

SENATE BILL REPORT

SB 5271

As Reported by Senate Committee On:
Health & Long Term Care, February 7, 2023

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: Senators Cleveland, Robinson, Kuderer, Nobles, Wellman and Wilson, C.; by request of Department of Health.

Brief History:

Committee Activity: Health & Long Term Care: 1/26/23, 2/07/23 [DPS-WM, w/oRec].

Brief Summary of First Substitute Bill

- Expands Department of Health enforcement actions against health care facilities.
- Expands Pharmacy Quality Assurance Commission enforcement actions against pharmacists.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5271 be substituted therefor, and the substitute bill do pass and be referred to Committee on Ways & Means.

Signed by Senators Cleveland, Chair; Robinson, Vice Chair; Muzzall, Assistant Ranking Member; Conway, Dhingra, Holy, Randall and Van De Wege.

Minority Report: That it be referred without recommendation.

Signed by Senators Rivers, Ranking Member; Padden.

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: Andie Parnell (786-7439)

Background: Sanctions for Health Care Facilities. The Department of Health (DOH) licenses several types of health care facilities, including hospitals, birthing centers, medical test sites, in-home services agencies, ambulatory surgical facilities, private establishments, and behavioral health agencies. If an inspection or survey identifies noncompliance with health care facility standards, DOH may require the facility to submit a plan of correction to address each of the deficiencies. DOH may also, for good cause, deny, suspend, revoke, or modify a license or provisional license.

DOH also evaluates whether facilities are complying with applicable laws and rules and uses enforcement tools to mitigate noncompliance. When DOH determines a facility has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, DOH may take the following actions:

- impose reasonable conditions on a license; or
- assess a civil fine per violation, based on facility type.

DOH may only use proceeds from these fines to provide technical assistance to facilities and to offset the cost of licensing activities.

Psychiatric Hospital Regulation. In 2020, the Legislature passed SHB 2426, which created new enforcement tools that DOH may use when a psychiatric hospital fails or refuses to comply with state licensing standards. Psychiatric hospitals are defined as hospitals caring for any person with mental illness or substance use disorder. The term does not include acute care hospitals, state psychiatric hospitals, or residential treatment facilities. If a licensed psychiatric hospital fails or refuses to comply with state licensing standards, DOH may take one or more of several actions. DOH may:

- impose reasonable conditions on a license or impose a civil fine up to \$10,000 per violation, with maximum total fines of \$1 million, if the psychiatric 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;
- impose civil fines up to \$10,000 for each day that a person operates a psychiatric hospital without a license;
- suspend, revoke, or refuse to renew a license;
- suspend the admission of a specific category or categories of patients by imposing a limited stop placement order if DOH finds the noncompliance results in immediate jeopardy; or
- suspend all new admissions to the facility by issuing a stop placement order if DOH finds the noncompliance results in immediate jeopardy and is not confined to a specific area of the hospital.

Acute Care Hospital Regulation. In 2021, the Legislature passed 2SHB 1148, which created

similar enforcement tools for acute care hospitals. Acute care hospitals are defined as hospitals that may offer inpatient services, outpatient services, continuous nursing services, pharmacy services, food services and necessary ancillary services. If a licensed acute care hospital fails or refuses to comply with state licensing standards, DOH may take one or more of several actions. DOH may:

- impose reasonable conditions on a license or impose a civil fine up to \$10,000 per violation, with maximum total fines of \$1 million, if the 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;
- impose civil fines up to \$10,000 for each day that a person operates an acute care hospital without a license;
- suspend, revoke, or refuse to renew a license;
- suspend a specific category or categories of services or care or recovery units within the hospital as related to the violation by issuing a limited stop service if DOH finds that noncompliance results in immediate jeopardy; or
- suspend all new admissions to the hospital by issuing a stop placement order if DOH finds the noncompliance results in immediate jeopardy and is not confined to a specific area of the hospital.

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, dispensing, labeling, administering, and distributing of drugs and devices;
- monitoring of drug therapy and use;
- initiating or modifying of drug therapy and use by practitioners authorized to prescribe drugs;
- participating in drug utilization reviews and drug product selection;
- proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; and
- providing information on legend drugs.

Uniform Disciplinary Act. The Uniform Disciplinary Act (UDA) is a standardized set of procedures for enforcing laws concerning licensure and misconduct of licensed health care professionals. The UDA includes the list of acts that constitute unprofessional conduct. All licensed health care professionals are subject to the UDA.

Summary of Bill (First Substitute): Immediate Jeopardy. 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. When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may:

- impose conditions on a license including correction within a specified amount of time, training, or hiring a DOH approved consultant if the facility cannot demonstrate to DOH that it has access to sufficient expertise;
- suspend a specific category or categories of services or care 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;
- suspend new admissions to the facility by imposing a stop placement, if DOH finds that noncompliance is not confined to a specific category or categories of patients or a specific area of the facility; or
- suspension, revocation, or refusal to renew a license and provides the right to an adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose immediate enforcement.

Prior to imposing a limited stop service, limited stop placement or stop placement, 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 from notification to develop and implement a DOH-approved plan to correct the deficient practices or conditions that constitute an immediate jeopardy. If the deficient practices or conditions are not verified by DOH as having been corrected in the same 24-hour period, DOH may issue a limited stop service or stop placement. DOH must conduct a follow-up inspection within five business days, or within the time period requested by the facility. The limited stop service or stop placement is terminated when:

- 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.

Birthing Centers. Birthing centers are facilities, not part of a hospital or in a hospital, that provides facilities and staff to support a birth service to low-risk maternity clients. A license approved by DOH is required to operate a birthing center.

When DOH determines a birthing center has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, DOH may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$3,000 per violation on a birthing center.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on a license;
- suspend a specific category or categories of services or birthing rooms within the birthing center as related to the violation by imposing a limited stop service;
- stop placement; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop, immediate stop placement, or immediate suspension.

Medical Test Sites. Medical test sites are facilities that analyze materials derived from the human body for the purposes of health care, treatment, or screening. A license approved by DOH is required to operate a medical test site.

DOH may place conditions on a license which limit or cancel a test site's authority to conduct any of the tests or groups of tests of any licensee who:

- fails or refuses to comply with DOH requirements, rules or standards, or other applicable state or federal statutes or rules regulating medical test sites;
- has knowingly made a statement of a material fact in the application for a license, in any data attached, or any record required by DOH;
- refuses to allow DOH representatives to examine any book, record, or file;
- willfully prevented, interfered with, or attempted to impede in any way the work of a DOH representative;
- willfully prevented, or interfered with preservation of evidence; or
- misrepresented, or was fraudulent, in any aspect of the licensee's business.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on a license;
- limited stop service; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop services or immediate suspension.

In-Home Services Agencies. In-home services agency is defined as a person licensed to administer or provide home health, home care, hospice services, or hospice care center services directly or through a contract arrangement to individuals in a place of temporary or permanent residence. A license approved by DOH is required to advertise, operate, manage, conduct, open, or maintain an in-home services agency.

When DOH determines an in-home services agency has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, DOH may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$3,000 per violation on an in-home services agency.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on a license;
- limited stop service;
- suspend new admissions to an in-home services agency that qualifies as a hospice care center by imposing a stop placement; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH imposes a stop placement, the hospice care center may not admit any new patients until the stop placement is terminated. When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop service, immediate stop placement, or immediate suspension.

Ambulatory Surgical Facilities. Ambulatory surgical facilities are any distinct entity that operates 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, and do not require inpatient hospitalization. A license approved by DOH is required to operate an ambulatory surgical facility.

When DOH determines an ambulatory surgical facility has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, DOH may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$7,500 per violation on an ambulatory surgical facility.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on a license;
- suspend a specific category and categories of services or care or operating rooms or recovery rooms within the ambulatory surgical facility as related to the violation by imposing a limited stop service;
- stop placement; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop service, immediate stop placement, or immediate suspension.

Private Establishments. Private establishments, include:

- every private or county or municipal hospital receiving or caring for any person with a behavioral health or substance use disorder; and
- facilities providing pediatric transitional care services.

DOH may at any time examine a licensed private establishment to determine whether it has failed or refused to comply with applicable requirements, standards, rules or statutes. When DOH determines a private establishment has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, DOH may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$10,000 per violation, not to exceed a total fine of \$1 million, on a private establishment.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on license;
- limited stop service;
- limited stop placement;
- stop placement; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop service, immediate limited stop placement, immediate stop placement, or immediate suspension.

Behavioral Health Agencies. A behavioral health agency is either certified or licensed by DOH. DOH must review reports or other information alleging failure of behavioral health agencies to comply with standards or rules and may initiate investigations and enforcement actions based on those reports. A behavioral health agency that fails to furnish any data, statistics, schedules, or information requested, or files fraudulent returns, may have their license or certification revoked or suspended.

When DOH determines a licensed or certified behavioral health agency has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an

agreed upon date, DOH may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$3,000 per violation on a licensed or certified behavioral health agency.

When DOH determines a licensee's noncompliance results in immediate jeopardy, DOH may impose the following:

- conditions on license;
- limited stop service;
- limited stop placement;
- stop placement; or
- suspension of a license effective immediately upon receipt of the notice by the licensee, pending adjudicative proceeding.

When DOH determines an alleged violation, if true, would constitute immediate jeopardy, and the licensee fails to cooperate with the DOH's investigation, DOH may impose an immediate limited stop service, immediate limited stop placement, immediate stop placement or immediate suspension.

Show Cause Hearing. As applicable, when DOH imposes an immediate action, a licensee is entitled to a show cause hearing before a presiding officer 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. At the show cause hearing, DOH has the burden of demonstrating that more than probably than not the alleged violation, if true, would constitute an immediate jeopardy. The presiding officer must provide the parties with an opportunity to provide documentary evidence and written testimony and to be represented by counsel. Prior to the show cause hearing, DOH must provide the licensee with all supporting documentation. If the presiding officer determines the alleged violation, if true, does not constitute immediate jeopardy, the presiding officer may overturn the action. If the presiding officer determines the allegation, if true, would constitute an immediate jeopardy, the immediate action shall remain in effect pending a full hearing. The licensee may request an expedited full hearing on the merits of DOH's action, which must be provided within 90 days of the licensee's request.

Injunctions. Upon the advice of the attorney general who shall represent DOH in all proceedings, 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 of operating a facility with a license from criminal prosecution or the imposition of a civil fine by DOH. 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. DOH may give written notice to cease and desist to any person whom DOH has reason to believe is engaged in the unlicensed operation of a private

establishment, birthing center, medical test site, in-home services agency, or ambulatory surgical facility. The requirement to cease and desist an unlicensed operation is effective 20 days after receipt of notice. DOH may make the date the action is effective sooner than 20 days after receipt when necessary to protect the public health, safety, or welfare. DOH may assess a civil fine not exceeding \$5,000 for each day a person operates an unlicensed facility. Neither the issuance of a cease and desist order nor payment of a civil fine would relieve an unlicensed facility from criminal prosecution.

Sanctions for Pharmacists. The UDA governs unlicensed practice of pharmacy of those required to obtain a license, registration or permit to practice.

The Commission governs the denial of licenses and discipline of licensees. The Commission may deny an application for license, or suspend, revoke, or modify an active license. The Commission must give written notice, and revocation, suspension and modification is effective 28 days after the licensee or the agent receives notice. The Commission must also give written notice when assessing a civil fine against a licensee or its agent. The civil fine is due and payable 28 days after receipt, and the licensee has the right to an adjudicative proceeding.

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 or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, the Commission may take the following actions:

- impose reasonable conditions on a license; or
- assess a civil fine per violation, not to exceed a total fine of \$1,000,000.

When the Commission determines a licensee has previously been subject to an enforcement action or given a previous notice of correction for the same or similar type of violation of the same statute or rule, or failed to correct noncompliance by an agreed upon date, the Commission may:

- impose reasonable conditions on a license, including correction, training or hiring; or
- assess a civil fine of up to \$10,000 per violation, not to exceed a total fine of \$1 million, on a licensee.

The Commission may only use proceeds from these civil fines to provide technical assistance to facilities and to offset the cost of licensing activities.

When the Commission determines a licensee's noncompliance results in immediate jeopardy, the Commission may impose the following:

- 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 stop placement, immediate limited stop service, immediate imposition of conditions or immediate suspension if the licensee fails to cooperate with investigation of alleged violation.

Prior to imposing a limited stop service or stop placement, the Commission must provide the licensee with written notification upon identifying deficient practices or conditions that constitute an immediate jeopardy. The licensee must have 24 hours from notification 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 Commission as having been corrected in the same 24-hour period, the Commission may issue a limited stop service or stop placement. The Commission must conduct a follow-up inspection within five business days, or within the time period requested by the licensee. The limited stop service or stop placement is terminated when:

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

In addition to any other grounds, the Commission may take action against a licensee, except nonresident pharmacies, upon proof that the licensee has:

- procured licensure through fraud, misrepresentation, or deceit;
- violated or has permitted any employee to violate any laws relating to drugs, controlled substances, cosmetics, or nonprescription drugs;
- violated any of the rules and regulations of the Commission; or
- been convicted of a felony.

EFFECT OF CHANGES MADE BY HEALTH & LONG TERM CARE COMMITTEE (First Substitute):

- Requires DOH to establish specific civil fine amounts for noncompliance based on the number of surgical procedures performed by an ambulatory surgical facility on an annual basis.
- Modifies the definition of technical assistance to apply to private establishments.
- Requires DOH to establish specific civil fine amounts for noncompliance based on the operation size of a pharmacy.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Original Bill: *The committee recommended a different version of the bill than what was heard.* PRO: The department lacks the intermediate enforcement tools as well as the authority to take swift action if a health care facility is out of compliance with the law. This bill gives the Pharmacy Quality Assurance Commission the authority to regulate pharmacy entities more effectively, including retail chains. Currently, the Commission can only revoke a location license, which is a nuclear option as it leaves patients instantly without access to pharmacy services.

OTHER: DOH rulemaking for ambulatory surgical facilities should differentiate between the sizes of facilities, so that a facility with one operating room is not treated equally to a facility with ten operating rooms. Consideration for the size of pharmacies is also necessary when addressing civil fine enforcement. By amending the term psychiatric hospital to private establishment in the definition of elopement, elopement would now apply to voluntary treatment programs. This is a problem because patients who are voluntarily admitted cannot elope, they simply self discharge when they leave. Requiring elopement for voluntary programs would infringe on the rights of the patients to leave the program. By amending the term technical assistance to apply to the regulation of behavioral health hospitals, instead of psychiatric hospitals, restricts technical assistance to other psychiatric facilities. Instead, technical assistance should apply to the regulation of private establishments.

Persons Testifying: PRO: Senator Annette Cleveland, Prime Sponsor; Jenny Arnold, Washington State Pharmacy Association; Ramiro Cantu, Washington State Department of Health.

OTHER: Roman Daniels-Brown, Washington Ambulatory Surgery Center Association; Cara Helmer, Washington State Hospital Association; Tom Russell, CEO, Daybreak Youth Services.

Persons Signed In To Testify But Not Testifying: No one.