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

Date: November 30, 2009

To: Enforcement Committee

Subject: Regulations Required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for Practitioner Recovery Programs

Agenda Item 1

Background

SB 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 consisting of staff from each of the healing arts boards to draft recommended standards for the SACC consideration during public meetings. The recommended standards were vetted during public meetings akin to an informational hearing. The draft standards were then presented during a public meeting to the SACC for consideration and action.

Business and Professions Code sections 4360 thru 4373 establish the Pharmacists Recovery Program (PRP) and establish some of the functions of the program as well as program participation criteria. The board contracts with a vendor, currently Maximus, Inc. to administer the PRP. However, under current law, this program only available to pharmacists and interns.

Recent Updates

On November 16, 2009, the SACC approved the attached standards as required by SB 1441. Below is a brief description of each of the 16 standards.

1. Clinical diagnostic evaluation
 - Specifies that a licensee in a diversion program or on probation will be required to undergo a clinical evaluation at the licensee's expense.
 - Sets forth the qualifications for the licensed practitioner performing the evaluation as well as the required elements of the evaluation.
 - Provides for the timeframes to complete the process and prohibits the evaluator from having a financial relation, etc. with the licensee.
2. Temporary removal of practice for clinical evaluation
 - Specifies that license will be placed on an inactive status 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
- 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 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 place a licensee's license on an inactive status 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.

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: placing the license on an inactive status; 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.

Today board staff received a letter from the director encouraging each board to implement these standards. A copy of adopted standards and the letter from the director are following this memo.

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee



Brian J. Stiger, Director
November 2009

STATE OF CALIFORNIA
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DEPARTMENT OF CONSUMER AFFAIRS

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#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

Any licensee in a board diversion program or whose license is on probation, who the board has reasonable suspicion has a substance abuse problem shall be required to undergo a clinical diagnostic evaluation at the licensee's expense. The following standards apply to the clinical diagnostic evaluation.

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:
 - holds a valid, unrestricted license to conduct a clinical diagnostic evaluation;
 - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,
 - is approved by the board.
2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.
3. The clinical diagnostic evaluation report shall:
 - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;
 - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,
 - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. His or her license shall be placed on inactive status during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.
2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least one (1) month of negative drug tests.

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following drug testing standards shall apply to each licensee subject to drug testing:

1. Licensees shall be randomly drug tested at least 104 times per year for the first year and at any time as directed by the board. After the first year, licensees shall be randomly drug tested at least 50 times per year.
2. Drug testing may be required on any day, including weekends and holidays.
3. The scheduling of drug tests shall be done on a random basis, preferably by a computer program.
4. Licensees shall be required to make daily contact to determine if drug testing is required.
5. Licensees shall be drug tested on the date of notification as directed by the board.
6. Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.
7. Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.
8. Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.
9. Collection of specimens shall be observed.
10. Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.
11. Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.
2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years.
3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.
4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to uniform standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional if no monitor with like practice is available.
3. The worksite monitor shall have an active unrestricted license, with no disciplinary action within the last five (5) years.
4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
5. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance, the board shall:

1. Place the licensee's license on inactive status; and
2. Immediately contact the licensee and instruct the licensee to leave work; and
3. Notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board should reactivate the license.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;
2. Communicate with the licensee and/or any physician who is treating the licensee; and
3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a “deferred prosecution” stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Inactivation of the license.
 - a) the license is put on inactive status, and
 - b) the licensee must undergo a new clinical diagnostic evaluation, and
 - c) the licensee must test clean for at least a month of continuous drug testing before being allowed to go back to work, and

2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to:

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

“Petition” as used in this standard is an informal request as opposed to a “Petition for Modification” under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.
2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee's substance abuse.
3. Negative screening report for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

“Petition for Reinstatement” as used in this standard is an informal request (petition) as opposed to a “Petition for Reinstatement” under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.
2. Demonstrated successful completion of recovery program, if required.
3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.
4. Demonstrated that he or she is able to practice safely.
5. Continuous sobriety for three (3) to five (5) year.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.
2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

Specimen Collectors:

- a) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.
- b) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.
- c) The provider or subcontractor must provide collection sites that are located in areas throughout California.
- d) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.
- e) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.
- f) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

- g) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.
- h) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.
- i) Must undergo training as specified in Uniform Standard #4 (5)

Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

- a) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;
- b) must be licensed or certified by the state or other nationally certified organization;
- c) must not have a financial relationship, personal relationship, or business relationship with the licensee in the last five (5) years;
- d) shall report any unexcused absence within 24 hours to the board, and,
- e) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

Work Site Monitors:

1. The worksite monitor must meet the following qualifications:
 - a) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.
 - b) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored or be another health care professional, if no monitor with like practice is available.
 - c) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

- d) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.
2. The worksite monitor must adhere to the following required methods of monitoring the licensee:
 - a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.
 - b) Interview other staff in the office regarding the licensee's behavior, if applicable.
 - c) Review the licensee's work attendance.
 3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.
 4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:
 - the licensee's name;
 - license number;
 - worksite monitor's name and signature;
 - worksite monitor's license number;
 - worksite location(s);
 - dates licensee had face-to-face contact with monitor;
 - staff interviewed, if applicable;
 - attendance report;
 - any change in behavior and/or personal habits;
 - any indicators that can lead to suspected substance abuse.

Treatment Providers

1. Treatment facility staff and services must have:
 - a) Licensure and/or accreditation by appropriate regulatory agencies;
 - b) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;
 - c) Professional staff who are competent and experienced members of the clinical staff;

- d) Treatment planning involving a multidisciplinary approach and specific aftercare plans;
 - e) Means to provide treatment/progress documentation to the provider.
2. The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:
- a) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.
 - b) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.
 - c) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.
2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.
3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation.
- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.



November 30, 2009

Virginia Herold, Executive Officer
Board of Pharmacy
1625 North Market Boulevard, Suite N219
Sacramento, CA 95834

Dear Ginny:

Thank you for your participation in the SB 1441 Substance Abuse Coordination Committee. Now that the committee has adopted the sixteen uniform standards required by SB 1441, each affected board must now implement these standards to protect the public from substance abusing healthcare practitioners.

At the earliest possible opportunity, I encourage you to promptly implement those standards that don't require your board to seek any additional legal authority. Some standards may require your board to promulgate regulations or seek legislation.

With regards to legislation, I need you to work with your assigned attorney to immediately review each standard to determine what additional statutory authorities your board needs if any to begin implementation. If your board needs additional legislation, please submit your proposed legislative language to Luis Portillo, Assistant Deputy Director, Legislative and Policy Review, by **December 15, 2009**.

I appreciate your attention to this matter. If you have any questions or need additional information regarding this correspondence, please contact Paul Riches, Deputy Director, Enforcement and Compliance.

Best regards,

A handwritten signature in black ink that reads "Brian J. Stiger".

Brian J. Stiger, Director
Department of Consumer Affairs

cc: Luis Portillo, Assistant Deputy Director, Office of Legislative and Policy Review
Paul Riches, Deputy Director, Enforcement and Compliance
Kristy Schieldge, Legal Affairs



California State Board of Pharmacy

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

Date: November 28, 2009

To: Enforcement Committee

Subject: Federal Proposal to Reclassify Carisoprodol

Agenda Item 2

Very recently, the federal Drug Enforcement Administration released proposed rules to reclassify carisoprodol to federal Schedule IV. Currently this drug is not scheduled either at the federal or state level.

Written comments on this reclassification are due by December 17, 2009.

Board supervising inspectors strongly support this reclassification. When investigating drug diversion and misuse of drugs, carisoprodol (or Soma) is a frequently misused and diverted drug. Patients often purchase such drugs from Web sites without legitimate prescriptions. In fact a recent citation and fine issued to a California pharmacy that was dispensing drugs to California patients involved carisoprodol in 52 percent of the more than 3,000 prescriptions identified by the board sent to California purchasers.

A copy of the federal notice follows this page.

Staff recommends that the board submit comments to the DEA in support of reclassifying carisoprodol into federal Schedule IV.

Breaking News!

DEA Issues Proposed Rules on Carisoprodol

The Drug Enforcement Administration today published the attached Notice of Proposed Rulemaking (NPRM) in the Federal Register to place Carisoprodol into Schedule IV.

This proposed rule is issued to place the substance carisoprodol into schedule IV of the Controlled Substances Act based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services and on an evaluation of relevant data by DEA. Written comments must be postmarked and electronic comments must be submitted on or before December 17, 2009.

<http://edocket.access.gpo.gov/2009/E9-27583.htm>



[Federal Register: November 17, 2009 (Volume 74, Number 220)]
[Proposed Rules]
[Page 59108-59112]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr17no09-16]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-333P]

Schedules of Controlled Substances: Placement of Carisoprodol
Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized, this action would impose the regulatory controls and criminal sanction of schedule IV on those who handle carisoprodol and products containin carisoprodol.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before December 17, 2009. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Standard Time (EST) on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ``Docket No. DEA-333'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

Comments may be sent to DEA by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this

[[Page 59109]]

document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight EST on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight EST on the day the comment period closes. Commenters in time zones other than EST may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Comments and Requests for Hearing: In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested person and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," may request a hearing. 21 CFR 1308.42. Please note that DEA may grant a hearing only "for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment, or repeal of a rule issuable" pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter should be submitted to the DEA using the address information provided above.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.)

voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ``PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ``CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the FOR FURTHER INFORMATION CONTACT paragraph.

Background

Carisoprodol is a centrally acting muscle relaxant and is indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions. Carisoprodol has been available since 1959 as a prescription drug in the United States under the trade name Soma[supreg]. It is also marketed as generic products. Carisoprodol is similar to a variety of central nervous system (CNS) depressants, including meprobamate (C-IV) and chlordiazepoxide (C-IV). The actual abuse data from several databases demonstrate that carisoprodol is abused in the United States. Because of growing concerns about abuse of carisoprodol, a number of states have regulated carisoprodol under their controlled substance regulations, and a number of additional states are currently considering such regulation.

Because of the evidence relating to diversion, abuse, and trafficking of carisoprodol, in March 1996, the DEA requested from the DHHS a scientific and medical evaluation and a scheduling recommendation for carisoprodol, in accordance with 21 U.S.C. 811(b).

In February 1997, the U.S. Food and Drug Administration (FDA) Drug Abuse Advisory Committee (DAAC) deliberated upon the abuse and scheduling issues and concluded that the data were insufficient to control carisoprodol under the CSA at that time. Since the FDA DAAC meeting, pharmacological studies addressing the abuse liability of carisoprodol have been conducted under the direction of the National

Institute on Drug Abuse (NIDA) and the College on Problems of Drug Dependence (CPDD). DEA acquired new carisoprodol-related data on actual abuse, law enforcement encounters and other information and sent this supplementary information to DHHS on November 14, 2005. FDA acquired new data from the Drug Abuse Warning Network (DAWN), National Survey of Drug Use and Health (NSDUH), Florida Medical Examiners Commission reports, FDA's Adverse Event Reporting System (AERS) and information from the published scientific literature and conducted a scientific and medical evaluation. These data collectively indicate that carisoprodol has abuse potential and is being diverted, trafficked, with increasing frequency and magnitude.

Carisoprodol abuse has been associated with increasing numbers of emergency department (ED) visits in recent years as indicated by DAWN. The "abuse frequency," calculated as ED visits per 10,000 prescriptions, of carisoprodol (frequency range during 2002-2007: 15.1 to 22.6 visits/10,000 prescriptions) is similar to that of a schedule IV drug, diazepam (frequency range during 2002-2007: 12.5 to 14.1 visits/10,000 prescriptions). Carisoprodol is used as either the sole drug or in combination with other substances such as opioids, benzodiazepine, alcohol, marijuana, and cocaine. Data from the AERS database show that carisoprodol is associated with adverse health events including dependence and withdrawal syndrome.

The data from National Poison Data System of the American Association of Poison Control Centers documented 8,821 carisoprodol toxic exposure cases including 3,605 cases in which it was

[[Page 59110]]

the sole drug mentioned in 2007. Medical Examiners Commission Reports released by the Florida Department of Law Enforcement (FDLE) indicate that carisoprodol/meprobamate related deaths in Florida increased by 100 percent from 208 deaths in 2003 to 415 deaths in 2008.

The National Forensic Laboratory Information System (NFLIS), a DEA system that tracks analyzed drug exhibits submitted by the federal, state, and local law enforcement, documented evidence of substantial diversion of carisoprodol. For example, law enforcement submitted a total of 3,873 carisoprodol drug items to participating forensic laboratories in 2008. NFLIS consistently listed carisoprodol in the top 25 most frequently identified drugs since 2000. The 2007 NSDUH data show that 2.7 million individuals used Soma[supreg] in their lifetime (i.e., ever used) for a non-medical purpose.

The data from in vitro electrophysiological studies using the whole-cell patch clamp technique demonstrate that carisoprodol elicits barbiturate-like effects. Intravenous drug self-administration studies in rhesus monkeys show that carisoprodol has positive reinforcing effects. Meprobamate, pentobarbital, and chlordiazepoxide substitute fully for the discriminative stimulus effects of carisoprodol in rats. Bemegride, a barbiturate antagonist, antagonizes the discriminative stimulus effects of carisoprodol.

Data from an animal study indicates that carisoprodol has

dependence liability similar to barbital (schedule IV), a central nervous system depressant. Carisoprodol administered orally fully prevented the appearance of abstinence phenomena in dogs tolerant and dependent on barbital. Several published reports document evidence of tolerance and dependence to carisoprodol and indicate the occurrence of abstinence symptoms during carisoprodol withdrawal in humans.

On October 6, 2009, the Acting Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that carisoprodol be placed into schedule IV of the CSA. Enclosed with the October 6, 2009, letter was document prepared by the FDA entitled, "Basis for the Recommendation for Control of Carisoprodol in Schedule IV of the Controlled Substance Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)). The factors considered by the Assistant Secretary of Health and DEA 21 U.S.C. 811(c) with respect to carisoprodol were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Based on the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

1. Carisoprodol has a low potential for abuse relative to the drug or other substances in Schedule III. Animal studies indicate that carisoprodol is similar to schedule IV drugs such as meprobamate and chlordiazepoxide in its central nervous system depressant effects. The documented data on law enforcement encounters and actual abuse of carisoprodol demonstrate that it has a potential for abuse and is being diverted and abused. Since 2000, DEA's NFLIS database consistently mentioned carisoprodol in the top 25 drugs that were most frequently identified by state and local forensic laboratories thereby indicating that carisoprodol is being diverted. Emergency department visits data from DAWN indicate that abuse frequency of carisoprodol is similar to that of diazepam, a schedule IV drug. Recent data from DAWN medical examiner reports and emergency department visits showed an increase in carisoprodol abuse.

2. Carisoprodol has a currently accepted medical use in treatment in the United States. Carisoprodol is an FDA approved drug and is used for the relief of discomfort associated with acute, painful musculoskeletal conditions.

3. Abuse of carisoprodol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in

schedule III. Carisoprodol, similar to barbital (schedule IV), prevent the abstinence syndrome in drug withdrawn barbital-dependent dogs. Published reports indicate that carisoprodol causes psychological or physical dependence and withdrawal syndrome.

Based on these findings, the Deputy Administrator of DEA concludes that carisoprodol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b)(4))

References to the above studies and data may be found in the Health and Human Services scheduling recommendation and DEA's independent analysis, both of which are available on the electronic docket associated with this rulemaking.

Requirements for Handling Carisoprodol

If this rule is finalized as proposed, carisoprodol would be subject to CSA regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, and exporting of a schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with carisoprodol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with carisoprodol, would need to be registered to conduct such activities in accordance with 21 CFR part 1301.

Security. Carisoprodol would be subject to schedules III-V security requirements and would need to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of carisoprodol which are distributed on or after finalization of this rule would need to comply with requirements of 21 CFR 1302.03-1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of carisoprodol would be required to keep an inventory of all stocks of carisoprodol on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304.11. Every registrant who desires registration in schedule IV for carisoprodol would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21

[[Page 59111]]

CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for carisoprodol or prescriptions

for products containing carisoprodol would be required to be issued pursuant to 21 CFR 1306.03-1306.06 and 1306.21, 1306.22-1306.27.

Importation and Exportation. All importation and exportation of carisoprodol would need to be in compliance with 21 CFR part 1312.

Criminal Liability. Any activity with carisoprodol not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after finalization of this proposed rule would be unlawful.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

In considering the impact on small entities, the first question is whether a substantial number of small entities are affected. In this instance, the entities affected are those now selling carisoprodol-containing products without registration. DEA has identified 22 firms manufacturing carisoprodol-containing products in 2009.\1\ Fifteen of these firms have existing DEA registrations. This leaves seven firms from this data set selling carisoprodol without registration. DEA has no information on the number of non-registrants distributing or importing carisoprodol, but there is every reason to believe that the number of such firms is well in excess of the seven already identified. The Small Business Administration size standard for a small wholesaler of drugs is 100 employees. It is clearly possible to operate a drug distributing firm with fewer than 100 employees. There can be no question that a substantial number of small entities will be affected by this rule.

\1\ IMS Health National Prescription Audit (NPA).

The impact on non-registrants now selling carisoprodol will occur in two forms: the cost of registration and the cost of meeting the security requirements in 21 CFR part 1301. There is also a potential

impact on firms not now selling carisoprodol who might have wished to enter the market.

The annual registration fee for a distributor, importer, or exporter is \$1,147. There is some uncertainty in estimating the cost of meeting the security requirements, because most nonregistrants already meet the security requirements, at least in part, for schedule III and IV substances. To be conservative, it is assumed that every nonregistrant will have to buy a safe to store carisoprodol. A safe with capacity of 13.5 cubic feet should be adequate. A safe of this size may be purchased for \$1,350. Annualized over 15 years at 7.0 percent, that is \$148 per year. Total annual cost of compliance with the rule, then, is \$1,295. The usual standard for a significant economic impact is 1.0 percent of revenue. For \$1,295 per year to be a significant economic impact, annual revenue of a firm would have to be under \$130,000. Any firm in the business of distributing drugs needs annual revenue well in excess of that amount to sustain itself.

\2\ NationwideSafes.com <http://www.nationwidesafes.com/capacity-more-than-4pt0-cu-ft.html>.

It should be acknowledged that, for a small firm, there may be some inconvenience and expense in preparing necessary forms for registration and registration renewal. These are minor costs. There are also recordkeeping requirements, but these impose little or no incremental cost for a firm that is already maintaining records needed for a wholesale business. The costs of registration and security requirement will not be a significant economic impact.

If a firm chose not to register and to drop its carisoprodol line, the cost to the firm would exceed its earnings on the carisoprodol sales. The firm might also lose some customers who do not want to buy from a vendor without carisoprodol in its product line. A competent manager will recognize this cost. In light of the very small cost of registering, he would presumably choose to drop carisoprodol from the firm's products only if the firm were earning a negligible profit from that line and he judged that dropping it would not turn away significant customers. In light of the foregoing analysis, DEA finds that this rule will not have a significant economic impact on a substantial number of small entities. DEA has no information regarding the number of persons who may distribute carisoprodol-containing products, but do not manufacture, package, repackage, or relabel those products. Therefore, DEA seeks comment on any entities that might be affected by this control action.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator

[[Page 59112]]

hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308--SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating paragraphs (c) (5) through (c) (52) as paragraphs (c) (6) through (c) (53) and adding a new paragraph (c) (5) to read as follows:

Sec. 1308.14 Schedule IV.

* * * * *
(c) * * *

(5) Carisoprodol..... 81

* * * * *

Dated: November 10, 2009.
Michele M. Leonhart,
Deputy Administrator.
[FR Doc. E9-27583 Filed 11-16-09; 8:45 am]

BILLING CODE 4410-09-P



California State Board of Pharmacy

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

Date: November 28, 2009

To: Enforcement Committee

**Subject: Proposal to Reduce the Volume of Drug Waste
From Pharmacies**

Agenda Item 3

At this meeting, the Enforcement Committee will hear a presentation by Anand Shukla on a proposal he believes will reduce the amount of outdated prescription drugs that occur annually in pharmacies by monitoring non-moving, slow moving, overstock and unwanted drugs within the inventories of participating pharmacies. His proposal is to better manage by a central coordinating firm so that these drugs do not become waste due to distribution problems among pharmacies.

A brief summary of his proposal follows this page.

GREENRx

ELIMINATING THE GENERATION OF EXPIRED DRUGS



Date: 09/02/2009

Prepared By: Anand Shukla

Introduction:

Mr. Anand Shukla is the founder and the sole proprietor of GREENRX (DBA). **GreenRx** is dedicated to bringing a more enlightened approach using technology to manage the flow of drugs by making pharmacies less wasteful, reducing the cost of medicines and thus making healthcare more affordable for Americans.

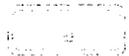
About the Founder:

Mr. Anand Shukla earned his Diploma and Bachelors degree in Pharmacy from India. He earned his MS degree in Pharmacy from the Long Island University, NY. Mr. Anand Shukla is been working in the healthcare industry since year 1997.

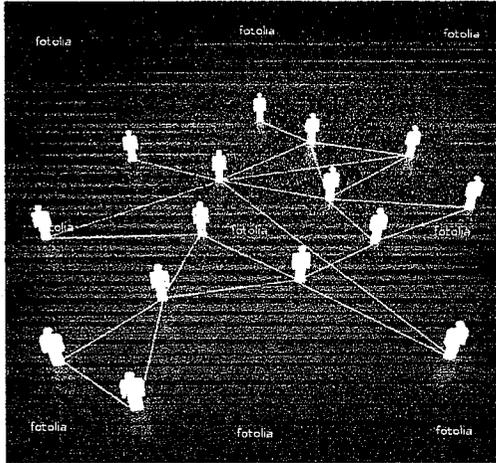
Current challenges:

A vast array of pharmaceuticals - including antibiotics, anti-convulsants, mood stabilizers and sex hormones - have been found in the drinking water supplies of at least 41 million Americans. Reducing expired medication waste is now a major societal concern that can significantly reduce the adverse effects of the toxic chemicals on millions of Americans and can significantly reduce the healthcare costs for the state.

P.O.Box 115
Hayward, CA 94557
(510) 461-0110 (Direct)



GREENRX solution (Uniting Pharmacies, Eliminating the generation of expired drug by Resale/Redistribution):



- Using technology to manage the pharmacy inventory
- Supply-demand logarithm identifies unused meds
- “E-bay” type model allows resale/redistribution of meds
- Inter pharmacy transfer of drugs before it reach expiration date

Greenrx is taking pharmacy inventory management outside the pharmacy.

Greenrx offers an on-line Windows based inventory database. GREENRx database tracks the movement of drugs and identifies non-moving, slow-moving, over stock and unwanted drugs within the inventories of participating pharmacies. These drugs are then resold and redistributed amongst Greenrx network pharmacies via a secure on-line database (similar to e-bay model). Greenrx provides an information technology platform and logistics for inter pharmacy drug transfers but does not take the possession of the drug.

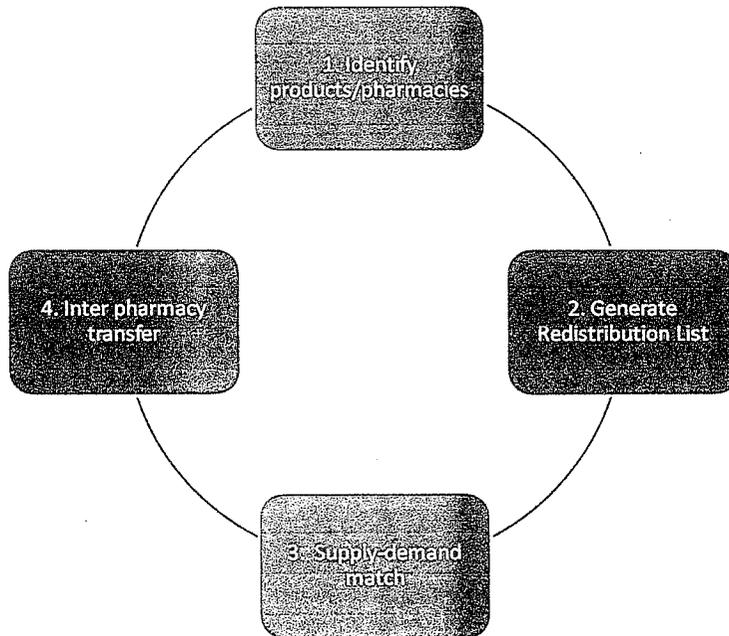
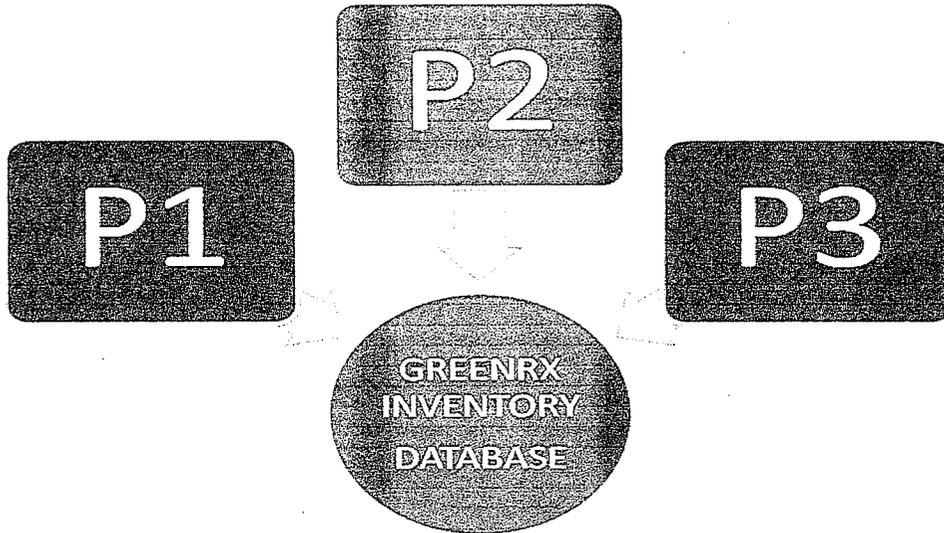
Services offered:

- **On-line Pharmacy Inventory**
 - o Perpetual inventory services: provide visibility and accountability, increase control, allow for informed decision-making and ordering, facilitate daily tracking
- **Expiry Drug Reduction Services**
 - o Expired drugs reduction/elimination (prevention) services: reduce manpower management, increase productivity, reduce loss, protect environment from toxic waste of expired or unwanted drugs
- **Inter Pharmacy Transfer Assistance**
 - o Re-sale and redistribute of over stock drugs: prevent losses due to non-returnable items, avoid stocking hard to sale drugs, reduce high inventory cost

Process:

- Step 1: Maintain on-line pharmacy perpetual inventory
- Step 2: Automatically identify over-stock, non-moving, slow moving and unwanted meds from the network pharmacies
- Step 3: Generate redistribution list: products for resale/redistribution.
- Step 4: Supply-demand match between network pharmacies (on-line)
- Step 5: Act as a broker for the inter pharmacy transfer (e-bay of unused/overstock drugs)
- Step 6: Charge client subscription fees and commission on inter pharmacy

GREENRx



Case Study:

Pharmacy 1: Location, 123 Greenland Street, Berkeley, CA. Purchased Geodon 40 mg, 60 tablets, NDC # 00049397060 for \$369.329 on January 1st, 2008. Pharmacy immediately dispenses 30 tablets to one patient. Pharmacy still has 30 pills remaining on a shelf and never sees another patient with similar needs. This drug is expiring in December 2009. This drug is non returnable and will expire if not used. In September 2009, Greenrx on-line database identify this drug idle on a shelf and notifies the pharmacist. Pharmacist immediately puts this drug for resale on Greenrx web-site. Through supply-demand logarithm match and verbal communication with other network pharmacies, Greenrx immediately find a match for this drug, negotiates the price and assist the inter pharmacy transfer.

Greenrx web-site advertisement

Following drug is available for transfer:

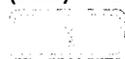
Geodon 40 mg Tablets
NDC # 00049397060
Quantity available: 30 tablets (Open bottle)
Asking price: \$184.66 (no shipping fees)
Available: Shipped or deliver within 24 hours
Shipping from: Berkeley, CA
Contact Greenrx for further details



We believe this model would allow transfers of prescription medications under B&P Code §4126.5(a)(4), (a)(5) or, in some cases (a)(7):

4126.5 Furnishing Dangerous Drugs by Pharmacy

- (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
 - (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
 - (3) A licensed wholesaler acting as a reverse distributor.
 - (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
 - (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
 - (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
 - (7) To another pharmacy under common control.





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

Date: November 28, 2009

To: Enforcement Committee

Subject: Update on California Drug "Take Back" Programs from Patients

Agenda Item 4

The next issue of the *The Script* will promote the California Integrated Waste Management Board's guidelines for model programs for the "take back" or return of unwanted prescription drugs from patients. The article will advise that the board expects pharmacies to use these guidelines if they participate in taking back drugs from patients. (The newsletter issue is undergoing legal review and will be released shortly.)

The board is aware that a number of communities are establishing collection programs for unwanted prescription drugs, which under California law are considered hazardous household waste. However, unlike used motor oil or plastic shopping bags, aggregations of prescription drugs have value. Few of these programs comply with the CIWMB guidelines and many also violate the federal Drug Enforcement Administration's requirements for the appropriate take back of controlled substances.

President Ken Schell, Executive Officer Herold and Supervising Inspector Judi Nurse recently attended a conference convened by the CIWMB on various recycling and disposal issues surrounding California. Representatives from various waste collection, recycling and disposal programs from most California cities and counties attended. The board's purpose in attending this conference was to emphasize support for the CIWMB's guidelines.

Recently the board's executive officer met with staff from Sharps, Inc. This is the firm that provided a presentation on mail back options at the July 2009 Board Meeting. They left Executive Officer Herold with a modified mail-back box that incorporates many of the suggestions made during the July Board Meeting.

The board also received statistics about the costs per pound of mail back. On the next page is a summary of two:

In July 2009 from Maine:

Number of envelopes received at the incinerator (7/17/09)	3,374
Total weight (pounds)	1,560
Average weight per envelope (pounds)	0.4624
Cost (\$3.49/envelope)	\$11,775
Price/weight (pounds)	\$7.55

San Francisco recently provided the board's executive officer with data from a San Francisco mail-back program (through November 9, 2009).

Number of envelopes distributed (before 11/09)	1,443
Number of envelopes returned to incinerator (11/09)	558 (38.7%)
Total weight (pounds)	417.4
Average weight per envelope (pounds)	0.7480
Cost	\$1,947.42
Price/weight (pounds)	\$4.67

San Francisco Household Hazardous Waste Collection Facility's manager is unable to explain the relatively low rate of return. Another factor perhaps influencing the low weight returned per envelope may be due to the instructions, which state that the original container be included in the envelope, which takes a lot of space.

Several recent articles on "collection programs" that do not follow the CIWMB's guidelines follow this memorandum.

After publication and release of the board's newsletter promoting the guidelines, the board's inspectors will begin discussing appropriate components for take back programs with pharmacies during inspections.

Drop your legal, illegal drugs; don't flush them

By CHARLES F. BOSTWICK
Valley Press Managing Editor

LANCASTER — People can get rid of drugs and needles — legal or illegal — at white mailbox-like containers just installed in front of the Lancaster and Palmdale sheriff's stations.

"Safe Drug Drop-Off" boxes were first installed in September at the Lomita Sheriff's Station, where officials said the boxes were intended to let residents safely and anonymously drop off expired or unused prescriptions, over-the-counter medications, syringes and illegal narcotics.

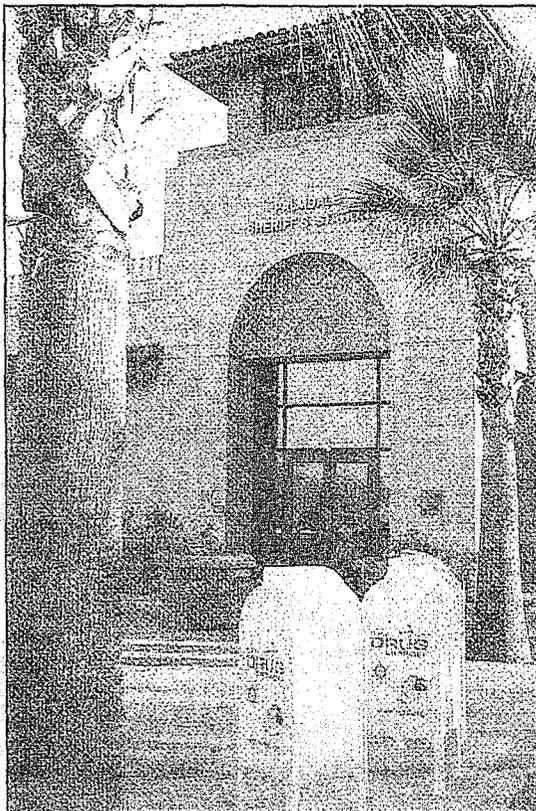
"It's no questions asked," said Deputy Robbie Royster, a spokesman for the Palmdale Sheriff's Station.

Flushing medicines down the drain can harm fish and other wildlife, since the drugs end up in rivers and oceans, or they can soak into the underground water table that supplies wells, officials said. Keeping unused and out-of-date medications in bathroom cabinets means children can get hold of them, or they otherwise could fall into the wrong hands for illegal and unintended uses, sheriff's officials said.

In front of each station are three white boxes, each labeled "Safe Drug Drop-Off." One is for hypodermic needles, one for prescription drugs and one for illegal drugs.

"This is a great program that not only helps reduce the amount of illegal or unwanted drugs in our community, it also helps the environment by keeping the substances out of our groundwater," Lancaster Sheriff's Station commander Capt. Axel Anderson said in the station's announcement.

"This is just another tactic Palmdale Station is using in an overall approach to keep these harmful items off of our streets and out of our children's hands," Palmdale Sheriff's Station commander Capt. Bobby Denham said.



DUMP DRUGS

These "Safe Drug Drop-Off" boxes have been installed in front of the Lancaster and Palmdale Sheriff's Stations. Legal and illegal drugs, as well as hypodermic syringes, can be dropped off at the boxes, without any questions asked. Los Angeles County Sheriff's Department photos



Karen
Abbe/Pharmacy/DCANotes
11/24/2009 10:49 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes, Carolyn
Klein/Pharmacy/DCANotes@DCANotes
bcc
Subject San Diego Union-Tribune: Psychiatrist in drug probe gives
up license

<http://www.signonsandiego.com/news/2009/nov/23/el-cajon-psychiatrist-surrenders-medical-license>

Psychiatrist in drug probe gives up license

By Keith Darcé

San Diego Union-Tribune

Originally published November 23, 2009 at 6:02 p.m., updated November 24, 2009 at midnight

EL CAJON — An El Cajon psychiatrist has surrendered his medical license to California authorities after investigators said he collected unused prescription drugs, including addictive pain pills, from some patients and handed them out to others.

Dr. Wayne A. Funk, 87, gave up his license last week, a spokeswoman for the Medical Board of California said Monday. He graduated from the University of Kansas School of Medicine in 1947 and was licensed to practice in California in 1954, according to medical board records.

Funk, who says he was the first psychiatrist to set up practice in East County, said Monday that he was trying to help his patients who were poor and couldn't afford full-priced medications.

"It's painful to go out with a cloud over your head, but I know what I've done. I had a great practice," he said.

When federal drug enforcement agents inspected Funk's office at 2606 Fletcher Parkway on Jan. 15, 2008, they found recycled oxycodone, diazepam, lorazepam and temazepam, according to a medical board complaint against the physician. The drugs are typically prescribed to treat pain, anxiety and insomnia.

At that time, the medical board already had opened its own investigation of Funk after receiving a complaint from another doctor who was treating a patient for addiction to Xanax. Funk had raised suspicion by prescribing large quantities of the anxiety drug to the patient.

Xanax is a powerful sedative and a popular recreational drug.

Over a two-month period in fall 2007, Funk signed off on 880 Xanax pills for the patient, according to a California Department of Justice database system that tracks prescriptions of controlled substances.

Investigators said Funk committed gross negligence by excessively prescribing drugs and prescribing

them without appropriately examining patients or establishing a medical need for the treatments.

Funk told investigators that he recycled old drugs to make them more affordable to other patients. Old bottles were kept in a basket on a counter and inside a drawer.

Funk's attorney, Robert Frank, said his client paid a price for habits that long ago became outdated because of changes in regulations and professional standards.

"It became a regulatory morass for him to catch up to and practice within," Frank said. "This isn't a guy who made a bunch of money and preyed on people."

Funk chose to surrender his license and retire rather than fight the charges in a hearing before the medical board.

"Patients will often give (their medication) away or sell it," Funk said. "These are the things that the medical board is really gung-ho about. I recognize that time and the tide catches up with an old man."

The board last year disciplined 28 doctors for inappropriately prescribing drugs, representing about 10 percent of the agency's successful cases, board spokeswoman Candis Cohen said.

Funk closed his practice on June 30. "I'm a golfer," he said. "I'm very active in my church, and I'll get on with my honey-do list at home."

Keith Darce: (619) 293-1020 or keith.darce@uniontrib.com



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

Date: November 28, 2009

To: Enforcement Committee

Subject: Consideration of Best Practices on How to Use CURES Data as Part of Drug Utilization Review

Agenda Item 5

In August, the California Department of Justice unveiled a new program allowing Internet access to prescribers and pharmacies for data regarding patients who had been dispensed controlled substances in Schedules II-IV as recently as three weeks in the past.

In California all drugs dispensed to patients by pharmacies or prescribers must be reported electronically to the Controlled Substances Utilization and Review System (CURES) each week. This is the data that is now accessible to prescribers and pharmacies via the Internet. The implementation of this feature is a major step forward in assuring that patients who are doctor shoppers are not able to obtain drugs from pharmacies or prescribers by going to multiple prescribers and pharmacies.

At the January 2010 Board Meeting, the Department of Justice will present a demonstration of the new system. In preparation for this meeting, on the following pages is a description of an article concerning a possible need for pharmacies to check the prescription monitoring programs operating in their state (such as CURES) before dispensing controlled drugs.

Currently the board requires pharmacists to use corresponding responsibility. Following this page is an article from the July 2001 *The Script* that discusses corresponding responsibility.

Karen
Abbe/Pharmacy/DCANotes
11/05/2009 10:14 AM

To Virginia Herold/Pharmacy/DCANotes@DCANotes
cc Anne Sodergren/Pharmacy/DCANotes@DCANotes, Carolyn
Klein/Pharmacy/DCANotes@DCANotes
bcc
Subject Wall Street Journal: Case Spurs Pharmacies' Fears of
Lawsuits Over Drug Abuse

THE WALL STREET JOURNAL.

WSJ.com

CASE SPURS PHARMACIES' FEARS OF LAWSUITS OVER DRUG ABUSE

By Amy Merrick
Wall Street Journal
October 29, 2009

When Patricia Copenig, a petite, 35-year-old doctor's office receptionist, bought nearly 4,500 doses of prescription painkillers one year, alarm bells sounded at the Nevada controlled-substance task force. The state board sent letters to 14 pharmacies in the Las Vegas area warning that Ms. Copenig could be abusing drugs.

On the afternoon of June 4, 2004 -- a year after the letters were sent -- Ms. Copenig climbed into a gray Dodge Durango, veered onto U.S. 95 and was seen weaving erratically in and out of three-lane traffic, witnesses later said. She plowed into 21-year-old Gregory Sanchez Jr., a delivery-van driver who had pulled over to repair a flat tire on the highway's shoulder, killing him at the scene. She also hit Robert Martinez, 33, who had been helping Mr. Sanchez move packages out of his van. Mr. Martinez suffered a head injury, a broken right leg and other wounds. Ms. Copenig wasn't injured.



Pill bottles from Lam's Pharmacy in Las Vegas were found in a customer's car after a fatal car accident.

A lawsuit filed by Mr. Martinez, his family and Mr. Sanchez's family, now pending before the Nevada Supreme Court, may be the first U.S. case to address whether pharmacies can be held liable when a customer causes a fatal car accident. The case, Sanchez vs. Wal-Mart Stores et al, asks whether drugstores must use information at their disposal to protect the public from potentially dangerous customers.

The Nevada case is part of a broader movement under way to place more responsibility for patients' prescription-drug use on pharmacies.

Abuse of prescription drugs has risen dramatically over the past two decades, along with a surge in the number of controlled-substance prescriptions being written.

In 2007, U.S. retail pharmacies dispensed nearly 180 million prescriptions for opiates, such as hydrocodone and oxycodone, up from about 40 million in 1991, according to congressional testimony last year from the National Institute on Drug Abuse.

At the same time, pharmacists have much more patient information at their disposal, thanks to pharmacy computer systems and a proliferation of state online prescription-tracking databases. The availability of patient information is only expected to increase as electronic health records are adopted by more and more doctors.

As a result, consumers, government officials and pharmacies themselves are increasingly asking what a pharmacy is legally and ethically obligated to do with this newly available information.

This week, the National Association of Boards of Pharmacy is convening a task force to discuss pharmacies' roles in prescription-tracking programs. Separately, the association is considering whether to develop new guidelines about pharmacists' responsibilities to the general public. The issue "is not even an area we'd thought about until recently," says Carmen Catizone, executive director of the group.

Prescription-tracking systems are operating in 33 states, with the goal of identifying potential addicts and referring them for treatment, or getting law enforcement involved if necessary. Most have been set up since 2002. Last month, California launched the largest such database, covering 7,500 pharmacies and 158,000 prescribers.

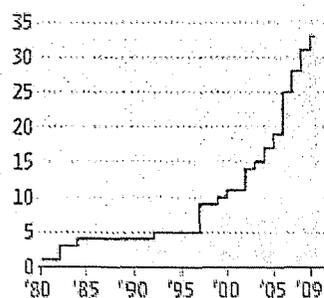
With such programs, "there's certified information coming across, and that's where pharmacies are struggling" to know exactly how to respond, Mr. Catizone says. Earlier this year, the association passed a nonbinding resolution urging pharmacists to help reduce the excessive use of controlled substances by their customers.

The pharmacy industry -- which includes big chains such as Wal-Mart Stores Inc., CVS Caremark Corp. and Walgreen Co., all parties in the Nevada case -- acknowledges the growing public pressure to curb prescription-drug abuse. At a recent conference of the National Association of Chain Drug Stores, conference materials called preventing prescription-drug abuse "the new focus in the war on drugs." It noted that "public and private initiatives are looking to the entire supply chain, including retail pharmacy, to be part of the solution."

The drugstore chains contacted for this story declined to comment on the issue. The National Association of Chain Drug Stores also declined comment.

Rising Record

Number of states collecting data under prescription-drug monitoring programs



Note: Washington suspended data collection in September 2008
Source: Drug Enforcement Administration

The chains are watching the Nevada case closely. Legally, it's one thing for a pharmacy to be held liable for hurting an individual customer by, say, filling a prescription with the wrong drug. But drugstores worry Sanchez could open them to broader and more ambiguous responsibility with significant consequences to the industry.

Some predict higher insurance costs and more expensive prescriptions, to absorb the costs of additional lawsuits. In court filings, Wal-Mart argued that pharmacies might decide not to stock certain regulated painkillers. Walgreen suggested that the judgment of pharmacists could be pitted against that of doctors, as pharmacists struggle to decide whether to refuse a prescription.

Michael Wall and L. Kristopher Rath, attorneys for Longs Drug, now owned by CVS Caremark, predicted a "tsunami of litigation" if the families prevail. Drugstores could be sued by their own customers if pharmacists refuse to fill valid prescriptions and customers are harmed, they said. Drugstores could also be sued by those who claim to be injured by a customer who purchased prescription drugs.

In their defense, the drugstore chains argue that they face a dilemma similar to that faced by bartenders in some states. Bartenders can be held liable for the acts of customers served too much alcohol. Similarly, doctors have been successfully sued by car-crash victims for failing to warn patients not to drive under the influence of certain medications.

Nevada was one of the first states to systematically share prescription information among doctors, pharmacists and law-enforcement officials when it set up a computer database to track potential drug abuse in 1997.

Under Nevada law, pharmacies must report their patients' controlled-substance prescription records each month. Staff members of the state's Prescription Controlled Substance Abuse Prevention Task Force filter that data for warning signs of abuse, such as purchasing drugs from multiple pharmacies. If a customer sets off enough red flags, the task force sends a form letter to the pharmacies the patient has visited.

"The focus of the task force is to get people into treatment and help them," says Larry Pinson, executive director of the state pharmacy board. "The primary option is for the pharmacist to speak with the patient."

But the law creating the task-force database isn't explicit about what pharmacies should do with the letters, he says.

Tracking Drug Use

Status of state prescription-drug monitoring programs

■ Program in place ■ Legislation enacted, not yet operational ■ No program



In June 2003, the task force sent letters to the 14 pharmacies in the Las Vegas area, including Wal-Mart,

Walgreen, CVS and others, warning them that Ms. Copenig had purchased during the prior year 60 prescriptions, or nearly 4,500 doses, of controlled substances. Most were for medications containing hydrocodone, a frequently abused narcotic.

"It is not the Task Force's intent to determine how you dispense prescriptions," the letter said. "Well-informed pharmacists can and will use their professional expertise to assist patients who may be abusing controlled substances."

In Ms. Copenig's case, there's no documentation of any pharmacist making a note in her customer records about the task-force letter, counseling her about drug addiction or refusing to give her prescriptions. She continued to buy large quantities of hydrocodone, as well as Soma, a muscle relaxant, from numerous pharmacies, according to her prescription records, which are part of the lawsuit. The combination of the two drugs, which is said to produce a euphoria similar to that induced by heroin, is known locally as the "Las Vegas cocktail."

That June afternoon in 2004, Ms. Copenig left the Las Vegas OB-GYN clinic where she worked as a receptionist. She drove a Durango owned by her employer, Richard M. Groom.

Witnesses reported later that Ms. Copenig was driving haphazardly, jerking her steering wheel from side to side. She appeared to be either laughing to herself or having a seizure.

Around the same time, Mr. Sanchez got a flat tire. He pulled his silver Airborne Express van onto the shoulder of U.S. 95 and sent a text message to a dispatcher: "Yo my tire blew."

Mr. Martinez, his co-worker, parked his own van behind Mr. Sanchez's vehicle, and the two men started moving freight out of the disabled vehicle. Ms. Copenig swerved off the road and hit them both. Mr. Sanchez died at the scene. The coroner discovered tire tracks across his lower back. Mr. Martinez suffered multiple injuries and was taken to the hospital.

In Ms. Copenig's car, police found prescription bottles and loose pills, 167 in total, of hydrocodone, Soma and other drugs. Police reports said Ms. Copenig appeared confused. She took off her low-heeled sandals and tried to walk barefoot in a straight line, following a patrol officer's directions, but struggled to keep her balance. When police asked, she couldn't remember the name of one of her two children.

She claimed she had taken only medicine for a migraine headache that day; a blood test detected hydrocodone. She was charged with reckless driving, driving while intoxicated and being involved in a fatal accident.

Ms. Copenig pleaded guilty to two counts of reckless driving and served nine months in jail. Through a spokeswoman, she and her attorney declined to comment. The state revoked the license of Dr. Groom's business partner, Doyle S. Steele, the doctor who wrote most of Ms. Copenig's prescriptions. A few months after the accident, the Sanchez and Martinez families sued Ms. Copenig and the doctors.

After the task-force records came to light in pretrial discovery, lawyers for Messrs. Sanchez and Martinez added seven pharmacy-chain owners -- including Wal-Mart, Walgreen, CVS Caremark and Rite Aid Corp. -- and one independent drugstore as defendants.

Individual pharmacists have been successfully prosecuted for knowingly filling controlled-substance prescriptions that weren't issued for legitimate medical needs. In guidelines to pharmacists, the federal Drug Enforcement Administration says: "The pharmacist who deliberately looks the other way when there is reason to believe that the purported prescription had not been issued for a legitimate medical purpose, may be prosecuted...." Pharmacies have said that the guidelines leave open questions about what practices are unacceptable.

In general, courts have found that doctors owe greater duties to patients when issuing prescriptions than pharmacists do when filling them.

But recent court decisions have expanded pharmacists' responsibility. In 1994, the Indiana Supreme Court ruled in *Hooks SuperRx Inc. vs. McLaughlin* that a pharmacy had a duty to stop dispensing painkillers to a patient who was refilling a prescription faster than normally would be appropriate.

In the Nevada case, Clark County district court Judge Douglas W. Herndon dismissed the pharmacies from the suit, noting that the Nevada law creating the task force doesn't specify what action, if any, is required by the pharmacies.

The families appealed to the state Supreme Court, which heard oral arguments in March.

Lawyers for the pharmacies argue that, while drugstores may choose not to sell drugs to a customer, they had no legal obligation to turn away Ms. Copening or to protect the general public from her actions.

In a statement, Walgreen said: "While we're sympathetic to those injured in Ms. Copening's car accident, we agree with the district judge's decision that our pharmacists fulfilled their legal duties." Similarly, Wal-Mart said, "This is a deep personal tragedy for the families involved." Because the court hasn't issued its decision, "we don't believe it's appropriate to say more at this time," the company said.

CVS Caremark, Rite Aid and Albertson's Inc., the parent company of Sav-On Drug, all declined to comment on the case. The parent company of Lam's Pharmacy, a Las Vegas drugstore, declined to comment.

Some regulators say that even if the drugstore chains are absolved of any legal responsibility in the Nevada case, their pharmacists still had ethical duties to respond to the task-force report. "That requirement is still there professionally, if not legally," says William Winsley, executive director of the Ohio Board of Pharmacy, which isn't involved in the Nevada case.

The Nevada Supreme Court is expected to issue its opinion by the end of the year.

Write to Amy Merrick at amy.merrick@wsj.com

Printed in The Wall Street Journal, page A18

Physicians and pharmacists have corresponding responsibility when writing and dispensing controlled substance prescriptions

If a physician writes a controlled substance prescription that is not for a legitimate medical purpose, the pharmacist shares a corresponding responsibility or liability with that physician if he or she fills that prescription while knowing or having objective reason to know that the prescription was not issued for a legitimate medical purpose.

A pharmacist's "objective reason to know" includes, but is not limited to, warnings or cautions or other suspicious information from a Board inspector, Board publications, the media, other pharmacy personnel, or personnel of other drug entities. These are all ways of putting a pharmacist on notice to be cautious and to use that information and his or her professional judgment to determine whether a prescription should be filled. The more the pharmacist is already on notice to be cautious, the less additional information or factors would be required to establish that he or she failed to properly consider prescriptions before filling them.

That said, how does a pharmacist evaluate a controlled substance prescription that appears—at least on its face—to have all the elements of a valid prescription? To make it easier to evaluate questionable prescriptions, the Board has developed a set of guideline questions that pharmacists may ask themselves before dispensing. However, it is important to remember that these guidelines do not cover every possibility; nor will every question apply in every case.

Questions Relating to the Patient

- Are you able to verify the true name and identity of the patient?
- Does the patient live within or outside the normal trading areas of the pharmacy? Is the distance so great that it is unlikely the patient would travel so far to fill a legitimate prescription?
- How far is the patient's residence from the prescriber's office?

- What do you know about the drug history of the patient?
- What is the patient's physical appearance and demeanor in relation to the drug being prescribed?
- When a third party picks up the prescription, what is his or her relationship to the patient? What is his or her physical appearance and demeanor?

Questions Relating to the Prescribing Physician

- Is information present in the pharmacy regarding the prescribing patterns of the physician, including the type of drugs, their frequency and volume? If not, is that information readily available to you?
- Of the physician's total prescriptions filled at your pharmacy, does there appear to be an excessive percentage of prescription written for controlled substances and other potentially abusable drugs? Is that information readily available to you?
- What is the nature of the physician's practice, including any recognized area of specialty? Are the drugs prescribed appropriate for that practice or specialty?
- Are you aware of any prior criminal or disciplinary action taken against the prescriber?

Questions Relating to the Therapeutic Appropriateness of the Prescription

- What are the abuse history and current patterns of abuse of the prescribed drug?

- If the patient's diagnosis is known, is the prescribed drug therapeutically appropriate?
- Is the frequency of refills or new prescriptions for the same drug the same as in the directions for use given by the physician?
- How do the length and quantity of the prescribed drug therapy compare to recognized and accepted prescribing practices?
- Is the physician prescribing unusual combinations of drugs or antagonistic or contraindicated drugs?

Regulatory References

Under federal law and regulations (21 United States Code section 841, taken together with 21 Code of Federal Regulations section 1306.04[a]), a pharmacist is criminally liable for knowingly filling prescriptions for controlled substances for other than a legitimate medical purpose. State law, Health & Safety Code section 11153(b) is similar.

For disciplinary liability, the standard is clearly excessive furnishing for other than a legitimate medical purpose (Business & Professions Code section 4301[e], taken together with H&SC section 11153[a]) or dispensing a controlled substance prescription when the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose (Title 16 of the California Code of Regulations section 1761[b]).



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

Date: November 28, 2009

To: Enforcement Committee

Subject: Pharmacies Dispensing Prescriptions for Internet Web Site Operators

Agenda Item 6

In recent months, the board's inspectors have investigated a number of cases where California pharmacies are filling prescriptions from Internet Web sites in situations where patients are in a number of states, a prescriber is writing prescriptions for the patients from a single state, and the California pharmacy is filling the prescription.

Many times these prescriptions are not valid because an appropriate exam by a prescriber has not occurred. California law allows the board to issue citations at \$25,000 per invalid prescription. Over the last 12 months, the board has issued multiple million dollar fines to California pharmacies for filling such false prescriptions. The Drug Enforcement Administration is also involved in some of these Web site investigations and has fined California pharmacies for their participation.

Pharmacies are facilitating the illegal distribution of prescription drugs from the Internet. From discussion with the owners of several of these pharmacies investigated by the board, the pharmacies receive an offer via a faxed notice offering between \$3 and \$6 per prescription plus drug costs to fill these orders. However the economics greatly benefit the Web site operator. The patient may pay more than \$100 to purchase a prescription from the Internet – the pharmacy may get \$6 or \$10 from such a sale.

At the Enforcement Meeting, the executive officer will provide a listing of the huge fines issued in the last year to California pharmacies aiding Internet providers in distributing prescription drugs without a valid prescription.

The *July 2008 The Script* reminded pharmacies not to participate in such scams. A copy of the article is attached.

A copy of California Business and Professions Code section 4067 also follows this page.

California Business and Professions Code

4067. Internet; Dispensing Dangerous Drugs or Devices without Prescription

(a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

Illegal Internet Dispensing: A Letter

During the previous year, information was publicized warning doctors and pharmacists about unsolicited faxed and e-mailed scams that recruit pharmacists to break the law. While appearing to be legal, these scams offered pharmacists higher than usual dispensing fees for participating in Internet dispensing pursuant to prescriptions that were illegal. Unfortunately, some pharmacists have agreed to engage in these activities, resulting in severe fines and disciplinary actions by the Board of Pharmacy.

Such solicitations are continuing in what appears to be in increasing numbers, so it seems appropriate to print the following open letter that was provided by a disciplined pharmacist who learned too late the consequences of filling and mailing illegal Internet prescriptions.

To Fellow Pharmacists:

I want to share with you things that I learned the hard way—the first being that you must live up to your obligation as a licensed professional by keeping yourself informed of the current rules regulating the practice of pharmacy. Next, you also should think very long and hard before you involve yourself or your pharmacy in dispensing Internet-generated prescriptions. The Internet is not panacea when it comes to generating pharmacy income.

The explosion of technology as an integral part of our society has presented pharmacists and pharmacies with the opportunity to fill patient prescriptions that are generated through the use of the Internet. This can seem like an enticing opportunity for increased revenue. It certainly seemed that way to me. I have practiced pharmacy for many years and consider myself to be a capable, conscientious and ethical pharmacist. As with many pharmacists practicing during this challenging time, my idea was to find a steady revenue stream of cash patients for my pharmacy. The Internet seemed like the ideal solution. It was not.

The following are some of the things I thought were true and later learned were not:

Myth 1: I can dispense and ship prescriptions throughout the United States without any restrictions.

Truth 1: Many, if not all, states require that a pharmacy be licensed as an “out-of-state” pharmacy before it may fill and mail prescriptions to residents of that state. Failure to obtain a license or registration in that state can lead to civil penalties and other sanctions. Those sanctions can then lead to disciplinary action by the California State Board of Pharmacy against your California license.

Myth 2: Prescriptions generated via the Internet are legal prescriptions as long as the physician has a current medical license and a valid DEA registration.

Truth 2: A valid medical license and DEA registration are not the only concerns. Business and Professions Code section 4067 requires a “good faith prior examination” by the physician in order to lawfully dispense or furnish dangerous drugs pursuant to a prescription, including those that are generated via the Internet. Further, the California Code of Regulations section 1761, prohibiting a pharmacist from dispensing drugs pursuant to an erroneous or uncertain prescription, also applies to prescriptions generated via the Internet.

Myth 3: The filling of an on-line questionnaire by a patient meets the statutory requirement of a good faith prior examination.

Truth 3: The Board of Pharmacy has taken a very firm position that this is not a good faith prior examination. The Board requires that there be a face-to-face encounter between the patient and prescribing physician, during which an appropriate history is obtained, a legitimate medical purpose is established, and contraindications for the drug are eliminated. This position is consistent with the position taken by the Medical Board of California.

Myth 4: It is OK to fill Internet prescriptions for dangerous drugs or devices, so long as the Internet prescription I fill is for a California-licensed physician, because my pharmacy and I are both licensed in California.

Truth 4: The locations of the physician, pharmacy or pharmacist are not germane to this issue. Effective January 1, 2001, B & P Code section 4067 prohibits the dispensing or furnishing of a dangerous drug or device thru the use of the Internet to a resident of California unless the prescription for that drug or device was issued pursuant to a good faith prior examination. The law authorizes the Board of Pharmacy to assess a fine of up to \$25,000 for each violation, e.g., each prescription filled.

to Pharmacists and Pharmacy Owners

Myth 5: As long as no patient is actually harmed or injured as a result of a prescription I fill, the Board of Pharmacy will just tell me to stop and not impose any fine or sanction.

Truth 5: The Board of Pharmacy has also taken a very firm position that the furnishing or dispensing of a dangerous drug or device pursuant to a prescription generated via the Internet when you knew or reasonably should have known that there was no good faith prior examination by the prescriber, is a serious violation of California law. Just because you were lucky enough not to harm or injure a patient, it does not mean you didn't put the public's health at risk. Accordingly, the Board of Pharmacy will do more than just tell you to stop. It will most probably impose a substantial fine.

Myth 6: If I was unaware that B & P Code section 4067 became effective on January 1, 2001, I cannot be held accountable for prescriptions I filled after that date and no fine can be imposed by the Board of Pharmacy.

Truth 6: Ignorance in this instance is not bliss, nor is it an excuse. It is the pharmacist's responsibility and obligation as a licensed professional to stay current with all new laws and regulations affecting the practice of pharmacy. Although the Board did advise me through its publication, *The Script*, of the existence of section 4067, I did not become familiar with requirements of the law prior to my filling prescriptions via the Internet. That was a big mistake. From my own experience, I can tell you that the Board of Pharmacy and the Legislature are serious about curbing the practice of unlawfully dispensing dangerous drugs or devices through the use of the Internet. The Board ordered me to stop, but it also imposed heavy fines on my pharmacy and me.

In conclusion, believe me when I tell you that I know whereof I speak. I filled Internet-generated prescriptions for California and out-of-state residents for a period of time, and both my pharmacy and pharmacist license were assessed fines by the Board that exceeded \$1,000,000. This did not include my own legal fees. Additionally, I was fined by another state for dispensing dangerous drugs via Internet-generated prescriptions to residents of that state without being licensed there. Therefore, I advise you to look past the potential short-term financial gain, and avoid the long-term mistake that I made.

The laws and regulations that govern our profession help and protect the patients, residents, and consumers of California. We need to take the initiative by making sure that we understand and comply with those laws and regulations.

We are all in this together. I write this "open letter" so that you can benefit from what I learned.

Sincerely,

A Sadder But Wiser Pharmacist

Future mailing of *The Script* will be limited Sign up for online delivery

The first Board of Pharmacy newsletter was published in January 1971, and copies were always sent to each pharmacist and pharmacy and other licensure groups. Because of budget constraints in 2003, the Board of Pharmacy found it could no longer provide the newsletter to pharmacists. Consequently, the Board began to mail newsletters only to pharmacies and wholesalers. The Pharmacy Foundation of California, because of their concern for assuring that the important information contained in the newsletter reached individual pharmacists, printed and mailed copies of *The Script* to all

California pharmacists. Unfortunately, the Foundation can no longer continue to do so.

**The Board of Pharmacy
acknowledges the Pharmacy
Foundation of California and is
grateful for its long and generous
support of the Board and the
profession of pharmacy.**

The Board will continue to mail *The Script* twice per year (January and July) to pharmacies and wholesalers for sharing with their licensed employees. *The Script*

will always be available online, and the Board strongly urges pharmacists and other licensees to download the newsletter from the Board's Web site, www.pharmacy.ca.gov under "Written Information and Publications."

Additionally, the Board encourages all licensees to sign up to receive "Subscriber Alerts" from the Board when important new items and newsletters are added to the Web site. The process is fast and easy. Just go to www.pharmacy.ca.gov and under the "Quick Hits" menu on the left, select "Join our E-Mail List."



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

Date: November 28, 2009

To: Enforcement Committee

Subject: Ongoing Discussion on Prevention of Medication Errors

Agenda Item 7

At every meeting of the Enforcement Committee in the last 18 months, there has been a discussion of medication errors and how to prevent them.

Since the beginning of 2009, the board has been interviewed for at least four major media segments that have focused on medication errors. The board's messages in these segments are that:

- (1) medication errors do occur, there are 350 million prescriptions filled each year in California,
- (2) the board has requirements for all pharmacies to operate vigorous quality assurance programs that the board forcefully enforces to ensure all errors are closely reviewed by the pharmacy, staff are educated and process changes are made to prevent a recurrence,
- (3) there is no acceptable number of medication errors a pharmacy or pharmacist can make,
- (4) no pharmacist wants to make an error, and most live in fear of making an inadvertent error,
- (5) a grossly negligent error will result in formal discipline, other errors reported to the board, if substantiated, will be cited and fined,
- (6) patients need to take some actions to prevent medication errors from reaching or occurring to them,
- (7) the board's Notice to Consumer posters are there at the critical point in the pharmacy to aid patients in getting the right medicine,
- (8) the board is working to redesign labels to improve them for patients so they better understand how to take their medication,
- (9) patient consultation will prevent errors and patients, and
- (10) patients need to speak with a pharmacist when they come into a pharmacy and not be in a rush to leave before doing so – such a discussion can save their lives.

Recently, the board partnered with the Department of Consumer Affairs and a private firm to produce a three-minute video for consumers on how patients can prevent receiving a medication error. We hope to be able to show this video during the meeting.

Once finalized, the video will be added to the board's Web site.



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

Date: November 28, 2009

To: Enforcement Committee

Subject: Reporting of Settlements to the Board as Required by California Business and Professions Sections 800-802

Agenda Item 8

The board's staff recently learned that some insurance companies and some licensees may not be aware of their responsibilities to report settlements to the board for errors and omissions pursuant to requirements in California Business and Professions Code sections 800, 801 and 802. As a result, these reports are not being submitted to the board.

The text of these sections is provided on the following pages.

The board uses these reports to initiate investigations. In 2008-09, the board received four reports under sections 800-802.

CALIFORNIA CODES
BUSINESS AND PROFESSIONS CODE
SECTION 800-809.9

800. (a) The Medical Board of California, the Board of Psychology, the Dental Board of California, the Osteopathic Medical Board of California, the State Board of Chiropractic Examiners, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians, the State Board of Optometry, the Veterinary Medical Board, the Board of Behavioral Sciences, the Physical Therapy Board of California, the California State Board of Pharmacy, and the Speech-Language Pathology and Audiology Board shall each separately create and maintain a central file of the names of all persons who hold a license, certificate, or similar authority from that board. Each central file shall be created and maintained to provide an individual historical record for each licensee with respect to the following information:

(1) Any conviction of a crime in this or any other state that constitutes unprofessional conduct pursuant to the reporting requirements of Section 803.

(2) Any judgment or settlement requiring the licensee or his or her insurer to pay any amount of damages in excess of three thousand dollars (\$3,000) for any claim that injury or death was proximately caused by the licensee's negligence, error or omission in practice, or by rendering unauthorized professional services, pursuant to the reporting requirements of Section 801 or 802.

(3) Any public complaints for which provision is made pursuant to subdivision (b).

(4) Disciplinary information reported pursuant to Section 805.

(b) Each board shall prescribe and promulgate forms on which members of the public and other licensees or certificate holders may file written complaints to the board alleging any act of misconduct in, or connected with, the performance of professional services by the licensee.

If a board, or division thereof, a committee, or a panel has failed to act upon a complaint or report within five years, or has found that the complaint or report is without merit, the central file shall be purged of information relating to the complaint or report.

Notwithstanding this subdivision, the Board of Psychology, the Board of Behavioral Sciences, and the Respiratory Care Board of California shall maintain complaints or reports as long as each board deems necessary.

(c) The contents of any central file that are not public records under any other provision of law shall be confidential except that the licensee involved, or his or her counsel or representative, shall have the right to inspect and have copies made of his or her complete file except for the provision that may disclose the identity of an information source. For the purposes of this section, a board may protect an information source by providing a copy of the material with only those deletions necessary to protect the identity of the source or by providing a comprehensive summary of the substance of the material. Whichever method is used, the board shall ensure that full disclosure is made to the subject of any personal information that could reasonably in any way reflect or convey anything

detrimental, disparaging, or threatening to a licensee's reputation, rights, benefits, privileges, or qualifications, or be used by a board to make a determination that would affect a licensee's rights, benefits, privileges, or qualifications. The information required to be disclosed pursuant to Section 803.1 shall not be considered among the contents of a central file for the purposes of this subdivision.

The licensee may, but is not required to, submit any additional exculpatory or explanatory statement or other information that the board shall include in the central file.

Each board may permit any law enforcement or regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes to inspect and have copies made of that licensee's file, unless the disclosure is otherwise prohibited by law.

These disclosures shall effect no change in the confidential status of these records.

801. (a) Except as provided in Section 801.01 and subdivisions (b), (c), and (d) of this section, every insurer providing professional liability insurance to a person who holds a license, certificate, or similar authority from or under any agency mentioned in subdivision (a) of Section 800 shall send a complete report to that agency as to any settlement or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(b) Every insurer providing professional liability insurance to a person licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) shall send a complete report to the Board of Behavioral Science Examiners as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(c) Every insurer providing professional liability insurance to a dentist licensed pursuant to Chapter 4 (commencing with Section 1600) shall send a complete report to the Dental Board of California as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(d) Every insurer providing liability insurance to a veterinarian licensed pursuant to Chapter 11 (commencing with Section 4800) shall

send a complete report to the Veterinary Medical Board of any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional service. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(e) The insurer shall notify the claimant, or if the claimant is represented by counsel, the insurer shall notify the claimant's attorney, that the report required by subdivision (a), (b), or (c) has been sent to the agency. If the attorney has not received this notice within 45 days after the settlement was reduced to writing and signed by all of the parties, the arbitration award was served on the parties, or the date of entry of the civil judgment, the attorney shall make the report to the agency.

(f) Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured, except that this prohibition shall not void any settlement entered into without that written consent. The requirement of written consent shall only be waived by both the insured and the insurer. This section shall only apply to a settlement on a policy of insurance executed or renewed on or after January 1, 1971.

801.01. (a) A complete report shall be sent to the Medical Board of California, the Osteopathic Medical Board, or the California Board of Podiatric Medicine, with respect to a licensee of the board as to the following:

(1) A settlement over thirty thousand dollars (\$30,000) or arbitration award of any amount or a civil judgment of any amount, whether or not vacated by a settlement after entry of the judgment, that was not reversed on appeal, of a claim or action for damages for death or personal injury caused by the licensee's alleged negligence, error, or omission in practice, or by his or her rendering of unauthorized professional services.

(2) A settlement over thirty thousand dollars (\$30,000) if it is based on the licensee's alleged negligence, error, or omission in practice, or by the licensee's rendering of unauthorized professional services, and a party to the settlement is a corporation, medical group, partnership, or other corporate entity in which the licensee has an ownership interest or that employs or contracts with the licensee.

(b) The report shall be sent by the following:

(1) The insurer providing professional liability insurance to the licensee.

(2) The licensee, or his or her counsel, if the licensee does not possess professional liability insurance.

(3) A state or local governmental agency that self-insures the licensee.

(c) The entity, person, or licensee obligated to report pursuant to subdivision (b) shall send the complete report if the judgment, settlement agreement, or arbitration award is entered against or paid by the employer of the licensee and not entered against or paid by the licensee. "Employer," as used in this paragraph, means a professional corporation, a group practice, a health care facility or

clinic licensed or exempt from licensure under the Health and Safety Code, a licensed health care service plan, a medical care foundation, an educational institution, a professional institution, a professional school or college, a general law corporation, a public entity, or a nonprofit organization that employs, retains, or contracts with a licensee referred to in this section. Nothing in this paragraph shall be construed to authorize the employment of, or contracting with, any licensee in violation of Section 2400.

(d) The report shall be sent to the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine, as appropriate, within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto, within 30 days after service of the arbitration award on the parties, or within 30 days after the date of entry of the civil judgment.

(e) If an insurer is required under subdivision (b) to send the report, the insurer shall notify the claimant, or if the claimant is represented by counsel, the claimant's counsel, that the insurer has sent the report to the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. If the claimant, or his or her counsel, has not received this notice within 45 days after the settlement was reduced to writing and signed by all of the parties or the arbitration award was served on the parties or the date of entry of the civil judgment, the claimant or the claimant's counsel shall make the report to the appropriate board.

(f) If the licensee or his or her counsel is required under subdivision (b) to send the report, the licensee or his or her counsel shall send a copy of the report to the claimant or to his or her counsel if he or she is represented by counsel. If the claimant or his or her counsel has not received a copy of the report within 45 days after the settlement was reduced to writing and signed by all of the parties or the arbitration award was served on the parties or the date of entry of the civil judgment, the claimant or the claimant's counsel shall make the report to the appropriate board.

(g) Failure of the licensee or claimant, or counsel representing the licensee or claimant, to comply with subdivision (f) is a public offense punishable by a fine of not less than fifty dollars (\$50) and not more than five hundred dollars (\$500). A knowing and intentional failure to comply with subdivision (f) or a conspiracy or collusion not to comply with subdivision (f), or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) and not more than fifty thousand dollars (\$50,000).

(h) (1) The Medical Board of California, the Osteopathic Medical Board of California, and the California Board of Podiatric Medicine may develop a prescribed form for the report.

(2) The report shall be deemed complete only if it includes the following information:

(A) The name and last known business and residential addresses of every plaintiff or claimant involved in the matter, whether or not the person received an award under the settlement, arbitration, or judgment.

(B) The name and last known business and residential address of every physician and surgeon or doctor of podiatric medicine who was alleged to have acted improperly, whether or not that person was a named defendant in the action and whether or not that person was

required to pay any damages pursuant to the settlement, arbitration award, or judgment.

(C) The name, address, and principal place of business of every insurer providing professional liability insurance to any person described in subparagraph (B), and the insured's policy number.

(D) The name of the court in which the action or any part of the action was filed, and the date of filing and case number of each action.

(E) A brief description or summary of the facts of each claim, charge, or allegation, including the date of occurrence.

(F) The name and last known business address of each attorney who represented a party in the settlement, arbitration, or civil action, including the name of the client he or she represented.

(G) The amount of the judgment and the date of its entry; the amount of the arbitration award, the date of its service on the parties, and a copy of the award document; or the amount of the settlement and the date it was reduced to writing and signed by all parties. If an otherwise reportable settlement is entered into after a reportable judgment or arbitration award is issued, the report shall include both the settlement and the judgment or award.

(H) The specialty or subspecialty of the physician and surgeon or the doctor of podiatric medicine who was the subject of the claim or action.

(I) Any other information the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine may, by regulation, require.

(3) Every professional liability insurer, self-insured governmental agency, or licensee or his or her counsel that makes a report under this section and has received a copy of any written or electronic patient medical or hospital records prepared by the treating physician and surgeon or podiatrist, or the staff of the treating physician and surgeon, podiatrist, or hospital, describing the medical condition, history, care, or treatment of the person whose death or injury is the subject of the report, or a copy of any deposition in the matter that discusses the care, treatment, or medical condition of the person, shall include with the report, copies of the records and depositions, subject to reasonable costs to be paid by the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. If confidentiality is required by court order and, as a result, the reporter is unable to provide the records and depositions, documentation to that effect shall accompany the original report. The applicable board may, upon prior notification of the parties to the action, petition the appropriate court for modification of any protective order to permit disclosure to the board. A professional liability insurer, self-insured governmental agency, or licensee or his or her counsel shall maintain the records and depositions referred to in this paragraph for at least one year from the date of filing of the report required by this section.

(i) If the board, within 60 days of its receipt of a report filed under this section, notifies a person named in the report, that person shall maintain for the period of three years from the date of filing of the report any records he or she has as to the matter in question and shall make those records available upon request to the board to which the report was sent.

(j) Notwithstanding any other provision of law, no insurer shall enter into a settlement without the written consent of the insured,

except that this prohibition shall not void any settlement entered into without that written consent. The requirement of written consent shall only be waived by both the insured and the insurer.

801.1. (a) Every state or local governmental agency that self insures a person who holds a license, certificate or similar authority from or under any agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) shall send a complete report to that agency as to any settlement or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

(b) Every state or local governmental agency that self-insures a person licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) shall send a complete report to the Board of Behavioral Science Examiners as to any settlement or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by that person's negligence, error, or omission in practice, or rendering of unauthorized professional services. The report shall be sent within 30 days after the written settlement agreement has been reduced to writing and signed by all parties thereto or within 30 days after service of the arbitration award on the parties.

802. (a) Every settlement, judgment, or arbitration award over three thousand dollars (\$3,000) of a claim or action for damages for death or personal injury caused by negligence, error or omission in practice, or by the unauthorized rendering of professional services, by a person who holds a license, certificate, or other similar authority from an agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200) or Chapter 5 (commencing with Section 2000) or the Osteopathic Initiative Act) who does not possess professional liability insurance as to that claim shall, within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties, be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if the person is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if the claimant is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall

himself or herself make the complete report. Failure of the licensee or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars (\$50) or more than five hundred dollars (\$500). Knowing and intentional failure to comply with this section or conspiracy or collusion not to comply with this section, or to hinder or impede any other person in the compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) nor more than fifty thousand dollars (\$50,000).

(b) Every settlement, judgment, or arbitration award over ten thousand dollars (\$10,000) of a claim or action for damages for death or personal injury caused by negligence, error, or omission in practice, or by the unauthorized rendering of professional services, by a marriage and family therapist or clinical social worker licensed pursuant to Chapter 13 (commencing with Section 4980) or Chapter 14 (commencing with Section 4990) who does not possess professional liability insurance as to that claim shall within 30 days after the written settlement agreement has been reduced to writing and signed by all the parties thereto or 30 days after service of the judgment or arbitration award on the parties be reported to the agency that issued the license, certificate, or similar authority. A complete report shall be made by appropriate means by the person or his or her counsel, with a copy of the communication to be sent to the claimant through his or her counsel if he or she is so represented, or directly if he or she is not. If, within 45 days of the conclusion of the written settlement agreement or service of the judgment or arbitration award on the parties, counsel for the claimant (or if he or she is not represented by counsel, the claimant himself or herself) has not received a copy of the report, he or she shall himself or herself make a complete report. Failure of the marriage and family therapist or clinical social worker or claimant (or, if represented by counsel, their counsel) to comply with this section is a public offense punishable by a fine of not less than fifty dollars (\$50) nor more than five hundred dollars (\$500). Knowing and intentional failure to comply with this section, or conspiracy or collusion not to comply with this section or to hinder or impede any other person in that compliance, is a public offense punishable by a fine of not less than five thousand dollars (\$5,000) nor more than fifty thousand dollars (\$50,000).

802.1. (a) (1) A physician and surgeon, osteopathic physician and surgeon, and a doctor of podiatric medicine shall report either of the following to the entity that issued his or her license:

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

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

(2) The report required by this subdivision shall be made in writing within 30 days of the date of the bringing of the indictment or information or of the conviction.

(b) Failure to make a report required by this section shall be a public offense punishable by a fine not to exceed five thousand dollars (\$5,000).

802.5. (a) When a coroner receives information that is based on findings that were reached by, or documented and approved by a board-certified or board-eligible pathologist indicating that a death may be the result of a physician's or podiatrist's gross negligence or incompetence, a report shall be filed with the Medical Board of California, the Osteopathic Medical Board of California, or the California Board of Podiatric Medicine. The initial report shall include the name of the decedent, date and place of death, attending physicians or podiatrists, and all other relevant information available. The initial report shall be followed, within 90 days, by copies of the coroner's report, autopsy protocol, and all other relevant information.

(b) The report required by this section shall be confidential. No coroner, physician and surgeon, or medical examiner, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her acting in compliance with this section. No board-certified or board-eligible pathologist, nor any authorized agent, shall be liable for damages in any civil action as a result of his or her providing information under subdivision (a).

803. (a) Except as provided in subdivision (b), within 10 days after a judgment by a court of this state that a person who holds a license, certificate, or other similar authority from the Board of Behavioral Science Examiners or from an agency mentioned in subdivision (a) of Section 800 (except a person licensed pursuant to Chapter 3 (commencing with Section 1200)) has committed a crime, or is liable for any death or personal injury resulting in a judgment for an amount in excess of thirty thousand dollars (\$30,000) caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license, certificate, or other similar authority.

(b) For purposes of a physician and surgeon, osteopathic physician and surgeon, or doctor of podiatric medicine, who is liable for any death or personal injury resulting in a judgment of any amount caused by his or her negligence, error or omission in practice, or his or her rendering unauthorized professional services, the clerk of the court that rendered the judgment shall report that fact to the agency that issued the license.