Qtr 1</td> <td>50</td> <td>0</td> </tr> <tr> <td>Qtr 2</td> <td>165</td> <td>0</td> </tr> <tr> <td>Qtr 3</td> <td>65</td> <td>0</td> </tr> <tr> <td>Qtr 4</td> <td>53</td> <td>0</td> </tr> </tbody> </table>		Number of Inspections	Number Inspected Late	Qtr 1	50	0	Qtr 2	165	0	Qtr 3	65	0	Qtr 4	53	0					
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Qtr 1	50	0																			
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3. Initiate investigations based upon violations discovered during routine inspections.																					
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 842"> <p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Oct. 2009: Executive Officer provides information about California's e-pedigree requirements at a SecurePharma Conference of drug manufacturers and wholesalers in Philadelphia and at a SpecialtyPharma Conference (contract drug manufacturers) in Phoenix.</i></p> <p><i>Dec. 2009: Executive Officer provides information about California's e-pedigree requirements at the Health Care Distributors Association Trace and Track Conference in Washington D.C.</i></p> <p><i>March 2010: Executive Officer provides information about California's e-pedigree requirements via a Webinar hosted by IBS.</i></p> <p><i>April 2010: Board reviews Food and Drug Administration guidance on a unique serialized identifier released March 26.</i></p> <p><i>Oct. 2010: Executive Officer provides information about California's requirements to a GS1 training session in San Francisco.</i></p> <p><i>Feb. 2010: Executive Officer provides presentation on California's e-pedigree requirements at FDA workshop on developing a track and trace.</i></p> <li data-bbox="370 842 1487 1066"> <p>2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.</p> <p><i>Sep. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.</i></p> <p><i>Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its website.</i></p> <li data-bbox="370 1066 1487 1646"> <p>3. Monitor the efforts of the Drug Enforcement Administration and Department of Health and Human Services to implement e-prescribing for controlled substances.</p> <p><i>Nov. 2006: Board submits letter supporting change in Drug Enforcement Administration policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.</i></p> <p><i>Sep. 2008: Board submits comments on Drug Enforcement Administration proposed requirements for e-prescribing of controlled substances.</i></p> <p><i>Dec. 2009: Executive Officer meets with DEA officials in Washington D.C. to discuss interest in e-prescribing of controlled drugs.</i></p> <p><i>April 2010: Board reviews proposed Drug Enforcement Administration requirements for electronic prescribing of controlled substances.</i></p> <p><i>June 2010: Enforcement Committee received updates on DEA rule change.</i></p> <p><i>Jan. 2011: Board prepares guidance document for pharmacies and prescribers.</i></p> <p><i>May 2011: Medical Board reviews guidance document prepared to approve portion for prescribers.</i></p>

4. **Evaluate establishment of an ethics course as an enforcement option.**
 - Oct. 2008:* Board holds regulation hearing on proposed requirements for the ethics class.
 - Jan. 2009:* Board adopts regulation.
 - Sept. 2009:* Regulation takes effect.
 - 3rd Qtr 09-10:* Board subcommittee of two board members begins work with staff on suggested specific components and topics for the program, in compliance with board regulations.
 - Oct. 2010:* First course provided.
 - March 2011:* Second provider begins offering course.
5. **Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**
 - Dec. 2009:* Executive Officer provides presentation on California's e-pedigree requirements to three national association meetings.
 - 3rd Qtr 09-10:* Board initiates rulemaking on a regulation to establish requirements for patient-centered prescription container labels (see report on Legislation and Regulation Committee's Goals, Outcomes, Objectives and Measures).
 - March 2011:* Executive Officer participates in PEW Trust's public forum on what was learned about the 2008 heparin adulteration.
 - April 2011:* DEA and board cohost day-long conference for pharmacies of controlled substances. Due to interest and success, more conferences planned.
6. **Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.**
 - Sep. 2007:* Provided comments on proposed statutory requirements.
 - Dec 2007:* Sought Department of Consumer Affairs' support for involvement in e-prescribing by the Administration.
Provided comments on proposed e-prescribing initiatives.
 - Oct. 2008:* Executive Officer Herold joins a task force to achieve e-prescribing coordinated by the California HealthCare Foundation.
 - Nov. 2008:* Board hosts conference on e-prescribing as part of department's professionals
Achieving Consumer Trust Summit. The Medical Board and Dental Board join us as sponsors.
 - Jan. 2009:* Executive Officer Herold works with California HealthCare Foundation and Medical Board to plan joint activities with licensees to facilitate e-prescribing.
 - March 2009:* Pharmacists and physicians in Visalia attend first of California HealthCare Foundation's public forums on e-prescribing.
 - April 2010:* Board reviews Drug Enforcement Agency proposed regulations on e-prescribing of controlled substance.
 - Nov. 2010:* Executive Officer provides presentations at annual California e-prescribing meeting.
 - Jan. 2011:* Board prepares guidance document for pharmacies on DEA's requirements.
 - May 2011:* Medical Board reviews same guidance document for prescribers.
7. **Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.**
 - Oct. 2008:* Requirements for security forms in place..
 - 2nd Qtr 09/10:* Board executive staff and several board members attend California Healthcare Foundation's annual summit to implement e-prescribing.

8. Liaison with other state and federal agencies to achieve consumer protection.

1st Qtr 07/08: *Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.*

2nd Qtr 07/08: *Bimonthly meeting with the Department of Health Care Services continue. Board inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services. Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.*

3rd Qtr 07/08: *Bimonthly meetings with the Department of Health Care Services continue. Board works with the Drug Enforcement Administration on joint investigations and receives specialized training.*

4th Qtr 07/08: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs.*

3rd Qtr 08/09: *Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations.*

4th Qtr 08/09: *Board staff meets with staff of the California Department of Public Health regarding joint inspections of licensed healthcare facilities in California to identify and remove recalled drugs. Executive staff meet with Department of Health Care Services investigators on cases of mutual concern. Board investigators work with federal and state drug enforcement officers on search warrants and mutual investigations. The federal Drug Enforcement Administration provides training to board staff on new requirements for online pharmacies selling controlled substances.*

2nd Qtr 09/10: *Executive staff meet with Department of Health Care Services staff on mutual investigations; DEA staff in Washington D.C. on enforcement issues involving controlled drugs; the U.S. Attorney General's office in Sacramento on two major enforcement matters; and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 09/10: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern. Board staff redirected to complete HIPDB reporting.*

4th Qtr 09/10: *Board staff continue to report to HIPDB.*

2nd Qtr 10/11: *Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern.*

3rd Qtr 10/11: Board supervising inspectors work with federal, state and local law enforcement agencies on emerging enforcement issues and investigations, and worked with the Licensing and Certification and Food and Drug Branch of the California Department of Public Health on issues of mutual concern. Executive staff attend joint meeting with California District Attorneys Association.

9. Work with the California Integrated Waste Management Board to implement requirements for model programs to take back unwanted prescription medicine from the public.

March 2008: Second meeting with state agency stakeholders on developing components for model programs that conform with diverse state agency security and safety requirements.

June 2008: Supervising pharmacist inspector attended a two-day multi-disciplinary conference hosted by the Integrated Waste Management Board on drug take-back programs.

Aug. 2008: Executive Officer Herold speaks at conferences sponsored by the California Integrated Waste Management Board.

Oct. 2008: Enforcement Committee hears presentations on drug take-back programs, medical waste management processes and the take-back of sharps. Board to submit comments to California Integrated Waste Management Board on model programs for take-back programs.

Nov. 2008: Executive Officer provides written and verbal testimony at California Integrated Waste Management Board hearing on the model guidelines.

Dec. 2008: Executive Officer participates in public hearing at the California Integrated Waste Management Board on possible changes to the model guidelines adopted by the California Integrated Waste Management Board in November.

Feb. 2009: California Integrated Waste Management Board amends model guidelines to include provisions advanced by the board.

Jan. 2010: Board writes article on the guidelines for publication in the next issue of The Script.

Board executive staff attend meetings on "take back drugs" at a statewide conference of the California Integrated Waste Management Board. Executive Officer provides presentation on the CIWMB Model Guidelines at a meeting of 20 rural California counties.

March 2010: Board publishes the guidelines in The Script.

April 2010: Board inspector will collect information about take back programs in California pharmacies during inspections.

Aug. 2010: Executive Officer provides information regarding board policy on drug take back programs in pharmacies to CalRecycle and its draft report on model take back programs. Written comments are later provided on behalf of the board.

Jan. 2011: Board reviews final version of CalRecycle's report.

May 2011: Final report released.

10. Inspect California hospitals to ensure recalled heparin has been removed from patient care areas.

4th Qtr 07/08: *Board initiates inspections of 40 California hospitals looking for counterfeit heparin and unlicensed sales but discovers recalled heparin still in 40 percent of hospitals inspected. Board notifies the Food and Drug Administration and California Department of Public Health and initiates inspections of 533 hospitals during April-June.*

Recalled heparin is found in 94 of these facilities. Data reported to board during June Board Meeting.

1st Qtr 08/09: *The Script highlights problems found in heparin inspections. Citations and fines issued to facilities with recalled heparin. Work with hospitals begins to strengthen drug control within facilities.*

2nd Qtr 08/09: *Hospitals and Pharmacists-in-Charge fined where recalled heparin was discovered by the board.*

3rd Qtr 08/09: *First stakeholder meeting scheduled to discuss drug distribution within hospitals.*

March 2009: *First stakeholder meeting convened.*

June 2009: *Second stakeholder meeting convened. Development of model guidelines for recalls underway.*

Sep. 2009: *Stakeholder meeting convened.*

Recall guidelines evaluated and additional comments solicited.

Jan. 2010: *Board reviews final version of recommended steps for addressing recalls in hospitals.*

April 2010: *Manuscript of addressing recalls in hospitals completed, compiled into finished report and posted on Website.*

Executive officer works with the Healthcare Distributors Management Association (representing drug wholesalers) to secure notices of recalls more timely to share with board subscriber list.

Appeals of citations and fines nearly complete.

May 2010: *Outstanding enforcement/compliance completed.*

2011: *Board receives copies of drug recalls at the pharmacy level and releases them through the subscriber alert system.*

March 2011: *Board participates in international conference convened by the PEW Trust on the 2008 heparin contamination to identify ways to prevent a reoccurrence.*

11. **Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards.**
4th Qtr 08/09: Draft proposals for required components 1-6 developed.
1st Qtr 09/10: Draft proposals for required components 7-13 developed.
3rd Qtr 09/10: Board hears presentation on uniform standards. Staff/counsel identifies changes required to implement standards.
1st/2nd Qtr 10/11: Proposed changes to Board Disciplinary Guidelines drafted. Staff continue working with DCA on standards.
2nd Qtr 10/11: Board staff begin incorporating standards for Board consideration.
3rd Qtr 10/11: Changes to standards are approved by Substance Abuse Coordination Committee.
4th Qtr 10/11: Board updated on progress of language development and incorporated into disciplinary guidelines for Board consideration. Board staff initiate review of reporting requirements.
12. **Develop and release Request for Proposal for vendor for Department of Consumer Affairs health care boards that operate license recovery programs.**
4th Qtr 08/09: Provisions for Request for Proposal developed: Request for Proposal released.
2nd Qtr 09/10: Contract awarded.
13. **Participate in Department of Consumer Affairs Consumer Protection Enforcement Initiative to strengthen board enforcement activities and reduce case investigation completion times for formal discipline.**
1st/2nd Qtr 09/10: Work with Department of Consumer Affairs on identification of Enforcement Best Practices. Board discusses SB 1441 components for Diversion Programs to strengthen consumer protection enforcement staff attend Enforcement Best Practices work group.
3rd Qtr 09/10: Board senior staff and Board President meet with Department of Consumer Affairs to discuss enforcement program enhancements in SB 1111. Board staff begin submitting monthly reports detailing workload and improvement efforts to the department.
4th Qtr 09/10: Board hears presentation on CPEI and current status of department and board efforts.
1st/2nd Qtr 10/11: Board sponsors legislation to secure records more timely from licensees. Board conducts civil service exams for inspector and supervising inspector classifications. Hiring freeze prevents hiring of staff.
2nd Qtr 10/11: Board submits freeze exemptions, all are denied.
3rd Qtr 10/11: Governor Brown established a formal hiring freeze. New hiring freeze exemptions prepared for eight inspector positions.
4th Qtr 10/11: Board staff secure an exemption to hire eight inspectors.

- 14. Initiate criminal conviction unit to review and investigate rap sheets received on licenses for arrests or convictions.**
- 1st Qtr 09/10: Unit created via budget change proposal, 6.5 staff hired, trained, initiate work.
There are 1,287 rapsheet investigations under review.*
- 2nd Qtr 09/10: There are 1,037 rapsheet investigations under review.*
- 3rd Qtr 09/10: There are 652 rapsheet investigations under review.*
- 4th Qtr 09/10: Post implementation review of Criminal Conviction Unit completed. Enforcement Committee advised of new unit outcomes.*
- 4th Qtr 10/11: Board staff secure a second exemption to hire three additional inspectors. Six new staff begin. Training is limited because of travel restrictions.*
- 15. Complete comprehensive review of investigative and enforcement internal processing to identify process improvements.**
- 1st Qtr 09/10: Board staff implemented on-line assignment of investigations.
Board staff implemented on-line review of draft pleadings.*
- 2nd Qtr 09/10: Board staff began drafting Default Decision and Orders.*
- 4th Qtr 09/10: Board staff began drafting Petition to Revoke Probation Pleadings.
Board staff implemented a pilot program to provide pre-populated investigation reports to the Compliance Team.*
- 3rd Qtr 10/11: Board staff review citation and fine program.*
- 4th Qtr 10/11: Board staff evaluates complaints closed without findings to ensure integrity of the process. Some deficiencies noted. Process improvements identified and staff educated.*
- 16. Complete review of pharmacies dispensing prescriptions for Internet web site operators.**
- 2010: Updates on disciplinary actions provided at board meetings and in The Script.*
- 17. Provide updates on the board's reporting to the Healthcare Integrity and Protections Data Bank (HIPDB).**
- 1st Qtr 10/11: 656 reports submitted (includes initial and revised submissions).*
- 2nd Qtr 10/11: 334 reports submitted (includes initial submissions).*
- 3rd Qtr 10/11: 432 reports submitted.*
- 4th Qtr 10/11: 96 reports submitted. Position vacant effective September 2011 due to employee retirement. Recruitment pending with Department of Consumer Affairs Human Resources.*