

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Olympia, Washington

NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Delegation of Decision-Making to Panels and Health Law Judges for Disciplinary Cases Involving Pharmaceutical Firms and Pharmacy Professionals | P009.2

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy clarifies the Pharmacy Quality Assurance Commission's approach to licensing, complaints, investigations, case disposition, and adjudication involving pharmaceutical firms and pharmacy professionals.

Effective Date: August 24, 2023

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Department of Health Pharmacy Quality Assurance Commission

Policy Statement

| Title: | Delegation of Desigion Making to Denals and Health | Number: P009.2 |
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| | Law Judges for Disciplinary Cases Involving | |
| | Pharmaceutical Firms and Pharmacy Professionals | |
| References: | Substitute Senate Bill <u>5753</u> (codified under RCW | |
| | 18.64.001; RCW 18.64.003; RCW18.64.005; RCW | |
| | 18.64.006; and RCW 18.64.310); RCW 18.130.050 | |
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| Effective Date: | August 24, 2023 | |
| Supersedes: | P009, effective June 9, 2022 | |
| Approved By: | Ken Kenyon, Pharmacy Quality Assurance | |
| , , | Commission | |

This policy statement establishes the approach of the Pharmacy Quality Assurance Commission (commission) to licensing, complaints, investigations, case disposition, and adjudication involving pharmacy professionals and pharmaceutical firms based on the requirements provided in chapter 18.130 RCW and the passage of <u>Substitute Senate Bill 5753</u> (SSB 5753) (chapter 240, Laws of 2022).

The commission is delegating the decision making of all applications, complaints, and disciplinary matters involving pharmaceutical firms and pharmacy professionals to panels of the commission and health law judges to act as the presiding officer as described below.

The commission has regulatory authority over a number of pharmaceutical firms. A pharmaceutical firm is defined in WAC 246-945-010(61) as a "a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state", and includes:

- Pharmacies
- Nonresident Pharmacies
- Controlled Substance Researchers
- Other Controlled Substance Act Registrations
- Drug Dog Handler K9 Registrations
- Health Care Entities
- Drug Manufacturers
- Drug Wholesalers

- Legend Drug Sample Distributors
- Position Manufacturers/Sellers
- Precursor Chemical Registrations
- Itinerant Vendors
- Sodium Pentobarbital for Animal Euthanization Registrations
- Shopkeepers
- Remote Dispensing Sites for Opioid Use Disorder Medications

SSB 5753, which became effective on June 9, 2022 amended chapter 18.64 RCW, The law now states:

RCW 18.64.005 Commission—Powers and duties.

The commission may authorize the secretary, or their designee, to serve as the presiding officer for any disciplinary proceedings authorized by the commission. The presiding officer shall not vote on or make any final decision in cases pertaining to standards of practice or where clinical expertise is necessary.

RCW 18.64.006 Commission – Panel membership – Quorum

- Allows the commission to appoint members of panels of at least three members.
- A quorum for transaction of any business by a panel is a minimum of three members. A majority vote of a quorum of the panel is required to transact business delegated to it by the commission including, but not limited to, licensing, disciplinary, and adjudicative actions.

The commission's process for licensing, complaints, investigations, case disposition, and adjudication for pharmacy professionals is covered in chapter 18.130 RCW with no recent significant changes.

Matters Involving Pharmaceutical Firms

For all current and future applications and complaints involving pharmaceutical firms, the commission delegates all decisions related to non-routine applications, exception applications, reports, investigations, and case disposition to a panel of at least three commissioners. *See* RCW 18.64.006.

For all current and future applications and disciplinary cases involving pharmaceutical firms, the commission delegates a health law judge (HLJ), designated by the Secretary of Health, to act as the presiding officer in any adjudicative proceeding to the extent authorized in the Commission's "Delegation and Authorization for Health Law Judges to Act as the Presiding Officer." *See* RCW 18.64.005(4).

Matters Involving Pharmacy Professionals

For all current and future applications, complaints, and disciplinary matters involving pharmacy professionals, the commission delegates all decisions related to non-routine applications, exception applications, reports, investigations, and case disposition to a panel of at least three commissioners. *See* RCW 18.130.050(18).

For all current and future applications, complaints, and disciplinary matters involving pharmacy professionals, the commission delegates a HLJ, designated by the secretary of health, to act as the presiding officer in any adjudicative proceeding to the extent authorized in the Commission's "Delegation and Authorization for Health Law Judges to Act as the Presiding Officer." *See* RCW 18.130.050(10).