



ENFORCEMENT COMMITTEE MEETING

Meeting Summary

September 10, 2002

**Department of Consumer Affairs
400 R Street, Suite 4070
Sacramento, CA 95814**

Present: John Jones, Chair and Board President
Stan Goldenberg, Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Board of Pharmacy Inspectors
Ron Diedrich, Liaison Deputy Attorney General
Dana Winterrowd, DCA Staff Counsel

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Department of Consumer Affairs (DCA) – Minimum Standards for Consumer Complaint Disclosure

The Director of the Department of Consumer Affairs, Kathleen Hamilton, presented the department's recommended minimum standards for consumer complaint disclosure. She explained that these recently adopted standards were a culmination of consumer forums and cooperative efforts with the regulatory boards to develop guidelines for disclosing information concerning complaints filed by consumers.

Ms. Hamilton stated that the department is requesting that the DCA boards review the standards and consider them when determining its own disclosure practices. The conditions of disclosure are when a substantiated consumer transaction has occurred, the business has been provided an opportunity to respond to the complaint, a probable violation of law has occurred or there is a possible risk of harm to the public, and the complaint will be referred to legal action. Ms. Hamilton emphasized the importance that consumers be informed of complaints when these conditions are met. This would also include when a complaint has been referred to the Attorney General's Office for possible disciplinary action.

Board of Pharmacy Complaint Disclosure Policy

Based on the guidelines provided by the Department of Consumer Affairs and the requirements of the Public Records Act, the Enforcement Committee is recommending that the board revise its disclosure policy to reflect the information that is available on all licensees.

Citation and Fine Process

Committee Chairman John Jones opened the discussion on the citation and fine process. The comment was made that the board's citation and fine process does not comport with the intent of California Code of Regulations, title 16, section 1775, in that it fails to provide the licensee the opportunity to have a hearing before the committee prior to the committee ever having the chance to consider whether or not a citation should even be issued. In response, it was explained that the board, thru the Citation and Fine Committee, has put a citation process in place that complies with the plain language and requirements of Business and Professions Code section 125.9; California Code of Regulations, title 16, sections 1775 – 1775.4; and Government Code section 11500 et seq.

It was further explained that the regulatory scheme regarding the issuance of a citation does not mandate that a hearing be held prior to the issuance of a citation. It simply allows the Citation and Fine Committee the option of requesting a licensee to appear before it if the committee wishes to obtain further information from the licensee before deciding whether or not to issue a citation. It also provides a procedure to follow should the committee exercise its discretion and choose that option. There is no provision that expressly gives the licensee the right to interfere into the investigative/prosecutorial processes and be given a hearing prior to the issuance of a citation by the committee. Legislation would be required to implement such a process.

It was also noted that the current citation process provides a licensee with even more procedural and appeal opportunities than does the well established process involved in taking disciplinary action against a license. Once a citation has been issued, the licensee has a number of options. The licensee can simply pay the levied fine and comply with the order of abatement contained within the citation. And in those cases, the payment of the fine does not constitute an admission of the violation charged.

The licensee can request a hearing to appeal the citation. At that hearing, the licensee is afforded all the due process rights provided by the California Administrative Procedure Act, including the right to discovery, the right to present witnesses, and the right to cross-examination of witnesses. While a citation is generally not considered to be a formal disciplinary action, if the appeal goes to hearing, the findings of fact, conclusions of law, and order in the decision are a matter of public record and are part of the licensee's record with the board.

At the same time or as an alternative, the licensee can also request an office conference to discuss the citation with a member of the committee (who is also a board member) and a supervising inspector. While this is not a hearing, the licensee may bring further information to the meeting, as well as a legal counsel or an authorized representative. After the office

conference, the citation may be affirmed, dismissed or modified. If it is modified, the licensee has yet another opportunity to request a hearing to appeal the modified citation.

Additionally, it was explained that the previous Northern Compliance Committee/Southern Compliance Committee (“NCC/SCC”) process might not have been consistent with the requirements of the California Administrative Procedure Act.

Citations issued under the former NCC/SCC process are part of the licensee’s record. However, the Notices of Violation, which were issued by the board’s inspectors and which were examined by the NCC/SCC, are not now considered a determination that the licensee did in fact violate pharmacy law. A Notice of Violation (in the past or currently outstanding) is merely an advisement to the licensee that the inspector believes that the licensee is in violation of the law noted on the form. It is neither a citation nor a disciplinary action, and will not be considered as such in evaluating the licensee’s prior conduct.

As a result, board inspectors will no longer be using the “Notice of Violation” document to advise a licensee of a possible violation(s) of law. Inspectors will continue to advise licensees of the violation(s) they believe occurred. However, that notification will be on a new form that also advises the licensee in writing of the opportunity to respond within 14 calendar days to the identified possible violation(s) of pharmacy law. This notification may occur at any time during the investigative process. This advisement is not the board’s final or formal determination regarding the matter. It is also neither a citation nor is it a disciplinary action.

It was requested that a copy of the inspector’s notification to the licensee of possible violations also be sent to the pharmacy chain’s corporate office. While the committee understood the importance of timely communication within the corporate organization, it was recognized that this is primarily an internal communication issue, which each pharmacy chain must address in a way that is best suited to its own unique needs. Moreover, very limited resources prevent the board from providing such a special service. The inspector is fulfilling his or her obligation by providing a copy of the advisement to the pharmacist at the pharmacy location.

It was suggested that the responsibility of notifying the pharmacy owner should be that of the pharmacist-in-charge or other designated pharmacy personnel as determined by the pharmacy management.

A request was made that the board send a copy of the citation that is issued to a pharmacist to the pharmacy where the alleged violation of pharmacy law took place. The committee responded that the board is required to serve the pharmacist at the pharmacist’s address of record and that any additional service is not feasible. It is the responsibility of the pharmacist to notify his or her employer if he or she has been served with a citation.

In response to concerns regarding privacy, it was noted that the current citation process affords greater privacy to the licensee than did the former NCC/SCC process. In the past, the public was privy to allegations of misconduct by the licensee that the NCC/SCC may have ultimately

concluded were without merit or did not warrant the issuance of a citation. Under the committee's current process, such allegations are not made public.

The citation processes used by the Ohio and Pennsylvania Boards of Pharmacy were put forward as models for California to consider. As described to the committee, it appears that in both states, it is the inspector (or similar type personnel) who determines that a violation of law did in fact occur. A notice of that violation is then issued and the licensee must respond within a specified time as to what actions he or she has taken to correct the violation or to prevent future incidents from occurring. If the licensee does not correct that the violation or there are repeat violations, then he or she may be subject to a fine or other board action.

The Enforcement Committee provided statistics on the citation and fine program since the first committee meeting in May. During that time, the committee reviewed 143 cases. About 19% of those cases were closed with no action taken, and about 3% were sent back for further investigation. Consequently, no citation was issued in nearly ¼ of the relatively few cases that make it as far as the committee.

In those cases where a citation was issued, about 19% of them were without any fine. In those cases where a fine was levied, the average amount of the fine was about \$1,000. That amount is less than half of the \$2,500 allowable maximum, and within about \$100 of the average fine issued under the former NCC/SCC process.

The 143 reviewed cases yielded the issuance of 309 citations. Of those 309 citations, only 35 were appealed and only 24 licensees filed those appeals. (Several of those licensees filed multiple appeals.)

The top two citations for pharmacists and pharmacies were for prescription errors and for failure to provide consultations. For the pharmacist-in-charge, it was for failure to provide patient consultation and for keeping the pharmacy secure, which resulted in a significant loss of drugs.

Chairman Jones noted that the average amount of time from the date the investigation is opened to the date the citation is issued is approximately 8 months. Efforts are underway to reduce this amount of time even further.

Chairman Jones noted that the licensees also benefits from the current citation process. The time the licensee has to wait for the possible issuance of a citation has already been markedly reduced from that under the NCC/SCC process, and is shortening. Also, under the former NCC/SCC process the licensees suffered the expense and inconvenience of appearing before that committee. Those costs often exceeded any potential fine. Under the current citation process, because the licensee is not routinely being requested to appear, the licensee is not invariably asked to bear those costs. To date, only one licensee has been asked to appear before the committee. Further, as discussed above, the licensees are now afforded greater privacy prior to the issuance of a citation than they were under the NCC/SCC process.

The Enforcement Committee emphasized that the board's overriding mandate is to protect the public. The citation process is a key component of fulfilling that responsibility. It provides a means whereby the board can meet its public protection obligation in a manner that does not require formal disciplinary action be initiated against licensees who have committed relatively minor infractions of pharmacy law. Without the citation process in place, there would be little alternative but to impose formal disciplinary action, up to and including the revocation of their license, on such licensees.

Moreover, the citation and fine process that is in place is both workable and fair to the licensees. The affected licensee is given multiple opportunities to provide the Board's inspector with a written response and/or documentation prior to the matter being submitted to the Citation and Fine Committee. Further, the inspector's report is reviewed at least twice (by the supervising inspector and the executive officer) prior to the matter ever being submitted to the Citation and Fine Committee. This is a rigorous screening process. It appears that less than 3% of the last 3,000+ inspections that could have resulted in a referral to the Citation and Fine Committee were actually submitted to the committee.

The Enforcement Committee concluded the discussion by reaffirming its commitment to continue its dialog with licensees and work mutually to improve the process.

Revisions to the Inspection Report Form

Supervising Inspector Robert Ratcliff reported that the inspection report form is undergoing revision. The form will be used to advise licensees of the outcome of the inspection. The inspector will note on the form the sections of pharmacy law that the pharmacy may be out of compliance. The form will also provide an area for the licensee to provide comments and inform the licensee that he/she has 14 days in which to respond to any possible violations that the inspector has identified. The inspector will no longer be using the "Notice of Violation" form.

The board will begin using the revised form once the board's legal counsel has approved it.

Enforcement Guidelines – Unprofessional Conduct

Based on comments received by licensees, the Enforcement Committee developed guidelines regarding when a licensee will be charged with unprofessional conduct. Chairman John Jones explained that for citation cases, whenever reasonably feasible, a licensee will not be charged with unprofessional conduct. Instead, the citations will advise the licensee that a citation is being issued pursuant to California Code of Regulations, title 16, section 1775, because of a violation of the Pharmacy Law (Bus. & Prof. Code sec. 4000 et seq.) and/or the regulations adopted pursuant thereto (C.C.R., title 16, sec. 1703 et seq.). Consequently, direct reference to Business and Professions Code section 4301 in citations will be limited.

In those unusual circumstances where a reference to one of the subdivisions in Business and Professions Code section 4301 is necessary in order to allege a violation of the laws and rules governing the practice of pharmacy, the citation will still not charge the licensee with

unprofessional conduct. Rather, the citation will advise the licensee that a citation is being issued pursuant to California Code of Regulations, title 16, section 1775, because of a violation of the pertinent subdivision of Business and Professions Code section 4301.

For example, it appears that the only prohibition on a licensee knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts is found in Business and Professions Code section 4301, subdivision (g). Accordingly, a citation would advise the licensee that the citation is being issued pursuant to California Code of Regulations, title 16, section 1775, because of a violation of Business and Professions Code section 4301, subdivision (g).

In the appropriate circumstances, the Board of Pharmacy will pursue allegations of unprofessional conduct through the usual administrative disciplinary process, such as an accusation or a petition to revoke probation.

Informational Hearing on Proposed Changes to Wholesaler Requirements

The Enforcement Committee requested comments on proposed adoption of California Code of Regulations, title 16, sections 1784 and 1785. Concerns were expressed that section 1784 would prohibit the intra-company transfers between chain pharmacies that also have wholesale facilities. Chairman John Jones asked for specific amendments to the regulations that would address this concern and stated that the Committee would hold another informational hearing on the proposal at its December meeting.

Quality Assurance Program

Chair John Jones announced that the regulation has been in place for approximately nine months. For the first six months the board's primary focus of enforcement efforts was on education. Now that pharmacies have had an opportunity to comply with the regulation, the inspector will review a pharmacy's operation to ensure compliance. He also announced that the *Health Notes* on the quality assurance requirements was being distributed to all pharmacies and pharmacists that week.

Board-Sponsored CE Program

Chairman Jones requested suggestions for a continuing education program for pharmacists that would be sponsored and presented by the Board of Pharmacy at local pharmacy associations statewide. Suggested areas were citation and fine process, quality assurance requirements, confidentiality, duties of the pharmacist-in-charge and HIPPA.

Future Meetings

The next meeting of the Enforcement Committee is December 10, 2002. Proposed agenda topics are: HIPPA, prescriber dispensing, quality assurance regulation – requirement to notify the patient of an error in specific practice settings.

Adjournment

Chairman John Jones adjourned the meeting at 12 noon.