



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Date: November 29, 2010

To: Enforcement Committee

Subject: Agenda Item 1 -- Request for Exemption from Labeling Requirements for the Patient-Centered Prescription Container Labels

Effective January 1, 2011, the board's requirements for patient-centered labels go into effect as 16 California Code of Regulations section 1707.5. A copy of the final text for the regulation follows this page.

Also effective January 1, 2011, provisions enacted by SB 1489 (Senate Business and Professions Committee, Chapter 653, Statutes of 2010) as 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.

To allow such an exemption, the board will need to promulgate regulations.

At this meeting, the board will hear presentations from two groups seeking an exemption from the labeling requirements for their specialized patient populations.

1. For Infusion Pharmacies:

A representative of Medco will provide a presentation of an overview of how infusion pharmacies operate, and explain how they can provide appropriate consumer protection and education without the patient-centered labels can be achieved.

The specific exemption for infusion pharmacies occurs in Business and Professions Code section 4076.5(e) (effective 1/1/11):

- (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.

2. Request from CPhA's Long-Term Care Academy

A representative of CPhA will attend this meeting to explain how patient safety in long-term care facilities can be ensured without patient-centered labels.

The relevant exemption from SB 1489 occurs in 4076.5(d):

- (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.

A list of the entities licensed under Health and Safety Code Section 1250 (and the relevant subdivision number) is:

1. General acute care hospital (a)
2. Acute psychiatric hospital (b)
3. Skilled nursing facility (c)
4. Intermediate care facility (d)
5. Intermediate care facility/developmentally disabled habilitative (e)
6. Special hospital (f)
7. Intermediate care facility/developmentally disabled (g)
8. Intermediate care facility/developmentally disabled-nursing (h)
9. Congregate living health facility (i)
10. Correctional treatment center (j)
11. Nursing facility (k)
12. Intermediate care facility/developmentally disabled-continuous nursing (m)

The board will need to determine whether it wishes to exempt from the patient-centered label requirements medications dispensed in any of these environments.

The full amendment to section 4076.5 contained in SB 1489 is provided following the board's new patient-centered label requirements (section 1707.5). The last document is the full text of Health and Safety Code section 1250.

Specific Language to Add Section 1707.5.

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

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

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

- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
 - (C) The directions for the use of the drug.
 - (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
- (2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
- (3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements

specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

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

- (A) Take 1 [insert appropriate dosage form] at bedtime
- (B) Take 2 [insert appropriate dosage form] at bedtime
- (C) Take 3 [insert appropriate dosage form] at bedtime
- (D) Take 1 [insert appropriate dosage form] in the morning
- (E) Take 2 [insert appropriate dosage form] in the morning
- (F) Take 3 [insert appropriate dosage form] in the morning
- (G) Take 1 [insert appropriate dosage form] in the morning, and
Take 1 [insert appropriate dosage form] at bedtime
- (H) Take 2 [insert appropriate dosage form] in the morning, and
Take 2 [insert appropriate dosage form] at bedtime
- (I) Take 3 [insert appropriate dosage form] in the morning, and
Take 3 [insert appropriate dosage form] at bedtime
- (J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert
appropriate dosage form] at noon, and 1 [insert appropriate dosage
form] in the evening
- (K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert
appropriate dosage form] at noon, and 2 [insert appropriate dosage
form] in the evening

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

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

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

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

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

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

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

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

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

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

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

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

EXCERPT FROM SB 1489

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.

Health and Safety Code section 1250:

1250. As used in this chapter, "health facility" means any facility, place, or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer, and includes the following types:

(a) "General acute care hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. A general acute care hospital may include more than one physical plant maintained and operated on separate premises as provided in Section 1250.8. A general acute care hospital that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital. In addition, a general acute care hospital that, on July 1, 1983, provided required surgical and anesthesia services through a contract or agreement with another acute care hospital may continue to provide these surgical and anesthesia services through a contract or agreement with an acute care hospital. The general acute care hospital operated by the State Department of Developmental Services at Agnews Developmental Center may, until June 30, 2007, provide surgery and anesthesia services through a contract or agreement with another acute care hospital. Notwithstanding the requirements of this subdivision, a general acute care hospital operated by the Department of Corrections and Rehabilitation or the Department of Veterans Affairs may provide surgery and anesthesia services during normal weekday working hours, and not provide these services during other hours of the weekday or on weekends or holidays, if the general acute care hospital otherwise meets the requirements of this section.

A "general acute care hospital" includes a "rural general acute care hospital." However, a "rural general acute care hospital" shall not be required by the department to provide surgery and anesthesia services. A "rural general acute care hospital" shall meet either of the following conditions:

(1) The hospital meets criteria for designation within peer group six or eight, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982.

(2) The hospital meets the criteria for designation within peer group five or seven, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982, and has no more than 76 acute care beds and is located in a census dwelling place of 15,000 or less population according to the 1980 federal census.

(b) "Acute psychiatric hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care for mentally disordered, incompetent, or other patients referred to in Division 5 (commencing with Section 5000) or Division 6 (commencing with Section 6000) of the Welfare and Institutions **Code**, including the following basic services: medical, nursing, rehabilitative, pharmacy, and dietary services.

(c) "Skilled nursing facility" means a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis.

(d) "Intermediate care facility" means a health facility that provides inpatient care to ambulatory or nonambulatory patients who have recurring need for skilled nursing supervision and need supportive care, but who do not require availability of continuous skilled nursing care.

(e) "Intermediate care facility/developmentally disabled habilitative" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, habilitation, developmental, and supportive health services to 15 or fewer persons with developmental disabilities who have intermittent recurring needs for nursing services, but have been certified by a physician and surgeon as not requiring availability of continuous skilled nursing care.

(f) "Special hospital" means a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity.

(g) "Intermediate care facility/developmentally disabled" means a facility that provides 24-hour personal care, habilitation, developmental, and supportive health services to persons with developmental disabilities whose primary need is for developmental services and who have a recurring but intermittent need for skilled nursing services.

(h) "Intermediate care facility/developmentally disabled-nursing" means a facility with a capacity of 4 to 15 beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have intermittent recurring needs for skilled nursing care but have been certified by a physician and surgeon as not requiring continuous skilled nursing care. The facility shall serve medically fragile persons with developmental disabilities or who demonstrate significant developmental delay that may lead to a developmental disability if not treated.

(i) (1) "Congregate living health facility" means a residential home with a capacity, except as provided in paragraph (4), of no more than 12 beds, that provides inpatient care, including the following basic services: medical supervision, 24-hour skilled nursing and supportive care, pharmacy, dietary, social, recreational, and at least one type of service specified in paragraph (2). The primary need of congregate living health facility residents shall be for availability of skilled nursing care on a recurring, intermittent, extended, or continuous basis. This care is generally less intense than that provided in general acute care hospitals but more intense than that provided in skilled nursing facilities.

(2) Congregate living health facilities shall provide one of the following services:

(A) Services for persons who are mentally alert, persons with physical disabilities, who may be ventilator dependent.

(B) Services for persons who have a diagnosis of terminal illness, a diagnosis of a life-threatening illness, or both. Terminal illness means the individual has a life expectancy of six months or less as stated in writing by his or her attending physician and surgeon. A "life-threatening illness" means the individual has an illness that can lead to a possibility of a termination of life within five years or less as stated in writing by his or her attending physician and surgeon.

(C) Services for persons who are catastrophically and severely disabled. A person who is catastrophically and severely disabled means a person whose origin of disability was acquired through trauma or nondegenerative neurologic illness, for whom it has been determined that active rehabilitation would be beneficial and to whom these services are being provided. Services offered by a congregate living health facility to a person who is catastrophically disabled shall include, but not be limited to, speech, physical, and occupational therapy.

(3) A congregate living health facility license shall specify which of the types of persons described in paragraph (2) to whom a facility is licensed to provide services.

(4) (A) A facility operated by a city and county for the purposes of delivering services under this section may have a capacity of 59 beds.

(B) A congregate living health facility not operated by a city and county servicing persons who are terminally ill, persons who have been diagnosed with a life-threatening illness, or both, that is located in a county with a population of 500,000 or more persons may have not more than 25 beds for the purpose of serving persons who are terminally ill.

(C) A congregate living health facility not operated by a city and county serving persons who are catastrophically and severely disabled, as defined in subparagraph (C) of paragraph (2) that is located in a county of 500,000 or more persons may have not more than 12 beds for the purpose of serving persons who are catastrophically and severely disabled.

(5) A congregate living health facility shall have a noninstitutional, homelike environment.

(j) (1) "Correctional treatment center" means a health facility operated by the Department of Corrections and Rehabilitation, the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, or a county, city, or city and county law enforcement agency that, as determined by the state department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. This definition shall not apply to those areas of a law enforcement facility that houses inmates or wards that may be receiving outpatient services and are housed separately for reasons of improved access to health care, security, and protection. The health services provided by a correctional treatment center shall include, but are not limited to, all of the following basic services: physician and surgeon, psychiatrist, psychologist, nursing, pharmacy, and dietary. A correctional treatment center may provide the following services: laboratory, radiology, perinatal, and any other services approved by the state department.

(2) Outpatient surgical care with anesthesia may be provided, if

the correctional treatment center meets the same requirements as a surgical clinic licensed pursuant to Section 1204, with the exception of the requirement that patients remain less than 24 hours.

(3) Correctional treatment centers shall maintain written service agreements with general acute care hospitals to provide for those inmate physical health needs that cannot be met by the correctional treatment center.

(4) Physician and surgeon services shall be readily available in a correctional treatment center on a 24-hour basis.

(5) It is not the intent of the Legislature to have a correctional treatment center supplant the general acute care hospitals at the California Medical Facility, the California Men's Colony, and the California Institution for Men. This subdivision shall not be construed to prohibit the Department of Corrections and Rehabilitation from obtaining a correctional treatment center license at these sites.

(k) "Nursing facility" means a health facility licensed pursuant to this chapter that is certified to participate as a provider of care either as a skilled nursing facility in the federal Medicare Program under Title XVIII of the federal Social Security Act or as a nursing facility in the federal Medicaid Program under Title XIX of the federal Social Security Act, or as both.

(l) Regulations defining a correctional treatment center described in subdivision (j) that is operated by a county, city, or city and county, the Department of Corrections and Rehabilitation, or the Department of Corrections and Rehabilitation, Division of Juvenile Facilities, shall not become effective prior to, or if effective, shall be inoperative until January 1, 1996, and until that time these correctional facilities are exempt from any licensing requirements.

(m) "Intermediate care facility/developmentally disabled-continuous nursing (ICF/DD-CN)" means a homelike facility with a capacity of four to eight, inclusive, beds that provides 24-hour personal care, developmental services, and nursing supervision for persons with developmental disabilities who have continuous needs for skilled nursing care and have been certified by a physician and surgeon as warranting continuous skilled nursing care. The facility shall serve medically fragile persons who have developmental disabilities or demonstrate significant developmental delay that may lead to a developmental disability if not treated. ICF/DD-CN facilities shall be subject to licensure under this chapter upon adoption of licensing regulations in accordance with Section 1275.3. A facility providing continuous skilled nursing services to persons with developmental disabilities pursuant to Section 14132.20 or 14495.10 of the Welfare and Institutions **Code** shall apply for licensure under this subdivision within 90 days after the regulations become effective, and may continue to operate pursuant to those sections until its licensure application is either approved or denied.



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

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 2 -- Reporting of Financial Settlements to the Board under Sections 801-804 of the California Business and Professions Code

The board recently undertook efforts to ensure that licensees and insurance companies are aware of their responsibilities to report to the board pursuant to sections 801 to 804 of the California Business and Professions Code. These provisions generally require the reporting to the board, by professional liability insurers and by licensees without professional liability insurance, of **any settlement or arbitration award over \$3,000 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.**

In the September 2010 *The Script* the board provided a notice of these reporting requirements. A copy of this article follows this page.

Reporting to the board of these settlements is rare. In 2009/10, the board received 2,331 complaints. Only 11 complaints were reports under these sections.

In 2009, there were approximately 360 million prescriptions filled and dispensed in California by pharmacies. The board received notice from patients and from other sources of 307 medication errors during 2009/10. This further indicates the high degree of under-reporting under these statutory sections.

During this agenda item, the committee will have an opportunity to discuss how it wishes to direct staff to proceed in this area.

Excerpt from *The Script*, September 2010

The Board recently learned that there are licensees and insurance companies that are unaware of their responsibilities to report to the Board pursuant to sections 801 to 804 of the Business and Professions Code. These provisions require the following reporting, by professional liability insurers and by licensees without professional liability insurance:

- Any settlement or arbitration award over \$3,000.00 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services, shall be reported to the Board by the insurer within 30 days after the settlement agreement has been reduced to writing and signed by all parties or within 30 days after service of the arbitration award on the parties (section 801);
- Any settlement or arbitration award over \$3,000.00 of any claim or action for damages or death or personal injury caused by a licensee's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services, shall be reported to the Board by a licensee who does not possess professional liability insurance within 30 days after the settlement agreement has been reduced to writing and signed by all parties or within 30 days after service of the arbitration award on the parties (section 802);

In addition, section 803 requires that the clerk of a court that renders a judgment that a licensee has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount over \$30,000.00 caused by the licensee's negligence, error or omission in practice, or his or her rendering of unauthorized professional services, report that judgment to the Board within 10 days after the judgment is entered.

Lastly, any required report is complete only if it includes all of the following:

1. The name and last known business and residential 1. addresses of every plaintiff or claimant involved in the matter;
2. The name and last known business and residential addresses of every provider who was claimed or alleged to have acted improperly, whether or not that person was a named defendant and whether or not any recovery or judgment was had against that person;
3. The name, address, and principal place of business of every insurer providing professional liability insurance to any of the providers identified in (2);
4. The name of the court in which the action or any part of the action was filed along with the date of filing and docket number of each action;
5. A brief description or summary of the facts upon which each claim, charge or judgment rested including the date of occurrence;
6. The names and last known business and residential addresses of every person who acted as counsel for any party in the litigation or negotiations, along with identification of the party whom said person represented;
7. The date and amount of final judgment and/or 6. settlement; and
8. Any other information Board regulations may require (section 804). If any person named in the report is notified by the Board of this obligation within 60 days of the filing of the report, he or she must maintain any records he or she has as to the matter in question and shall make those available to the Board upon request.

The Board subsequently enters the reported information into a licensee's central file (section 800). That central file provides an individual historical record for each licensee. The contents of the file that are not public records are kept confidential. The licensee or his or her attorney or

representative may inspect the file and have copies made except any materials disclosing the identity of an information source. The Board may also permit a law enforcement or regulatory agency to inspect and copy the file when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes.

Failure(s) to report such financial settlements may result in action by the Board.



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

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 3 -- Update on the Board's Efforts to Implement Components of the Department of Consumer Affairs Consumer Protection Enforcement Initiative

Background

Beginning in July 2009, the Department of Consumer Affairs has been work with health care board to improve capabilities to investigate and discipline errant licensees to protect the public from harm. These results yielded the Consumer Protections Enforcement Initiative (CPEI). The CPEI was comprised of a three pronged solution designed to ensure that investigation were completed and final action taken against a licensee within 12 – 18 months. The solution included legislative changes designed to remove barriers to investigations, a new computer system that would meet the boards needs to collect information and monitor performance, and additional staff resources.

Many of the legislative changes identified by the department were incorporated in SB 1111 (Negrete McLeod). Unfortunately this bill failed passage early in the year during its first policy committee. Subsequent to that, the department identified provisions in the bill that could be implemented through regulation and encouraged boards to develop language and initiate the rulemaking process.

In addition to working with the department on a department wide solution, the board also identified statutory changes that would specifically address pharmacy related issues. Language for these provisions was discussed during the January 2010 Board Meeting, and the board voted to pursue the changes. Because of the timing with the legislative cycle, these provisions were not pursued this year.

More recently, during the June 2010 Board Meeting, the board discussed proposed regulatory language developed by counsel, designed to implement the provisions requested by the department. The board expressed concern on many of the provisions and with one exception, did not take action on the items.

Recent Board Action

During the October 2010 Board Meeting, board members were advised that the department continues to encourage boards to pursue regulations changes that were previously incorporated into SB 1111. Consistent with this department's request, the board considered several proposed regulation changes:

1. Amendments to section 1760 regarding standardized disciplinary guidelines for violations dealing with sexual contact. As drafted, the change would provide that findings of sexual contact with a patient, client or customer or conviction of a sex offense would be grounds for revocation by the

Administrative Law Judge (ALJ); however, the board would have discretion to impose a lesser penalty under this proposal. **Board Action:** The board rejected this proposal.

2. Amendments to section 1762 regarding the proposed amendments to this section that would specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and failure to notify the board about an arrest, indictment, conviction or discipline as specified. The section also would specify that the board is authorized to revoke a license or deny an application for an act requiring an individual to register as a sex offender.
Board Action: The board voted to direct staff to modify amendments to section 1762 to specify records within the board's purview and to bring revisions back to the Enforcement Committee for possible recommendation to the board.
3. Amendment to section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated; the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report must be received from the evaluator.
Board Action: The board voted to amend the proposed language for section 1769 to require that once it has been determined that an applicant is to be evaluated, the evaluation and report shall be completed within 60 days and directed staff to take all necessary steps to initiate the formal rulemaking process.

During this Meeting

Proposed language to amend section 1762 for committee discussion is provided for discussion and possible action. The language provided on the next page is a start to the modifications discussed during the October Board Meeting.

Proposed addition of Section 1762. to Article 8 in Division 17 of Title 16 of the California Code of Regulations to read as follows:
(this whole section is new)

§1762. Unprofessional Conduct Defined

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later, ~~unless the licensee is unable to provide the documents within this time period for good cause. For the purposes of this section, "good cause" includes physical inability to access the records in the time allowed due to illness or travel.~~

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Failure to report to the board, within 30 days, any of the following:

(1) The bringing of an indictment or information charging a felony against the licensee.

(2) The arrest of the licensee.

(3) The conviction of the licensee, including any verdict of guilty, or pleas of guilty or no contest, of any felony or misdemeanor.

(4) Any disciplinary action taken by another licensing entity or authority of this state or of another state or an agency of the federal government or the United States military.

(e) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority cited: 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301 Business and Professions Code.



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

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 4 -- Discussion and Possible Action to Implement DCA's Recommendations of the Substance Abuse Coordination Committee, Pursuant to SB 1441, for the Pharmacists Recovery Program.

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 the SACC consideration during public meetings. The most recent version of the standards was approved in April 2010, however discussion on standard 4 continues via a subcommittee.

Below is a brief description of each of the 16 standards in their current form.

1. Clinical diagnostic evaluation
 - Specifies that if a licensee in a diversion program or on probation is required to undergo a clinical evaluation it shall comply with :
 - i. Qualifications for the licensed practitioner performing the evaluation
 - ii. Acceptable standards for such evaluations
 - iii. Identified elements of the report
 - iv. Timeframes to complete the process and prohibition of the evaluator having a financial relation, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
 - Specifies that board will issue a cease practice order during the evaluation and review of the results by board staff.
 - Specifies that the licensee will be subject to random drug testing at least two times per week.
 - Sets forth the evaluation criteria that must be considered by the diversion or probation manager when determining if a licensee is safe to return to work and under what conditions.
3. Communication with a licensee's employer, if applicable
 - Requires a licensee to notify the board of the names, physical addresses, mailing addresses and telephone numbers of all employers.
 - Requires a licensee to give written consent authorizing the board and employers and supervisors to communicate regarding the licensee's work status, performance and monitoring.

4. Drug testing
 - Sets forth a minimum testing frequency of 104 random drug tests per year for the first year and a minimum of 50 random drug tests per year (from then on.)
 - Specifies that testing shall be observed; conducted on a random basis, as specified; and may be required on any day, including weekends or holidays.
 - Requires licensees to check daily to determine if testing is required and specifies that the drug test shall be completed on the same day as notification.
 - Establishes criteria for the collection sites and laboratories processing the results.
5. Group meeting attendance
 - Sets forth the evaluation criteria that must be considered when determining the frequency of group support meetings.
 - Specifies the qualifications and reporting requirements for the meeting facilitator.
6. Type of treatment
 - Sets for the evaluation criteria that must be considered when determining whether inpatient, outpatient, or other type of treatment is necessary.
7. Worksite monitoring
 - Allows for the use of worksite monitors.
 - Specifies the criteria for a worksite monitor
 - Establishes the methods of monitoring that must be performed by the worksite monitor.
 - Sets forth the reporting requirements by the worksite monitor; specifies that any suspected substance abuse must be verbally reported to the board and the licensee's employer within one business day; and specifies that a written report must be provided to the board within 48 hours of the occurrence.
 - Requires the licensee to complete consent forms and sign an agreement with the worksite monitor and board to allow for communication.
8. Positive drug test
 - Requires the board to issue a cease practice order to a licensee's license and notify the licensee, employee and worksite monitor that the licensee may not work.
 - Specifies that after notification, the board should determine if the positive drug test is evidence of prohibited use and sets forth the criteria the board must follow when making such a determination.
 - Specifies that if the board determines that it was not a positive drug test, it shall immediately lift the cease practice order.
9. Ingestion of a banned substance
 - Specifies that when a board confirms a positive drug test as evidence of use of a prohibited substance, the licensee has committed a major violation.
10. Consequences for major and minor violations
 - Specifies what constitutes a major violation including: failure to complete a board ordered program or undergo a clinical diagnostic evaluation; treating patients while under the influence of drugs/alcohol, and drug/alcohol related act which would constitute a violation of the state/federal laws, failure to undergo drug testing, confirmed positive drug test, knowingly defrauding or attempting to defraud a drug test.
 - Specifies the consequences for a major violation including: issuing a cease practice order to the licensee; requiring a new clinical evaluation; termination of a contract/agreement; referral for disciplinary action.
 - Specifies what constitutes a minor violation including: untimely receipt of required documentation; unexcused group meeting attendance; failure to contact a monitor

when required; any other violations that does not present an immediate threat to the violator or the public.

- Specifies the consequences for a minor violation including: removal from practice; practice restrictions; required supervision; increased documentation; issuance of a citation and fine or working notice; re-evaluation/testing; other actions as determined by the board.

11. Return to full time practice

- Establishes the criteria to return to full time practice, including demonstrated sustained compliance, demonstrated ability to practice safely, negative drug screens for at least six months, two positive worksite monitor reports and compliance with other terms and conditions of the program.

12. Unrestricted practice

- Establishes the criteria for a licensee to request unrestricted practice including sustained compliance with a disciplinary order, successful completion of the recovery program, consistent and sustained participation in recovery activities, demonstrated ability to practice safely and continued sobriety of three to five years, as specified.

13. Private-sector vendor

- Specifies that the vendor must report any major violation to the board within one business and any minor violation within five business days.
- Establishes the approval process for providers or contractors that work with the vendor consistent with the uniform standards.
- Requires the vendor to discontinue the use of providers or contractors that fail to provide effective or timely services as specified.

14. Confidentiality

- For any participant in a diversion program whose license is on an inactive status or has practice restrictions, requires the board to disclose the licensee's name and a detailed description of any practice restrictions imposed.
- Specifies that the disclosure will not include that the restrictions are as a result of the licensee's participation in a diversion program.

15. Audits of private-sector vendor

- Requires an external independent audit every three years of a private-sector vendor providing monitoring services.
- Specifies that the audit must assess the vendor's performance in adhering to the uniform standards and requires the reviewer to provide a report to the board by June 30 of each three year cycle.
- Requires the board and department to respond to the findings of the audit report.

16. Measurable criteria for standards

- Establishing annual reporting to the department and Legislature and details the information that must be provided in the report.
- Sets forth the criteria to determine if the program protects patients from harm and is effective in assisting licensees in recovering from substance abuse in the long term.

The board did not take action on this item during the October Board Meeting specifically, however it did direct board staff to work on the disciplinary guidelines. Consistent with the recommendation made during the board meeting, some of the proposed changes to the disciplinary guidelines would facilitate implementation of portions of these uniform standards. They will be discussed during the next agenda item.



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 5 -- Discussion Regarding Proposed Modifications to the Board's Disciplinary Guidelines

California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action. This regulation section was last amended in May 2009.

During the October Board Meeting, the board voted to direct staff to work on updating the Disciplinary Guidelines for the board. We have initiated work on identification of proposed changes, many of which have been developed by counsel, but there is still additional work that needs to be done. In addition to identifying changes to the language, we are recommending that the guidelines be reorganized.

Work on the guidelines will continue over the next several months and will be discussed during the next committee meeting for possible action.

The following pages contain the recommended changes that have been identified thus far.

Proposed Changes to Disciplinary Guidelines Terms and Conditions

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a ~~pharmacist~~ [fill in the license type] as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) his or her direct supervisor, (b) his or her pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor (including each new pharmacist-in-charge employed during respondent's tenure of employment) and (c) the owner or owner representative of his or her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. ~~It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

If respondent works for or is employed by or through a ~~pharmacy~~ an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity ~~his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity.~~ A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a ~~pharmacy an~~ employment service, respondent shall cause the person(s) described in (a), (b), and (c) his or her direct supervisor with the pharmacy at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board ~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision ~~shall include~~ any full-time, part-time, temporary, relief, or employment/management service position as a _____, or any position for which a _____ license ~~or pharmacy management service as a pharmacist or any position for which a pharmacist license~~ is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

12. ~~Notification of a Change in Name, Residence Address, Mailing Address or Employment~~ Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. ~~Tolling of Probation License Practice Requirement - Tolling~~

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a ~~pharmacist~~ _____ in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless the respondent is informed otherwise in writing by the board or its designee.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California, if respondent does not practice as a _____ in California for a minimum of

_____ hours in any calendar month, for any reason (including vacation), respondent must notify the board in writing within ten (10) days of the ~~cessation~~ conclusion of that calendar month. This notification shall include at least the date(s), locations(s), and hours of practice; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a _____ in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

Option #1: As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a _____ in a licensed _____ in California [that dispenses dangerous drugs] for a minimum of one (1) year. [After the first year or probation, the board or its designee may consider a modification of this requirement.] Failure to comply with this requirement (or as modified) shall be considered a violation of probation. ~~Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.~~

Option #2: Possible option (or we could make it part of this term or a separate term if we want it to be standard) for premises licenses. "Respondent shall remain open and engaged in its ordinary business as a _____ in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a _____ in California for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s) and hours respondent was last open; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a _____ in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation."

Option #3: [For a first-year pharmacist intern.] During respondent's first academic year of enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] compliance with academic and vocational requirements, and on [his/her] academic progress. This exemption shall apply only once, and only during respondent's first academic year. Respondent must comply with all other terms and conditions of probation, unless informed otherwise in writing by the board or its designee."

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

17. Pharmacist Examination

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until he or she takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that he or she has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

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 where dangerous drugs and 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. Respondent shall not direct or control any aspect of the practice of pharmacy. 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.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. Failure to complete coursework as required shall be considered a violation of probation. Failure to take the examination(s) within one (1) year of the effective date of this decision shall be considered a violation of probation.

18. Mental Health Examination (Appropriate for those cases where evidence demonstrates that mental illness or disability was a contributing cause of the violations.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis as may be required by the board or its designee, respondent shall undergo, at his or her own expense, psychiatric evaluation(s) by a board-appointed or board-approved licensed mental health practitioner. The approved evaluator shall be provided with a copy of the board's [accusation or petition to revoke probation] 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 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, 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.

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: Commencing on the effective date of this decision, respondent shall not engage in the practice of _____ pharmacy 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.

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 where dangerous drugs and 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. Respondent shall not direct or control any aspect of the practice of pharmacy. 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 any such this suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)

Option: If recommended by the evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from the practice of _____ ~~practicing pharmacy~~ until respondent's treating therapist recommends, in writing, stating the basis therefore, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.

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 where dangerous drugs and 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. Respondent shall not direct or control any aspect of the practice of pharmacy. 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 any such ~~this~~ suspension shall be considered a violation of probation.

21. Pharmacists Recovery Program (PRP) (Appropriate for chemical dependency (alcohol, drugs), or psychiatric disorders (mental illness, emotional disturbance, gambling))

~~By no later than ten (10) days after~~ Within thirty (30) days of the effective date of this decision, ~~the~~ respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract plus any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee.~~ Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP and approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362(c)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall be considered a violation of probation.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

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 result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

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 where dangerous drugs and 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. Respondent shall not direct or control any aspect of the practice of pharmacy. 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 any such this suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will

collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in addition to standard language)

Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing probation. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

25. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

27. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his or her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

28. ~~Pharmacy Self-Assessment Mechanism~~

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education.~~

32. No Ownership or Management of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

33. Separate File of Controlled Substances Records ~~(For pharmacist owners and pharmacists in charge)~~

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

34. Report of Controlled Substances ~~(For pharmacist owners and pharmacists in charge)~~

Respondent shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

39. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent shall surrender his or her federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option: Respondent shall not order, receive, or retain any federal order forms, including 222 forms, for controlled substances.

Technician Specific only

- 16. Attend ~~Substance Abuse Recovery Relapse Prevention and Support~~ Group(s)** (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

Site License Specific only

- 11. Posted Notice of Probation**

Respondent ~~owner~~ shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. ~~The probation notice shall remain posted during the entire period of probation.~~

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 6 -- Questions and Answers on the Compounding Regulations

At the June Enforcement Committee Meeting, Supervising Inspector Robert Ratcliff provided a question and answer session on the new compounding regulations that took effect in July. The answers to these and other submitted questions have been compiled into a document and follow this page. The board is responding to these questions to aid pharmacies in complying with the new requirements.

At the October Board Meeting, President Weisser formed a two-person committee to review the questions and answers as they are developed. The current version of the questions and answers follow this page.

The questions and concerns voiced earlier with the regulations have not occurred since mid-summer. Nevertheless, during this portion of the meeting, Supervising Inspector Ratcliff will accept and answer additional questions if they are posed.

Compounding Questions and Answers, September 14, 2010

Question: Does every product and/or formulation compounded by a pharmacy have to undergo qualitative and quantitative analysis? If not, can the board provide guidance for selecting products to be analyzed?

Answer: The pharmacy, and the pharmacist, are responsible for insuring the compounded product complies quantitatively and qualitatively with the prescriber's prescription.

For compounded product that is compounded on a one-time basis for immediate dispensing, it would not be likely there would be a quantitative or qualitative analysis conducted.

For products compounded for on-going therapy it would be expect there would be analysis done initially and on a periodic basis to validate the product and compounding process.

The same holds true for sterile injectable drug products too.

However, for batch (two or more) produced sterile injectable drug products that are compounded from one or more non-sterile ingredients, the batch shall be quarantined until end-product testing confirms sterility and acceptable levels of pyrogens.

Reference: CCR 1735.8(c); 1751.5(c)

Question: Do cytotoxic agents and other hazardous substances have the same requirements for qualitative and quantitative analysis?

Answer: Yes

Question: If using a barrier isolator/glove box, is a gown required to prepare a cytotoxic parenteral product?

Answer: No.

CCR 1751.5 subdivision (a) requires the wearing of gowns and gloves when preparing a cytotoxic agent and subdivision (b) goes on to define "garb" requirements.

However, subdivision (c) of the same section goes on to state that if a barrier isolator is used the requirements do not apply.

Reference: CCR 1751.5(a)

Question: Is a non-resident pharmacy (NRP) that provides compounded product into CA required to meet the same staffing requirements as CA pharmacies?

Answer: No.

A non-resident pharmacy (NRP) is a pharmacy located in another state that furnishes dangerous drugs to patients in CA, and is required to be licensed with the board. Part of the licensure requirement is that the NRP be in compliance with pharmacy laws in the state where it is located.

The board has no authority to dictate staffing requirements for pharmacies located in states other than CA. The board expects the NRP to be staffed in accordance with requirements where it is located.

Reference: Business and Professions Code § 4112(a); 4112(d)

Question: What constitutes sterile compounding?

Answer: First, let's define "compounding" in general:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a drug product from chemicals or bulk drug substances

With the above in mind, sterile compounding is a specific sub-type of general compounding whereby there is a requirement for the compounded drug product to be sterile. Sterile compounding almost exclusively involves sterile parenteral compounding for which there are additional requirements.

Reference: CCR 1735(a) 1735(d); 1751 et seq.

Question: Is the adding of 20 mEq of potassium chloride to 1000cc of normal saline for intravenous administration considered sterile compounding.

Answer: Yes, and this is also considered sterile parenteral compounding

Question: Can a pharmacy mix three liquids (Maalox, Benadryl, and Xylocaine) in equal parts or two creams in equal parts, and would this be considered compounding.

Answer: Yes in the examples given, a pharmacy may mix those products in equal parts. And yes, it is considered compounding.

Reference: CCR 1735(a)

Question: What happens in a situation where an IV is made to be used on a one time basis for administration within 24 hours for a registered inpatient of a health care facility and product is not used and returned to the pharmacy? Can it be reused?

Answer: No.

The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (7) The equipment used in compounding the drug product.
- (8) A pharmacy assigned reference or lot number for the compounded drug product.
- (9) The expiration date of the final compounded drug product.
- (10) The quantity or amount of drug product compounded.

If all the information is not recorded [as provided by the exemption in (6)] then there is a lack of complete traceability and accountability for the compounded drug product and thus it cannot be reused.

Reference: CCR 1735.3

Question: Our medical center's policies and procedures have the initial dose of an IV admixture compounded in the pharmacy satellite to assure timely initiation of therapy, with all subsequent doses mixed in the central pharmacy.

Is the initial IV admixture compounded in the satellite pharmacy subject to the recording requirements.

Answer: Yes, with the possible exception of documenting the manufacturer and lot number of each component of the admixture.

Reference: CCR 1735.3(a)(6)

Question: Is a master formula record equivalent to a "recipe card?"

Answer: Basically, yes.

Like a recipe card the master formula record includes the active and inactive ingredients to be used, the process and/or procedure used to prepare the drug, quality reviews required at each step in the preparation of the drug, post-compounding process or procedures required, and the expiration dating requirements.

The master formula record must be created prior to compounding the drug product.

The prescription document itself may be as the master formula record if a pharmacy does not routinely compound a particular drug product.

Reference: CCR 1735.2(d)

Question: When compounding a product, is it required to have master formula record available and used when the product is compounded?

Answer: Yes, the master formula record must be created prior to compounding the drug product and its use will provide guidance for compounding personnel and consistency in the product produced.

Reference: CCR 1735.2(d)

Question: **Is it required to inspect the master formula record as part of pre-check process?**

Answer: The law is silent on a “pre-check process.” However, the master formula record will provide guidance to compounding personnel in what to use and how to compound the particular drug product. So the master formula record could be used in a “pre-check” process to insure consistency in the compounding process.

Reference: CCR 1735.3

Question: **What are the requirements for compounding documentation?**

Answer: The compounding regulations require specific records for compounded drug products. For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements of this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient in a health care facility.
- (7) The equipment used in compounding the drug product.
- (8) A pharmacy assigned reference or lot number for the compounded drug product.
- (9) The expiration date of the final compounded drug product.
- (10) The quantity or amount of drug product compounded.

Reference: CCR 1735.3

Question: When using the record-keeping exemption in 1735.3(a)(b) to compound a one time Vancomycin IV with a seven day expiration date and to be used within 24 hours, is the manufacturer and lot number required?

Answer: No.

The regulations provide for an exemption for sterile products compounded on a one-time basis for administration within twenty-four hours to an in-patient of a health care facility.

Reference: CCR 1735.3(a)(6)

Question: When must the manufacturer and lot number be recorded?

Answer: This information must be documented if the product is not for a one time use for a specific patient to be used within 24 hours.

Reference: CCR 1735.3(a)(6)

Question: How will the board insure compliance by non-resident pharmacies (NRP's) that provide compounded drug products into CA?

Answer: The board does not have the ability to inspect NRPs.

However, NRPs are required to be licensed with the board and to maintain compliance with pharmacy regulations of their home state. Also, a NRP performing sterile parenteral compounding as a condition of renewal will be required to submit a completed Compounding Self Assessment Form.

Reference: B&P §§ 4112, 4127.2

Question: Is the dilution per the manufacturer's instructions and adding to the IV solution considered compounding?

Answer: Yes if done in a pharmacy. However, statute provides for exemption from sterile compounding licensure if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

Question: Are proprietary drug delivery systems such as ADD-Vantage, Mini-Bag Plus, and At-Eas considered compounded products after the vials have been attached to the IV bags?

Answer: These types of delivery systems are exempt from the compounding requirements if the sterile powder was obtained from a manufacturer and the drug is reconstituted for administration to patients by a health care professional licensed to administer drugs by injection.

Reference: CCR 1735(a)(1); B&P 4127.1(e)

Question: What specifically will be required or what process is acceptable to achieve quality assurance?

Answer: Quality assurance, as the term implies, is designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded products.

A quality assurance plan will touch all parts of the compounding process – drug product and equipment acquisition/storage; compounding processes; documentation of compounding and related analysis; employee training and monitoring; recall procedure; etc

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.

Question: When recycling an IV that was previously compounded by the pharmacy, can the previous lot number of the recycled IV be used as long as the lot number can be traced to all the requirements listed in section 1735.3?

Answer: Yes.

Reference: CCR 1735.3

Question: What is a “reliable supplier?”

Answer: FDA licensed manufacturers, CA licensed wholesalers, and CA licensed pharmacies are examples of reliable suppliers. These types of entities must be licensed and meet/maintain their premises to stay licensed.

Reference: B&P §§ 4160, 4163, 4126.5, 4169; CCR §§ 1780, 1783

Question: Does CCR section 1735.5 require a pharmacy to test each and every compounded product for integrity, potency, quality, and labeled strength of the compounded product?

Answer: No. However, if the compounded product involves a complex process it would seem prudent to have documentation of the final product. This is even more important when the product is compounded on a more routine basis.

Compounding involves not just the QA process, but staff training, equipment maintenance, proper documentation and appropriate analysis of products compounded.

Reference: CCR 1735.8; 1735.3; 1735.5; 1735.6; 1735.7; 1751 et seq.

Question: For the purposes of CCR section 1735.3(a)(6) and 1751.2(a), would patients receiving chemotherapy administered in an infusion center that is part of a health care facility be considered “inpatients” and exempt from the labeling requirements?

Answer: If the infusion center is part of the licensed health care facility and the patients receiving care there are registered as hospital inpatients, then yes the exemption provided by CCR 1735(a)(6) would apply. However, the labeling requirements as defined in CCR 1751.2 would apply and compliance would be expected.

Reference: B&P §§ 4027, 4019, 4029; CCR 1735.3(a)(6), 1751.2

Question: CCR section 1735.3 defines what must be recorded for each compounded drug product. CCR 1735.3(a)(7) states, “The equipment used in compounding the drug product.” Does this include tubing sets, spikes, needles, syringes, etc.?

Answer: Yes, all equipment used compounding the drug product must be recorded.

Reference: 1735.3(a)

Question: Where would the lot number, manufacturer, and expiration date be recorded?

Answer: The law does not specify where or how the information is to be recorded. A pharmacy may develop its own form(s) for the proper documentation.

The pharmacy shall maintain the record for three years from the date it was created.

Reference: 1735.3

Question: **Some equipment used in compounding (needles, syringes, spikes, etc.) have lot numbers but not an expiration date. What information should be recorded?**

Answer: As much required information as is available. If there is no expiration date on a device, there would be no expiration date recorded.

Reference: 1735.3

Question: **CCR section 1751.2(d) states, “All cytotoxic agents shall bear a special label which states ‘Chemotherapy – Dispose of Properly.’” This appears to give no wiggle room for the text of the message.**

Answer: There are no exceptions. If a drug is classified as a cytotoxic agent then the special label must be used.

Reference: CCR 1751.2(d)

Question: **Gancyclovir is a cytotoxic agent but is not a chemotherapeutic agent. Does the special label need to be applied?**

Answer: Yes, the regulation does not provide for exceptions. However, nothing prevents the pharmacist from consulting the patient on the drugs classification and use.

Reference: CCR 1751.2(d)

Question: **CCR section 1751.5(b)(1) states, in pertinent part,, “Cleanroom garb consisting of low-shedding coverall, head cover...must be worn inside the designated area at all times.” USP 797 does not require the use of a coverall, only a gown.**

Answer: The board does not enforce USP 797, but expects compliance with board regulations.

A coverall is much more encompassing than a gown and would provide better protection during the compounding process.

Reference: CCR 1751.5(b)(1)

Question: For a compounded drug product can a pharmacy use an expiration date, or beyond use date, of greater than 180 days?

Answer: Yes, if the longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging.

Reference: CCR 1735.2(h)

Question: Master formulas and compounding records are filed in separate locations, can easily be linked together, and are readily retrievable. Is it an absolute requirement to file these documents together?

Answer: No, there is no such requirement for the above records to be maintained together as long as they are readily retrievable and available for inspection. These records may be maintained in a paper or electronic manner.

However qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated (kept together) with the compounding record and master formula.

Reference: CCR 1735.8(c)

Question: Is record keeping for compounding just referring to products that are administered intravenously or intraocular (e.g. where sterile preparation is imperative) or does it extend to oral and topical compounding?

Answer: The regulations apply to all forms of compounding – oral, inhalation, topical, sterile parenteral, etc.

Reference CCR §§ 1735 et seq & 1751 et seq.

Question: What is meant by proper acquisition?

Answer: Records of proper acquisition of dangerous drugs and dangerous devices would include purchase records that correctly give the date, the names and address of the supplier and the buyer, the drug or device, and its quantity.



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

Date: November 30, 2010

To: Enforcement Committee

Subject: Agenda Item 7 -- Should Patients be Allowed to Take Their Multi-Dose Medications Home Upon Discharge from a Hospital

Several weeks ago, the executive officer met with representatives of drug manufacturer Sanofi-Aventis regarding the disposal of multi-dose containers of medication ordered for patients in hospitals that are not allowed to go home with patients at discharge because they are not labeled for patient self use. These multidose products include inhalers, eye drops, insulin, topical creams that are ordered for the patient during a hospital stay but are not in the patient's control while the patient is in the hospital. Because they are not labeled for patient self-use, they are destroyed when the patient is discharged, even though the patient has been charged for the whole product. An example of the problem is provided in the article that follows this article.

At this meeting, the committee will hear a presentation by Deanne Calvert, JD from Sanofi Aventis on this issue.

The committee may want to explore this topic in the future with hospital pharmacists for possible solutions.

MedWise: Preventing Medication Waste While Promoting Safe Administration

By Jeffrey Conzelmann, PharmD; Karyl King, PMP; Sharon Sarnicola, RN; and Brenda Wierenga, RN, BSN

Hospitals face a frustrating medication dilemma: should inpatients be allowed to take their multi-dose medications (e.g., inhalers, topical creams, eye drops, insulin) home upon discharge? The natural inclination is for patients to ask, "These are paid for; why can't I take them home? What's the big problem?"

The problem is to comply with federal regulations for the labeling of medications that are sent home. Regulations require that any medication a patient takes home must be labeled as if it were coming from an outpatient pharmacy. If these labeling requirements cannot be met, then the multi-dose medications must be discarded (Michigan Public Health Code, 2008). This labeling requirement creates difficulties, but on the other hand, it seems that no one is served when expensive medications are thrown away.

At Spectrum Health in Grand Rapids, Michigan, three of us — two RNs and a pharmacist — addressed that dilemma as a work team. Instead of just accepting the status quo, we went to Spectrum Health's Innovation Lab — What I.F.? — and enlisted the help of its project manager. Together, we presented our concern to a leadership team, the Spectrum Health Innovation Committee, which includes executive-level administrators from finance, information and technology services, marketing and communications, medical affairs, research and education, patient affairs, general counsel office, and is chaired by the president.

Some of the questions discussed initially included:

- How can Spectrum Health document and track medication history at discharge while complying with all federal and state regulations?
- How can we create a virtual outpatient pharmacy function at the point of discharge that converts inpatient multi-dose medications to outpatient medications for home use?
- What labeling is required and appropriate?
- What patient education services are needed?

The Innovation Committee gave its approval for the work team to begin an initiative called "MedWise" to conduct a literature search, collect data, and obtain an independent legal opinion.

Literature Search and Data Collection

First, we conducted a literature search to determine if any other hospitals had implemented similar programs. That search resulted in finding little or no information. Second, we carried out an internal data analysis to try to validate our assumption. Were we, in fact, wasting valuable resources? The data showed that the average potential out-of-pocket cost for multi-dose medications per patient was \$120; the range was between \$6 and \$520. In another component of our data analysis, a sampling was kept of medications thrown away from all types of inpatients at Spectrum Health's Blodgett Hospital for the week of July 2, 2007. *The total value of those medications was approximately \$5,000.* We also kept a sampling of medications thrown away from all types of inpatients at the other major Spectrum Health hospital — Butterworth Hospital — for the week of August 6, 2007. *The total value of those medications was approximately \$25,000.* Annualized, the total value of medications thrown away at both facilities was a staggering \$1,560,000!

Legal Analysis

Based on recommendations from the Spectrum Health Risk and Compliance Department, we requested an independent legal opinion. In its opinion, the firm stated that neither the Michigan Public Health Code (2008) nor the Board of Pharmacy's General Rules (R 338.471) directly address the question of whether patients may take home unused portions of medications dispensed to them while they are in the hospital. However, the destruction of unused medication dispensed to hospital patients is not an absolute requirement; single-use packages and IV solutions designed to be tamper-evident and which show no evidence of tampering may be returned to stock. On the other hand, medications that leave the institution may not be returned to stock for redispensing. Thus, the General Rules implied that medications can leave the hospital with the patient at discharge.

Technology Solution

Based on all of these preliminary findings, the work team returned to the Spectrum Health Innovation Committee and was given permission to find a solution. After rechecking the literature for potential appropriate solutions and not finding any, we began to evaluate the various types of technology options within our system.

The first option we investigated was to create one label that provided all the required information, but existing systems were not able to accurately differentiate between multi-dose and other types of medications. The second option we evaluated was the use of a generic preprinted label added to the Cerner patient barcode label (Figure 1). This solution proved to be workable within our system, and it met all federal and state regulations regarding properly labeling medication for dispensing at discharge.

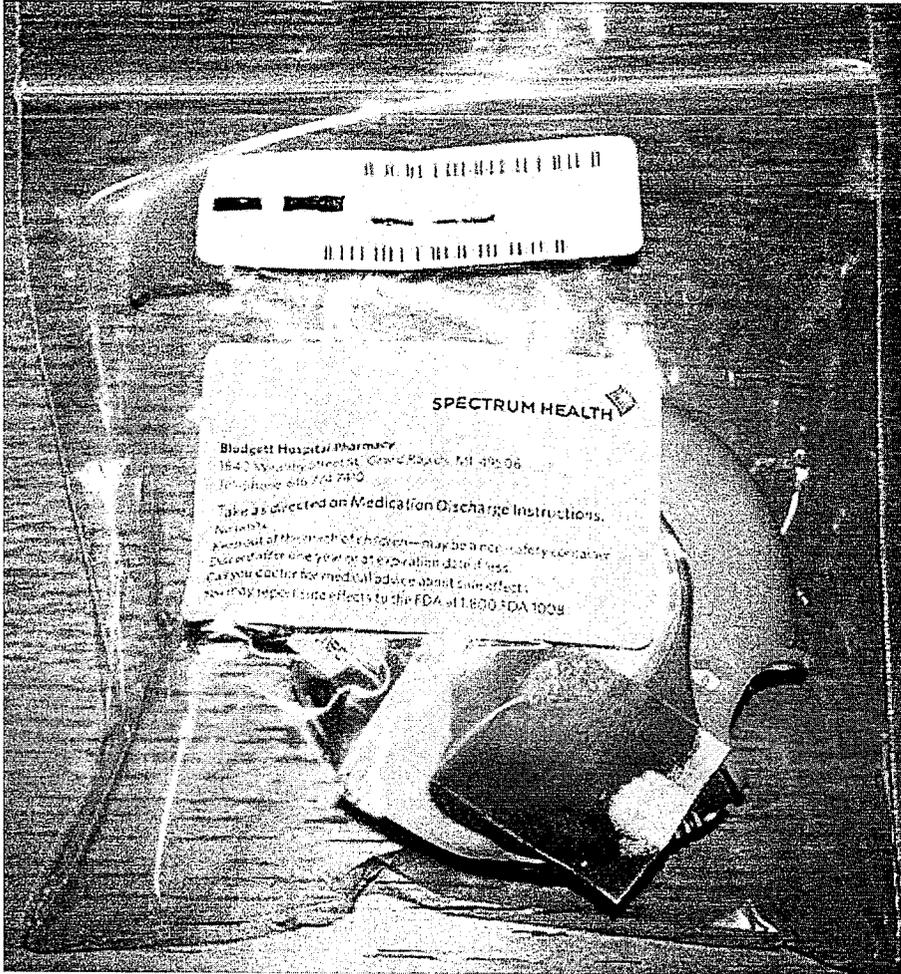


Figure 1: Labeling Solution: Generic Hospital Label with Cerner Patient Barcode

Policy Requirements

While we were designing the technology solution, we also began to revise our policy related to dispensing medications to discharged and clinic patients. The revised policy, which needed to address both the processes for dispensing and patient education issues, states that:

Multi-dose medications including inhalers, ophthalmic products, insulin products, and topical preparations may be provided to patients upon discharge provided the following criteria have been met (injectable medications other than insulin products are excluded):

- The specified multi-dose product must be a continuation of hospital-initiated therapy.
- The physician must write a physician order in the chart indicating that the multi-dose product may be sent home with the patient.
- The product must be labeled according to federal labeling requirements:
 - Pharmacy will label the product prior to dispensing for inpatient use with the following information: the patient name, product name and strength, and date of initial dispensing.
 - Pharmacy will then dispense initial product in a clear plastic bag with a label on the plastic bag indicating name, address, and phone number of the hospital pharmacy. The label will contain instructions for use by the patient as indicated on the patient's discharge medication sheet. The label will include the statement: "Discard this medication one (1) year after the date it is dispensed or on the manufacturer's expiration date, whichever is sooner."
 - Once initial product is received by the nursing unit, a patient label will be placed on the bag by the nurse. This label will include the patient name, numerical identifier, and attending physician.
 - The multi-dose product will be maintained in the plastic bag during the patient's hospital stay and be kept in the patient's locked medication drawer.
 - The patient must be provided the opportunity for counseling from nursing, pharmacy, or a licensed independent practitioner; questions regarding their medications must be addressed and documented. Documentation of this activity is entered on the patient's education record.
 - If a licensed independent practitioner does not want the patient to take home the hospital-issued multi-dose medication, but does desire the patient to continue therapy, the practitioner must provide the patient with a written prescription. A record of such discharged prescriptions must be noted in the patient's chart.

The Emergency Department (ED) follows the same process, except patients discharged from the ED may receive starter medications when circumstances prevent prompt access to prescriptions through an outpatient pharmacy.

Education and Communication Strategy

Once a technology solution was defined, the entire process was reviewed with the key stakeholders: the Nursing Education Committee, hospitalists, nursing leadership, the pharmacy, and the risk and compliance leadership.

After obtaining approval from all key stakeholders, we worked with nursing education to define the educational requirements. These included developing an online training course, information about the new policy, information about the change in process, a Frequently Asked Questions flier, and a description of new roles and tasks for nursing staff.

A critical key to successful change was to ensure we had a broad, far-reaching communication plan that targeted the entire hospital as well as external independent practitioners. We leveraged a variety of vehicles to communicate the change in medication dispensing, its rationale, the change in process, and new role definitions. These included the use of Hot Topics (a monthly physician newsletter), department meetings, a letter to physicians from senior management, and various announcements and memos to everyone involved.

We decided to launch the MedWise initiative in two phases approximately 6 weeks apart. Phase 1 focused on Blodgett Hospital, which has 297 beds. Phase 2 targeted Butterworth Hospital, which has 614 beds, and Helen DeVos Children's Hospital, which has 152 beds.

An important part of the launch involved communicating the benefits of the change to patients, their families, physicians and other practitioners, payers, and the community. These included:

- Improve patient satisfaction by enhancing their quality of life and reinforce our partnership by providing them with an exceptional experience.
- Improve fiscal responsibility for expensive resources.
- Safe and responsible use of resources in a manner that supports our hospital policies, federal and state regulations.

Measuring Success and Course Correction

To define success for the MedWise initiative and determine any ongoing changes needed, we identified two measurement procedures:

- Include in our quality audits an evaluation of the medication reconciliation discharge form to ensure that every form contains three signatures (physician, patient, and nurse).
- Collect medication returns to the pharmacy at each hospital location to determine if there has been a reduction in returns.

Currently, we are in the implementation phase of the initiative. Although we are early in the implementation phase, we are seeing a reduction in medication waste by 50%, and staff and patients report positive feedback as they follow the new process. We are partnering with the Spectrum Health Quality Department to evaluate the audit results, offer further education, and review the new policy as appropriate.

Value of MedWise

Before implementing MedWise, there were times when patients with limited resources had to choose between paying for medication they received in the hospital or taking care of their other needs. By implementing the MedWise process we are:

- Allowing them to take home their unused multi-dose medications. This increases patient satisfaction and is seen as actively "doing the right thing" for our consumers and their families.
- Engaging physicians and staff more fully in promoting patient safety and compliance in medication dispensing.
- Being fiscally and environmentally responsible by decreasing medication waste.

An additional benefit for the hospital involves our patient leave-of-absence policy. The MedWise initiative allows the hospital to remain in compliance with federal and state regulations while patients take needed medications with them during a leave defined in their clinical path.

Conclusion

The MedWise initiative is new and initial evaluation is incomplete. As technology changes with the introduction of computerized provider order entry (CPOE), we know we will need to revise our process to ensure an easy transition from paper orders to computerized orders.

However, it appears we have successfully created a virtual pharmacy that allows patients to take home their prescribed and paid-for medications. Initial feedback from Spectrum Health staff supports the MedWise initiative. It is seen as actively "doing the right thing" for patients while being fiscally and environmentally responsible by decreasing medication waste.

Jeffrey Conzelmann has been a practicing pharmacist for 20 years, both as a staff pharmacist and for 5 years as a clinical pharmacist specializing in cardiology. He has served on various continuous improvement teams focused on heart failure and acute myocardial infarction, with responsibility for ensuring that patients receive appropriate therapies indicated by national guidelines. He is currently the pharmacy manager for Blodgett Hospital at Spectrum Health in Grand Rapids. Conzelmann earned his bachelor of science in pharmacy from Ferris State University and his PharmD from the University of Florida.

Karyl King has 18 years of leadership in project management, specifically in developing project management methodologies in the new product development and healthcare industries. She has extensive experience in leading and working collaboratively with team members to complete projects in new product development, quality enhancement, rapid tooling, and information technology development, using the Toyota lean methodology for process improvement. She is currently a project manager at Spectrum Health, leading innovation projects through

Spectrum Health

Spectrum Health is a not-for-profit health system in West Michigan that offers a full continuum of care through the Spectrum Health Hospital Group, a collection of seven hospitals and more than 140 service sites; the Spectrum Health Medical Group, a multispecialty team of nearly 100 providers; and Priority Health, a health plan with nearly 500,000 members. Spectrum Health's 14,000 employees, 1,500 medical staff members, and 2,000 volunteers are committed to delivering the highest quality care to those in medical need. The organization provided \$111.1 million in community benefit during its 2008 fiscal year. As a system, Spectrum Health has earned more than 100 awards during the past 10 years.

the What I.F.? Innovation Lab. King graduated from Davenport University with a bachelor's degree in general business and currently serves on the board for the West Michigan Project Management Chapter. She may be contacted at Karyl.King@spectrum-health.org

Sharon Sarnicola has been in nursing for 25 years, the last 23 of which have been with Spectrum Health in Grand Rapids. Her nursing background includes positions as a critical care nurse in neurology and medical critical care, endoscopy, and as a clinical manager. Sarnicola is currently a coordinator in the patient relations department. She graduated with an associate of science nursing degree from Lansing Community College.

Brenda Wierenga has been in nursing for 21 years with Spectrum Health in Grand Rapids. She has served as a neuroscience bedside nurse, a neuro-trauma and rehabilitation nurse manager, and neuro care manager. She is currently a coordinator in the patient relations department. She earned her bachelor of science in nursing degree from Hope College.

References

Michigan Public Health Code. (2008). Article 15, Michigan Board of Pharmacy's General Rules (R 338.471).

Last Updated on Friday, 13 November 2009 11:14



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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

ARNOLD SCHWARZENEGGER, GOVERNOR

Date: December 2, 2010

To: Enforcement Committee

Subject: Agenda Item 8 -- Update on the Board's Ethics Course

In mid-November, the Institute for Medical Quality provided the first ethics course for pharmacists under the requirements specified in 16 California Code of Regulations sections 1773 and 1773.5. We believe that 12 pharmacists, ordered to complete this course as a condition of their probations, were enrolled. The course will follow these individuals over the next 12 months. Periodic reports of the progress of this course will be provided to the committee and board in the future.

There is a second course provider interested in providing a course that meets the parameters of section 1773.5; however, we are not aware that this course has actually been provided or scheduled at this time.

Whereas the board is not specifically involved in the course provided, as a new program, the board will be kept updated as probationers take and complete these courses.



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

Date: December 2, 2010

To: Enforcement Committee

Subject: Agenda Item 9 -- Enforcement Performance Measures

The following page provides the first quarter's reporting on the DCA's enforcement performance measures. The department has developed the reporting parameters for this report.

I will bring the standard enforcement performance measures we have in our strategic plan to the meeting. These better reflect the performance of our enforcement program.

Performance Measures

Q1 Report (July - Sept 2010)

To ensure stakeholders can review the Board's progress toward meeting its enforcement goals and targets, we have developed a transparent system of performance measurement.

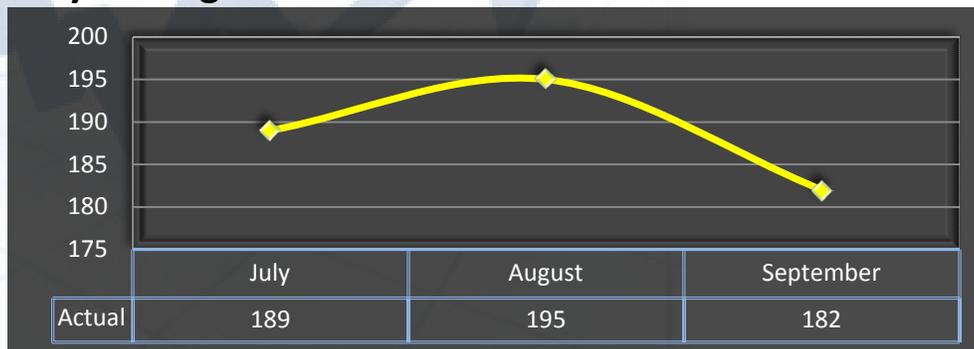
These measures will be posted publicly on a quarterly basis. In future reports, additional measures, such as consumer satisfaction and complaint efficiency, will also be added. These additional measures are being collected internally at this time and will be released once sufficient data is available.

Volume

Number of complaints received.*

Q1 Total: 566 (Complaints: 306 Convictions: 260)

Q1 Monthly Average: 189

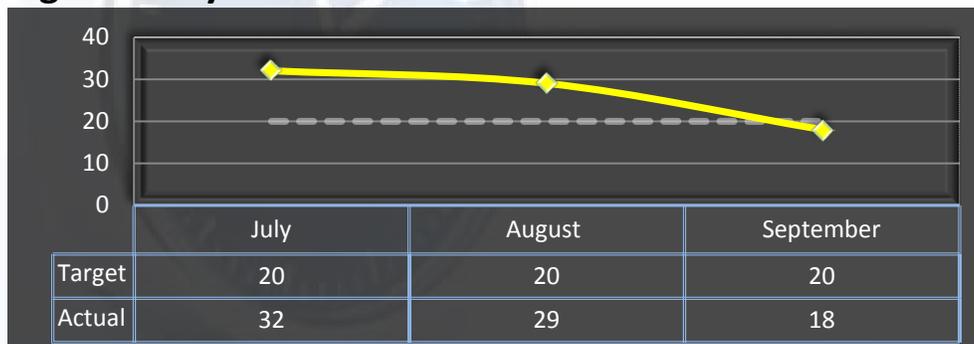


Intake

Average cycle time from complaint receipt, to the date the complaint was assigned to an investigator.

Target: 20 Days

Q1 Average: 27 Days

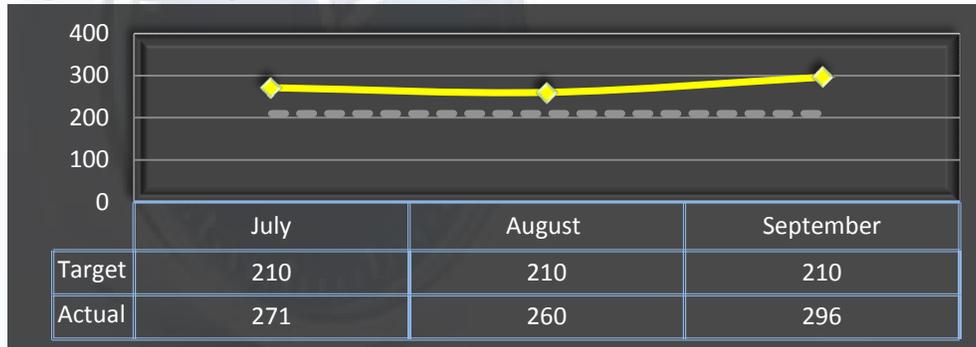


Intake & Investigation

Average cycle time from complaint receipt to closure of the investigation process. Does not include cases sent to the Attorney General or other forms of formal discipline.

Target: 210 Days

Q1 Average: 277 Days

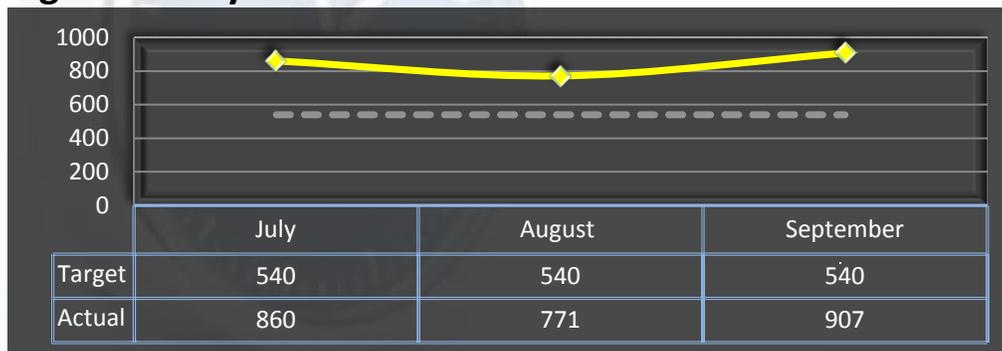


Formal Discipline

Average cycle time from complaint receipt to closure, for cases sent to the Attorney General or other forms of formal discipline.

Target: 540 Days

Q1 Average: 801 Days



Probation Intake

Average number of days from monitor assignment, to the date the monitor makes first contact with the probationer.

Target: 30 Days

Q1 Average: N/A

The Board did not report any probation monitoring data this quarter.

Probation Violation Response

Average number of days from the date a violation of probation is reported, to the date the assigned monitor initiates appropriate action.

Target: 7 Days

Q1 Average: N/A

The Board did not report any probation violation data this quarter.