

HOUSE BILL REPORT

ESSB 5271

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to protecting patients in facilities regulated by the department of health by establishing uniform enforcement tools.

Brief Description: Protecting patients in facilities regulated by the department of health by establishing uniform enforcement tools.

Sponsors: Senate Committee on Health & Long Term Care (originally sponsored by Senators Cleveland, Robinson, Kuderer, Nobles, Wellman and Wilson, C.; by request of Department of Health).

Brief History:

Committee Activity:

Health Care & Wellness: 2/16/24, 2/20/24 [DP].

Brief Summary of Engrossed Substitute Bill

- Establishes a uniform enforcement framework for health care facilities regulated by the Department of Health and for pharmacies and other licensees regulated by the Pharmacy Quality Assurance Commission.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass. Signed by 9 members: Representatives Riccelli, Chair; Bateman, Vice Chair; Bronoske, Davis, Macri, Orwall, Stonier, Thai and Tharinger.

Minority Report: Do not pass. Signed by 5 members: Representatives Schmick, Ranking Minority Member; Hutchins, Assistant Ranking Minority Member; Caldier, Graham and Maycumber.

Minority Report: Without recommendation. Signed by 2 members: Representatives Harris and Mosbrucker.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Staff: Emily Poole (786-7106).

Background:

Health Care Facilities Licensed by the Department of Health.

The Department of Health (DOH) licenses several types of health care facilities, including:

- acute care hospitals, which are hospitals that may offer inpatient services, outpatient services, continuous nursing services, pharmacy services, food services, and necessary ancillary services;
- psychiatric hospitals, which are hospitals caring for any person with mental illness or substance use disorder;
- birthing centers, which are facilities, not part of a hospital or in a hospital, that provide birthing support and services to low-risk maternity clients;
- in-home services agencies, which are licensed to administer or provide home health, home care, hospice services, or hospice care center services to individuals in a place of temporary or permanent residence;
- ambulatory surgical facilities, which are distinct entities that operate for the primary purpose of providing specialty or multispecialty outpatient surgical services in which patients are admitted to and discharged from the facility within 24 hours;
- private establishments, which include certain hospitals and other places receiving or caring for any person with mental illness or chemically dependent person, and which may include facilities that provide pediatric transitional care services;
- medical test sites, which are facilities that analyze materials derived from the human body for the purposes of health care, treatment, or screening; and
- behavioral health agencies, which are either certified or licensed by the DOH, and which may be certified to provide mental health, substance use disorder, problem gambling and gambling disorder services, or a combination of these types of services.

The DOH evaluates whether facilities are in compliance with applicable laws and rules and uses various enforcement mechanisms to address noncompliance, including denying, suspending, revoking, or modifying a license or provisional license. In certain circumstances, the DOH may also impose civil fines or require a facility to submit a plan of correction to address deficiencies.

Regulation of Psychiatric Hospitals and Acute Care Hospitals.

In 2020 the Legislature passed Substitute House Bill 2426, which created new enforcement tools that the DOH may use when a psychiatric hospital fails or refuses to comply with state licensing standards. In 2021 the Legislature passed Second Substitute House Bill 1148, which created similar enforcement tools for acute care hospitals.

If a licensed psychiatric hospital or acute care hospital fails or refuses to comply with state licensing standards, the DOH may take one or more of several actions, including:

- imposing reasonable conditions on a license or imposing a civil fine of up to \$10,000 per violation, with maximum total fines of \$1 million, if the psychiatric hospital or

- acute care hospital has been subject to multiple enforcement actions for the same or similar violation, has been given a previous statement of deficiency for the same or similar violation, or has failed to correct noncompliance by an agreed-upon date;
- imposing civil fines of up to \$10,000 for each day a person operates a psychiatric hospital without a valid license;
 - suspending a specific category or categories of services or care or recovery units within the acute care hospital by issuing a limited stop service if the DOH finds that noncompliance results in immediate jeopardy;
 - suspending the admission of a specific category or categories of patients to a licensed psychiatric hospital by imposing a limited stop placement if the DOH finds that noncompliance results in immediate jeopardy;
 - suspending new admissions to a licensed psychiatric hospital or acute care hospital by issuing a stop placement if the DOH finds that noncompliance results in immediate jeopardy and is not confined to a specific category of patient or area of the facility; or
 - suspending, revoking, or refusing to renew a license.

Pharmacy Quality Assurance Commission.

The Pharmacy Quality Assurance Commission (Commission) governs the denial of registration, licenses, and permits for the practice of pharmacy. The practice of pharmacy includes the practice of and responsibility for interpreting prescription orders, compounding and dispensing drugs, providing information on legend drugs, and participating in drug utilization reviews, among other activities. Entities and individuals licensed, permitted, or registered by the Commission include pharmacies, pharmacists, and manufacturers of drugs, drug samples, and poisons.

Discipline of Health Care Professionals.

Health care providers are licensed and regulated by the relevant disciplining authority for each health care profession. Under the Uniform Disciplinary Act (UDA), disciplining authorities have the authority to investigate all complaints or reports of unprofessional conduct. Upon a finding, after a hearing, that a license holder has committed unprofessional conduct, the disciplining authority is required to issue an order including appropriate sanctions.

Summary of Bill:

Definitions.

"Immediate jeopardy" is defined as a situation in which a health care facility's noncompliance with one or more statutory or regulatory requirements has placed the health and safety of patients in its care at risk for serious injury, serious harm, serious impairment, or death.

"Private establishment" is defined as every private, county, or municipal hospital, including public hospital districts, homes, behavioral health hospitals, residential treatment facilities,

or other places receiving or caring for any person with a behavioral health or substance use disorder, including facilities providing pediatric transitional care services. References to psychiatric hospitals are changed to refer to private establishments or behavioral health hospitals.

Regulation of Birthing Centers, In-Home Services Agencies, Behavioral Health Agencies, Ambulatory Surgical Facilities, Private Establishments, and Medical Test Sites.

When the DOH determines a birthing center, in-home services agency, behavioral health agency, ambulatory surgical facility, or private establishment has previously been subject to an enforcement action for the same or similar type of violation, has been given a previous statement of deficiency that included the same or similar type of violation, or failed to correct noncompliance with a statute or rule by an established date, the DOH may:

- impose reasonable conditions on a license, including correction, training, or hiring an approved consultant; or
- assess a civil fine of up to \$3,000 per violation on a birthing center, in-home services agency, or behavioral health agency, up to \$7,500 per violation on an ambulatory surgical facility, or up to \$10,000 per violation on a private establishment.

When the DOH determines a licensee's noncompliance results in immediate jeopardy, depending on the type of facility, the DOH may:

- suspend a specific category or categories of services as related to the facility's violation by imposing a limited stop service;
- suspend new admissions of a specific category or categories of patients as related to the violation by imposing a limited stop placement (only for a behavioral health agency or private establishment);
- suspend new admissions to the facility by imposing a stop placement, if the DOH finds that noncompliance is not confined to a specific category of patients or a specific area of the facility (not applicable to medical test sites); or
- impose conditions on a license.

When the DOH determines that a licensee's noncompliance results in immediate jeopardy, or that an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, the DOH may impose an immediate limited stop service, immediate limited stop placement, immediate stop placement, immediate suspension, or immediate imposition of conditions, as applicable.

Prior to imposing a limited stop service, limited stop placement, or stop placement, the DOH must provide the facility with written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The facility must have 24 hours to develop and implement an approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions are not verified by the DOH as having been corrected in the same 24-hour period, the DOH may issue a limited stop service or stop placement, as applicable. The limited stop service or stop placement is terminated when:

- the DOH verifies the violation has been corrected or that the facility has taken intermediate action to address the immediate jeopardy; and
- the facility establishes the ability to maintain correction of the violation previously found deficient.

As applicable, when the DOH imposes an immediate action, a licensee is entitled to a show cause hearing within 14 days of making the request. The licensee must request the show cause hearing within 28 days of receipt of the notice of an immediate action. The licensee may request an expedited full hearing on the merits of the DOH's action, which must be provided within 90 days of the licensee's request.

Injunctions.

The DOH may maintain an action for an injunction or other process against any person to restrain or prevent the advertisement, operation, maintenance, management, or opening of unlicensed birthing centers or medical test sites. The injunction does not relieve the person operating a facility without a license from criminal prosecution or the imposition of a civil fine. A person that violates the injunction must pay a civil penalty, as determined by the court, of not more than \$25,000.

Cease and Desist Notice.

The DOH may give written notice to cease and desist to any person whom the DOH has reason to believe is engaged in the unlicensed operation of a birthing center, private establishment, medical test site, in-home services agency, or ambulatory surgical facility. The DOH may assess a civil fine not exceeding \$5,000 for each day a person operates an unlicensed facility. Neither the issuance of a notice to cease and desist nor payment of a civil fine relieves an unlicensed facility from criminal prosecution.

Pharmacy Quality Assurance Commission.

The Commission may assess civil fines, deny an application for a license, or suspend, revoke, or modify an active license upon written notice. The Commission is authorized to take actions against licenses, registrations, permits, or other credentials or approvals in any case in which the Commission finds the licensee has failed or refused to comply with any statute or rule regulating the license. When the Commission determines a licensee has previously been subject to an enforcement action for the same or similar type of violation, has been given a previous statement of deficiency that included the same or similar type of violation, or failed to correct noncompliance by an established date, the Commission may impose reasonable conditions on a license or assess a civil fine of up to \$10,000 per violation.

When the Commission determines a licensee's noncompliance results in immediate jeopardy, or that an alleged violation, if true, would constitute immediate jeopardy, the Commission may impose the following, as applicable:

- conditions on a license;
- limited stop service;

- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding; or
- immediate limited stop service, immediate imposition of conditions, or immediate suspension, if the licensee fails to cooperate with the Commission's investigation.

Before or when imposing the above sanctions, the Commission must follow the same administrative procedures as those established for other health care facilities regulated by the DOH. A licensee whose license has been suspended may petition the Commission for reinstatement.

The UDA governs the unlicensed practice of those required to obtain a license, registration, or permit from the Commission.

The Commission is responsible for registering an applicant to dispense or conduct research with controlled substances, in addition to applicants to manufacture or distribute controlled substances.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) This bill protects patients by extending important enforcement tools to all facilities regulated by the DOH. The DOH currently has limited options for enforcement, and this bill will provide more appropriate ways of addressing repeat violations and unlicensed operations. This bill also gives the Commission the authority to regulate licensees more effectively. Current enforcement mechanisms are often too drastic for a specific violation. This bill will allow the Commission to hold entities responsible for their actions, instead of taking enforcement actions against individual practitioners. It is good that this bill includes staggered fines based on the size of the entity, and it also provides entities an opportunity to address a violation before a civil fine is issued.

(Opposed) None.

Persons Testifying: Jenny Arnold and Ken Kenyon, Washington State Pharmacy Association; and Ramiro Cantu, Department of Health.

Persons Signed In To Testify But Not Testifying: None.