



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Enforcement Team Meeting
June 20, 2000
9:00 a.m. – 3:10 p.m.

Present: Chair and Board Member Darlene Fujimoto
Board Member John Jones
Executive Staff
Supervising Inspector
Inspectors
Enforcement Staff

Inspector Issues

The inspectors provided their requests for reference materials. These requests were noted and orders will be placed.

Announcements/Introductions

Committee Chair Darlene Fujimoto called the meeting to order and asked team members to introduce themselves and their current positions.

It was announced that Dennis Ming and Tim Black were hired as inspectors and will begin June 26, 2000. In addition, inspector examination interviews will be held during the week of June 26th.

Quality Improvement Efforts

The leads from the Compliance, Drug Diversion/Fraud, Pharmacist Recovery Program (PRP)/Probationer, Complaint Mediation and Administration teams reported on their activities. Each team provided information on their workload, significant accomplishments and presentations to outside organizations.

Some of the significant accomplishments reported were: near completion of 179 mediated cases over one year old, completion of administrative cases, participation in four PC 23 criminal hearings, participation in search warrants conducted by FBI-OCI, referral of bid diversion case to

AG where \$8 million drugs were missing, referral of case to FBI to include wholesale distributors in Sacramento, Nevada, Montana and California pharmacies, revocation of the licenses of two probationers, monitored 143 probationers, and completed 23 extensive probation inspections, completed procedure manuals for the Complaint Mediation Team, completed a customer survey for implementation July 1, and proposed revisions to the disciplinary guidelines.

Committee Chair Darlene Fujimoto reported that the CURES Workgroup meetings have been suspended pending the outcome of AB 2018, which would make CURS permanent and eliminate the triplicate prescription requirement.

Supervising Inspector Robert Ratcliff reported on the status of completed cases since the last team meeting. He commended the inspectors and mediation analysts on their hard work and efforts to complete those cases over one year old. He reiterated that the direction was to complete all cases over one year old by this meeting; however, not all were able to meet this performance expectation. He directed that all outstanding cases over one year old must be completed by August 1, 2000. He displayed the workload of the teams. Some inspectors commented that the data did not include their entire workload because they have intermittent tasks such as prepare and testify at hearings. Also, some inspectors felt that they were doing a good job but because of vacancies are carrying a high caseload and are unable to close cases. It was noted though that inspectors are no longer doing routine inspections and therefore, time should only be dedicated to completing their cases. Copies of the enforcement data were provided to all team members

At the last meeting, the team discussed the implementation of a routine compliance inspection program. Originally the implementation date was set for July 1. However, due to other priorities the goal is to implement January 1, 2001. A plan will be presented at the next Enforcement Team meeting.

Proposed Changes to the Disciplinary Guidelines

Enforcement Coordinator Anne Sodergren presented proposed revisions to the disciplinary guidelines. The Enforcement Team reviewed the changes and made some modifications for recommendation for board approval. Chair Darlene Fujimoto acknowledged Ms. Sodergren, and Enforcement Analysts Candace Raney and Susan Cappello for a job well done.

Legislation Update

Paul Riches, Legislative Analyst, reported on the status of the three bills that the board is sponsoring, SB 1339, AB 2018, and SB 1554 (technical clean up). He also provided information on SB 1828, which would increase the fines for unlicensed dispensing of drugs by Internet pharmacies.

Review of Comments for Cite and Fine Regulations

Mr. Riches reported that the regulation hearing on these proposed regulations is scheduled for the July board meeting. To date no comments have been received; however, the final date for submitting written comment is June 26th. And comments can be provided during the regulation hearing.

Request to Repeal or Modify CCR 1717.3 Regarding Preprinted, Multiple Checkoff Prescription Blanks

The Enforcement Team reviewed the request from Kaiser Permanente to amend the regulation as a means to better prevent prescription errors, to standardized the drugs used in protocols, to assure completeness and accuracy of the prescription and provide important patient information to the pharmacist. A similar request for expansion of this prescription was also received from the County of Los Angeles.

The Enforcement Team discussed the request. The team recommended that the board amend the regulations to allow for the dispensing of more than one dangerous drug from the preprinted, multiple checkoff prescription blank as long as the prescriber has indicated the number of dangerous drugs that are being prescribed from this blank. However, the team agreed that the regulation not be modified to authorize the dispensing of controlled substances.

Review of Strategic Objectives for 2000-2001

The Enforcement Team reviewed the proposed strategic objectives for next year and agreed with the recommendations.

Implementation of New Regulations

The team discussed the implementation of new regulations regarding the temporary absence of a pharmacist and central refill pharmacies. The team discussed the implementation of the refill pharmacy regulation. Specifically, section (a)(5) that states that both pharmacies are responsible for ensuring that the prescription order has been properly filled. It was clarified that it is not intended to require each pharmacy to check the prescription but should an error occur and there is no audit trail to determine how it occurred then both pharmacies would be held responsible. It was suggested that that this section be clarified in a future newsletter article.

Evidence Procedures

Revised evidence procedures were given to the Enforcement Team.

Public Committee Agenda for July Board Meeting

The Enforcement Team discussed proposed agenda topics for the public meeting of the Enforcement Committee. One topic that was presented at the last board meeting was the board's policy on expiration dates. After discussion, the Enforcement Team recommended that the board's policy is consistent with the USP and that the board's only other concern is that the pharmacy not dispense expired drugs.

The next topic for the agenda will be patient confidentiality issues that have recently become enforcement matters. It was suggested that examples be provided with guidance from the board. Another topic will be prescriber dispensing. The committee will give the board's legal interpretation of pharmacy law as it relates to prescriber dispensing and whether reimbursement to the prescriber is considered retailing as questioned by some pharmacists. Finally, an overview of the board's Enforcement Process will be given as to what the board can and cannot do when it receives "anonymous" complaints and what information the board would need to investigate.

Future Meetings

The next meeting of the Enforcement Team is September 14, 2000.

Adjournment

The meeting was adjourned at 3:10 p.m.