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MEMORANDUM

DATE: January 26, 2015

TO: Dan Rubin, Commissioner
Pharmacy Quality Assurance Commission

FROM: Joyce A. Roper, Sr. Assistant Attorney General *JAR*
Agriculture and Health Division, MS 40109

SUBJECT: **Overview of Regulatory Authority For Licensed Business Entities**

Background

The Commission has regulatory authority over licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy assistants under RCW 18.64 and 18.64A. The disciplinary process for these health care providers is specified in RCW 18.130, the Uniform Disciplinary Act (UDA). RCW 18.64.163; RCW 18.64A.055.

The Commission also licenses or registers pharmacies (resident and non-resident), shopkeepers, manufacturers, wholesalers, itinerant vendors or peddlers, poison distributors, health care entities, and precursor chemical distributors. RCW 18.64.043 through RCW 18.64.047; RCW 18.64.370; RCW 18.64.450. The Commission is authorized to take action against these business entities' licenses under RCW 18.64.165.

The Commission has had questions about its authority to take action against the license of business entities, because the process has not been as clear as the process used to discipline the health care providers under the UDA. Often, when complaints were submitted against a pharmacy, the focus of the authorized investigation has been the pharmacist-in-charge, rather than on the business entity itself. Once the investigation focused on the pharmacist-in-charge, the decision whether to proceed with a disciplinary action would be based on the grounds specified in the UDA, because the pharmacist's license is disciplined under that act, rather than RCW 18.64.165.

On occasion, the investigation reveals that the conduct, which adversely impacted the delivery of safe health care, was due to the business conditions, policies and procedures, and operations of the pharmacy, which were not entirely within the control of the pharmacist-in-charge, or there was otherwise a shared responsibility. On these occasions, the Commission is sometimes interested in proceeding against the firm license as authorized in RCW 18.64.165. The purpose

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of this memo is to explain what is authorized under that statute and what processes the Commission would use after authorizing a case under RCW 18.64.165.

Discussion

1. Grounds for Disciplinary Action

RCW 18.64.165 authorizes action against the licenses of "any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor upon proof that:

- (1) The license was procured through fraud, misrepresentation, or deceit;
- (2) The licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the commission or has been convicted of a felony.

When disciplinary action is being considered against a firm, the most likely basis will be in the second category, i.e. "[t]he licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to drugs, controlled substances, cosmetics, or nonprescription drugs." Complaints should only be authorized for investigation of the business entity if they include allegations which, if true, would demonstrate a violation of statutes or rules in Washington or federally relating to "drugs, controlled substances, cosmetics, or nonprescription drugs." Disciplinary action against the firms should only be authorized if the investigation demonstrates that such statutes or rule have been violated.

2. Disciplinary Sanctions —

RCW 18.64.165 only authorizes refusal of a license application or suspension or revocation of a license as the disciplinary sanctions. The other sanctions authorized against a health care provider in RCW 18.130.160 (fines, restriction of practice, probation, etc.) are not authorized in RCW 18.64.165.

However, the parties can agree to a lesser sanction in resolution of the disciplinary action, with the exception of payment of a fine or reimbursement of investigative costs. For example, the case manager could negotiate an agreement with the respondent pharmacy to stay a suspension based on compliance with specific conditions remedying the situation which gave rise to the charges, which the Commission would then have to approve, just as currently occurs in disciplinary cases involving pharmacists and pharmacy technicians. The State cannot agree to a payment of a fine or costs if there is no statutory authority for the agency to assess and collect those funds.

3. Disciplinary Process

The process and procedure for taking disciplinary action against a business license is not specified in RCW 18.64. However, the Commission adopted WAC 246-856-001 and

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WAC 246-856-202 in 1994. WAC 246-856-001 states that the purpose of this chapter of the rules "is to combine the common rules adopted by the board of pharmacy for all holders of licenses, registrations and certifications, as well as any other authorizations, issued by the board of pharmacy." Then, WAC 246-856-020 states that "[t]he board adopts the model procedural rules for adjudicative proceedings as adopted by the department of health and contained in chapter 246-11 WAC, including subsequent amendments."

Therefore, the procedures specified in WAC 246-11 have been adopted for the disciplinary actions taken against firm licenses.

Conclusion

This memo contains a brief overview of the authority and process for taking disciplinary action against firm licenses. In summary:

- the Commission has authority to take disciplinary action against firm licenses;
- the range of sanctions is substantially narrower than the range of sanctions available under the UDA;
- the Commission and the respondent firm could agree to resolve the case by a lesser sanction, with the exception of a fine or cost recovery, because the Commission has no statutory authority to receive and account for those funds; and
- the disciplinary process is the same as the process specified in WAC 246-11 for disciplinary actions under the UDA.

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cc: Chris Humberson, Executive Director
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