Report to the Legislature



Prepared by the Health Systems Quality Assurance Division



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Executive Summary

<u>Substitute House Bill 2426</u> (Chapter 15, Laws of 2020) directed the Department of Health (department) to conduct a review of the statutes for health care facilities licensed by the department, and to identify opportunities to consolidate and standardize licensing and enforcement requirements. SHB 2426 further directed the department to work with stakeholders, and to create recommendations to share with stakeholders and the Washington State Legislature on a uniform health care facility enforcement act for the 2021 legislative session.

Due to the COVID-19 pandemic, the department was unable to convene stakeholders to the degree necessary during the spring and early summer of 2020 to have the in-depth discussions required to develop recommendations for a uniform facility enforcement act. As a result, this report serves as an interim progress report on the statutory review and captures the initial stakeholder conversations completed to date.

Variability exists in the enforcement actions available to the department across facility types as well as the circumstances under which enforcement action can be taken. While the department may suspend, revoke, or deny a license across all facility types, there is no consistency in other available actions.

The department researched various models of enforcement to inform future discussions of a uniform approach to facility enforcement. It reviewed enforcement statutes for long-term care facilities in Washington (regulated by the Department of Social and Health Services), analyzed health care facility enforcement statutes for 14 other states, and reviewed Washington's Uniform Disciplinary Act (UDA). The department found that eight of the 14 states have a uniform statute. All 14 states had progressive enforcement options (e.g., fines or conditions on a license) that extended beyond the authority to suspend, revoke, or deny a license. There was similarity, though not consistency, in tools available for enforcement in Washington-licensed nursing homes, assisted living facilities, and adult family homes. Finally, it was noted that the legislature has already acted to create a common disciplinary framework for health care providers by creating a UDA that covers all 85 health professions regulated by the department, and profession-specific board and commissions.

The department met with stakeholders in August to provide an overview of the legislative direction, to review the statutory research conducted, and to seek input on the concept of a uniform approach to health care facility enforcement. Stakeholders identified potential benefits to greater uniformity across facility types, but also raised several concerns. The department will reconvene stakeholders in spring of 2021 to continue these discussions and to report recommendations to the legislature by the end of the year.

Introduction

The Department of Health works with others to protect and improve the health of all people in Washington state. In the Health Systems Quality Assurance Division, its mission is to protect patient safety through the licensure and regulatory oversight of health care providers and health care facilities.

During the 2020 session, the legislature passed SHB 2426, an act relating to protecting patient safety in psychiatric hospitals and other health care facilities. This was department-request legislation that provided the department with stronger enforcement authority and additional, progressive enforcement tools for psychiatric hospitals licensed under chapter 71.12 RCW.

The bill also directed the department to conduct a review of statutes for health care facility types the department regulates to evaluate appropriate levels of oversight, and to identify opportunities to consolidate and standardize licensing and enforcement requirements across facility types. The department was further directed to work with stakeholders to develop recommendations to the legislature for a uniform facility enforcement act.

Due to the COVID-19 pandemic, the department was not able to convene stakeholders to the degree necessary during the spring and early summer to develop recommendations for uniform facility enforcement act for the 2021 legislative session. At that time, the department and the health care system were focused intensively on the pandemic emergency response, preparing for a health care surge, and responding to the rapid rise in COVID-19 cases. However, the department held a stakeholder meeting on August 20, 2020 to initiate discussions about legislative recommendations for a uniform facility enforcement act.

This report will address research the department has conducted on health care facility enforcement. It will provide a summary of the initial stakeholder meeting. The department will reconvene stakeholders following the 2021 legislative session to discuss recommendations for a Uniform Facility Enforcement Act and will submit a follow up report to the legislature by December 31, 2021.

Background

The department licenses childbirth centers (chapter 18.46 RCW), pharmacies and other pharmacy-related facilities (chapter 18.64 RCW), hospitals (chapter 70.41 RCW), medical test sites (MTS) (chapter 70.42 RCW), in-home service agencies (chapter 70.127 RCW), ambulatory surgical facilities (ASF) (chapter 70.230 RCW), private establishments (psychiatric hospitals and residential treatment facilities - chapter 71.12 RCW), and behavioral health agencies (BHA) (chapter 71.12 RCW), including those that provide outpatient, inpatient, and involuntary treatment services.

The Pharmacy Quality Assurance Commission (commission) has regulatory authority over the licenses issued under chapter 18.64 RCW, including retail and hospital pharmacies, health care entities, hospital pharmacy-associated clinics, manufacturers, wholesalers, and nonresident pharmacies.

Inspection, Complaint and Investigation Process

The department conducts inspections and investigations of health care facilities. Inspections, sometimes referred to as surveys, are unannounced, onsite visits done routinely based on a frequency that may be identified in statute or rule. Investigations may be conducted in response to a complaint alleging patient safety concerns or violations of a rule or statute.

Inspection

When inspecting onsite, the Department's inspector surveys the entire facility noting any deficiencies. When the inspection is complete, the inspector may conduct an exit conference with facility representatives to provide a preliminary overview of deficiencies noted during the inspection. Written notice of any deficiencies is later provided to the facility in the form of a statement of deficiencies (SOD) following the onsite inspection. The SOD details all deficiencies identified during the survey. An overview of the process is:

- A SOD is provided to a facility within 10 business days following the inspection.
- A facility has 10 calendar days to submit a plan of correction (POC) to the department explaining how the facility will address each deficiency identified in the SOD.
- The department reviews the POC to determine if it adequately addresses all the deficiencies. When a POC is approved, the inspection is closed.
- Based on the severity of the deficiencies, the department may conduct a follow-up inspection to ensure the POC has been implemented.
- If the facility is unable to provide the department with a POC that adequately addresses the deficiencies, the matter is brought to a case management team (CMT) to consider next steps, which could include authorizing an enforcement action.

The available enforcement actions are explained in the next section.

Investigation

The department may investigate a facility after it receives a report that alleges a facility violated applicable law. Anyone may submit a report to the department. A department CMT reviews every report to decide if it should be investigated. A report that the department authorizes for investigation is called a complaint. A department investigator goes to the facility to investigate the violation(s) alleged in the complaint. A complaint could result in issuing a SOD if the department substantiates the allegations in the complaint. When a SOD is issued, the department uses the same deficiency resolution process as it does for inspections, described above. However, the department may not issue a SOD when it substantiates a complaint if it verifies that the facility has already addressed the deficiency.

Immediate Actions

During an onsite survey, an inspector or investigator could identify a deficient practice that creates an immediate risk to public health, safety or welfare. When this occurs, the inspector or investigator may pause the survey and consult with their manager and a case management team to decide if the deficiency must be addressed on a more expedited basis than usual. If the manager, CMT, and the inspector/investigator agree there is an immediate risk, the department may issue a notice of immediate risk. This notice directs the facility to address the imminently dangerous deficient practice expeditiously. The amount of time the facility has to correct the immediately risky deficiency depends on the deficiency, but it is generally five days or less. The department may authorize a notice of intent of formal enforcement if the facility cannot address the imminently dangerous deficient practice in five days or less.

The kinds of enforcement action the department may take can differ, depending on the type of facility (e.g. the department has different enforcement options for psychiatric hospitals than it does for acute care hospitals).

The notice of intent is effective 28 days after it is received by the facility, but it can take effect sooner if the risk is severe enough.² However, in general, if a facility requests an adjudicative proceeding, implementation of the enforcement action is placed on hold until after a hearing occurs or the facility and the department enter into an agreed order.

acting as a contractor for the federal government. When an inspector or investigator finds a situation that poses immediate jeopardy to the health and safety of patients in a

CMS-certified facility, they may issue an "immediate jeopardy" finding which places the facility on a 45-day termination track for CMS reimbursement. Enforcement actions

taken by CMS are not addressed in this report since the focus is on state regulatory authority.

¹ The department also conducts inspections and complaint investigations of facilities certified by the Centers for Medicare and Medicaid (CMS),

Current Enforcement Actions for Health Care Facilities

The department conducted a review of the health care facility statutes listed in SHB 2426 to identify the current enforcement options for each type of facility, as well as the circumstances under which enforcement action may be taken. It found that enforcement options vary, sometimes substantially, across facility types. A detailed matrix comparing these enforcement tools is in Appendix A.

The department may take enforcement action against all facilities under its jurisdiction for failure to comply with the laws or rules established in the chapter under which the facility is licensed.³ The enforcement actions common to all facility types include the authority to deny, suspend, modify, or revoke a license. RCW 43.70.115 requires the department to provide written notice to the applicant of denial of an application or written notice to the licensee or its agent for suspension, modification, or revocation of a license. A suspension, modification, or revocation is effective 28 days after receipt of the notice. A licensee may appeal an enforcement action taken by the department under the Administrative Procedures Act, chapter 34.05 RCW, which generally delays implementation of the enforcement action until after a hearing.

As shown in Table 1, the department has additional authority to take intermediate enforcement actions, although this authority varies across facility types.

The department has the authority to place conditions or modifications on a license for most facility types. While the department has this authority, it is not generally used as an initial enforcement action. This is largely because modification or condition is undefined in statute. The department's use of modifications or conditions typically occurs through an agreed order. Some examples of a modification or condition on a license include hiring of a third-party consultant, additional unannounced surveys within a specified period, limitations on performing certain services, or increased reporting requirements to the department.

Fines and civil penalties are an enforcement option for some types of facilities (ASFs, MTS, inhome service agencies, and non-resident pharmacies). A fine of \$250 can also be charged to an ASF for a failure to report a restriction, suspension, limitation, or termination of a health care provider.⁴

In a few instances, the department can issue a notice of intent to issue a cease-and-desist order for the unlicensed operation of a facility. The order is then signed and issued by a department health law judge (in-home service agencies and ASFs).

70.42.120, RCW 70.42.130, RCW 70.42.140, RCW 70.42.150, RCW

70.42.160, RCW 70.127.170, RCW 70.230.070, RCW 71.12.590, RCW 71.24.037 ⁴ RCW 70.230.120

³ RCW 18.46.050, RCW 18.64.165, RCW 70.41.130, RCW

With the passage of SHB 2426, the department has additional authority for psychiatric hospitals to impose an immediate stop placement (i.e., halting new admissions of all or a certain class of patients) and, in limited circumstances, an immediate suspension of a license.

Table 1: Comparison of Enforcement Actions⁵



The department or the commission can take enforcement action on a MTS, in-home service agency, ASF, and pharmacy-related license if it was procured through fraud, misrepresentation, or deceit.⁶

The commission can also impose fines on a nonresident pharmacy for failure to comply with applicable laws, or when conduct causes serious bodily or psychological injury to a resident of this state.⁷

The department can take additional types of enforcement actions on MTS and in-home service agencies under certain circumstances. This includes a licensee refusing or interfering with a department inspection or investigation. The department can also take action against MTS for false advertising, failing to pay a penalty, and operating without a license. There are 25 specific circumstances in which action can be taken against an in-home service agencies (RCW 70.127.170).

⁵ See Appendix A for additional 70.42.130, RCW 70.42.140, RCW information and citations 70.42.150, RCW 70.42.160, RCW 70.230.070 70.230.070 7 RCW 18.64.390 70.42.120, RCW	⁸ RCW 70.42.120, RCW 70.42.130, RCW 70.42.140, RCW 70.42.150, RCW 70.42.160, RCW 70.127.170	⁹ RCW 70.42.120, RCW 70.42.130, RCW 70.42.140, RCW 70.42.150, RCW 70.42.160
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Research

The department researched enforcement laws for long-term care facilities in Washington along with a review of current statutes for health care facilities it regulates. The department also conducted an analysis of health care facility licensing and enforcement laws in 14 other states. Finally, the department considered Washington's Uniform Disciplinary Act (chapter 18.130 RCW) as a framework for a uniform approach to regulatory compliance.

Long-Term Care Facilities

The department reviewed statutes for three long-term care facility types regulated by the Department of Social and Health Services (DSHS): assisted living facilities (chapter 18.20 RCW), nursing homes (chapter 18.51 RCW), and adult family homes (chapter 70.128 RCW). These were chosen because they provide similar patient/resident/client care services as those the department regulates and because they may employ health care professionals licensed by the department.

Table 2: DSHS Enforcement Authority¹⁰

Nursing Homes (RCW 18.51.060 & .065)	Assisted Living Facilities (RCW 18.20.190)	Adult Family Homes (RCW 70.128.100 & .160)
Suspend, revoke, deny	Suspend, revoke, deny	Suspend, revoke, deny
	Conditions on a license	Conditions on a license
Stop placement	Stop placement Limited stop placement	Stop placement Limited stop placement
Fines	Fines	Fines
Deny Medicaid payment		
Appoint temporary management		

DSHS may suspend, revoke, refuse to renew, issue a stop placement or limited stop placement, place conditions, and impose civil monetary penalties on the license of assisted living facilities, supported living certifications, nursing homes and adult family homes. In addition, nursing homes can be denied Medicaid payments and have temporary management and/or court

¹⁰ This table provides an overview of the facility types that the

appointed receivership imposed. Assisted living facilities, and adult family homes can have reasonable conditions imposed on their license. 11

The circumstances under which these actions may be taken vary based on facility type. DSHS may take action against these facilities for a failure to comply with the laws and rules established by or under their respective chapters, operating without a license, making a false statement on an application or in an investigation, or willfully preventing or interfering with an inspection, evaluation, or investigation.¹²

In addition, DSHS must issue a stop placement effective upon notice when a nursing home no longer substantially meets the requirements of chapter 18.51 or 74.42 RCW or, for Medicaid contractors, Title XIX of the Social Security Act, and the deficiencies jeopardize the health and safety of the patients/residents/clients or limit their ability to provide care. The stop placement is not delayed or suspended because of the request for a hearing. If DSHS determines there is an emergency or an immediate jeopardy to the health and safety of the residents/clients, DSHS may immediately close and transfer patients/residents/clients or appoint temporary management and/or court-appointed receivership. 13

14 State Survey Licensed Health Care Facilities

The department reviewed health care facility laws for 14 other states. The facility types reviewed varied depending on each state's specific authority, but usually included at least hospitals, various types of behavioral health facilities, and ambulatory surgical centers. These 14 states were chosen due to their comparable population size to Washington or due a similarity between the type of facilities that they regulate. The matrix in Table 3 identifies whether a state has a "uniform act" and what enforcement actions can be taken by the regulatory entity. Uniform act means the regulatory body for health care facilities has common enforcement provisions that apply to various facility types under its jurisdiction.

Table 3: Summary of 14-State Review¹⁴

Summary of 14-State Review									
	Uniform Act	Suspend, Revoke, Deny	Suspend or Limit Admissions	Modification/ Conditions	Immediate Action	Cost Covering	Fines	Provisional License	
Colorado	Х	Χ		X		Χ	Χ	Χ	
Florida	Х	Χ	Х	Χ	Χ	Χ	Χ	X	
Idaho		Х					Х		
Illinois		Χ			Χ		X		
Iowa		Χ		Χ					
Massachusetts		Х	X	Х			Х		
Minnesota	Х	Х		Х		Χ	X		
Montana	Х	Χ	Х	X			X	X	
New Jersey	Х	Χ	Х	X	Χ		X	X	
North Carolina		Х	Χ	X	X		X	X	
Oregon	Х	Х	Х			Χ	X		
Tennessee	Х	Х	Х	X		Χ	X	X	
Utah	Х	Х	Χ	X	Χ	Χ	X	X	
Virginia		Х		X			X		

The 14 states reviewed were Colorado, Florida, Idaho, Illinois, Iowa, Massachusetts, Minnesota, Montana, New Jersey, North Carolina, Oregon, Tennessee, Utah, and Virginia. Of the 14 states reviewed:

- all can suspend, revoke or deny a license,
- 13 can issue fines,
- 11 can place modifications or conditions on a license,
- eight can suspend or limit patient admissions,
- eight have uniform enforcement acts,
- seven can issue a provisional license,
- six have the ability to charge facilities for certain compliance costs, and
- five can take immediate action pending a hearing.

Appendix B provides a summary of each state's enforcement actions. Examples of the types of actions available to other states are shown below.

¹⁴ See Appendix B for detailed explanation and specific citations.

Suspensions or Limiting Admissions

- Florida can impose an immediate moratorium on elective admissions to a facility when it presents a threat to public health or safety. 15
- Massachusetts can revoke specific parts of a hospital license, limiting admissions to certain units.16
- Montana can take administrative enforcement action including ceasing new admissions or relocating residents.¹⁷
- New Jersey, in addition to being able to curtail admissions to a facility, can withhold authorization of additional beds or services. 18
- North Carolina can suspend admissions of new patients or suspend specific services. When admissions are suspended the North Carolina Department of Health must provide consultation to correct the conditions that led to the suspension. 19
- Tennessee can impose a suspension of admissions, but a special monitor must be appointed, and the facility is responsible for the cost of the special monitor.²⁰

Modifications or Conditions

- Montana can have a receiver appointed by the court to take over management of the facility if there is an immediate and serious threat to the health and safety of patients.²¹
- New Jersey can appoint a receiver or other temporary management for violations of licensure regulations or other statutory requirements.²²
- Virginia can use administrative sanctions or initiations of court proceedings to ensure prompt correction of violations.²³

Immediate Action

- Illinois can immediately close a facility when the inspector determines that the continued operation of a facility constitutes an imminent and serious risk to the health or safety of the patients.²⁴
- New Jersey can issue a summary suspension that takes effect immediately; the facility is provided 72 hours to correct the violations.²⁵
- Utah can immediately close a facility if it is found that conditions represent a clear hazard to public health.²⁶

MGLA 111D §11; 105 CMR 130.130

¹⁵ F.S.A. §395.1065 ¹⁶ MGLA 111 §57D;

¹⁷ M.C.A 50-5-114

¹⁸ N.J.A.C. 8:43E-3.1, 8.43E-3.8

¹⁹ NC ST § 131E-78

²⁰ TN ST §68-11-221 ²¹ M.C.A 50-5-115

²² N.J.A.C. § 8:43E-3.1

²³ VA ST § 32.1-127.01

²⁴ 210 ILCS 5/9a

²⁵ N.J.A.C. § 8:43E-3.8

²⁶ UT ST §26-21-14

Cost Covering

- Florida inspects and investigates facilities for initial licensure as well as for "life safety" and charges a separate fee for these inspections.²⁷
- Oregon may charge a hospital a fee for additional surveys or investigations.²⁸
- Tennessee and Utah both can require special monitors be placed to oversee a facility coming back in compliance, and the cost of the monitor is to be borne by the facility.²⁹

Fines

Most states can issue fines, including the ability to issue fines for the unlicensed operation of a facility. In addition;

- Illinois may impose penalties on facilities for violations as well as for a failure to report patient deaths.30
- Massachusetts specifies that fines are based on a per violation per day.³¹
- Minnesota can charge a fine of \$1,000 for each deficiency not corrected after the facility is issued a statement of deficiencies.³²

Provisional License

Provisional/conditional licenses are used in several states. Some states use them to allow a new facility to begin operation without being fully compliant. Others use it as an intermediary step to allow a facility to come into compliance before moving to suspend or revoke the license.

- Colorado has the authority to issue a provisional license instead of a regular license when a health care entity fails to fully conform to the applicable statutes and regulations, but it is determined that the entity is making a substantial good faith attempt to comply. The license is good for 90 days and can be renewed once. 33
- Iowa allows for the conditional operation of no more than a year while a facility addresses issues that led to its noncompliance. This can be done as an alternative to other enforcement actions. If the licensee does not make diligent efforts to come into compliance, then the license can be suspended or revoked.³⁴
- Montana may issue a provisional license for less than one year of operation if it will not result in undue harm.35
- New Jersey may reduce a license to a provisional status. When a facility is on a provisional license status the department must withhold authorization of additional beds or services, notify the Certificate of Need Program (which may result in withholding of approval or denial), and notify any public agency that provides funding to the facility.³⁶
- Utah may issue a provisional or conditional license that is in substantial compliance if the interests of the public will not be jeopardized.³⁷

³³ 6 CCR1011-1:2-2.5

³⁶ N.J.A.C. § 8:43E-3.10

37 UT ST §26-21-13

^{30 210} ILCS 5/10d; 210

ILCS 85/7

³¹ MGLA 111 §51G(6)

ST §26-21-11

³⁴ I.C.A. 135C.12 ³⁵ M.C.A. 50-5-207

Uniform Disciplinary Act

The department also reviewed the Uniform Disciplinary Act (UDA),³⁸ which covers all 85 health professions licensed by the department, boards, and commissions, as an existing model for a uniform approach to regulatory compliance.

Before the passage of UDA in 1984, each profession had its own procedures and acts that constituted unprofessional conduct. This led to inconsistency across how disciplinary actions were taken and what constituted a violation. For example, a discipline case could be reviewed and decided by a single person for one profession and four people for another profession. Some professions would take an informal route for discipline, not noting any actions or discipline in the provider's record, while others would take a formal route, for example, revoking a license. Without uniform standards for unprofessional conduct, an act done by one professional could result in discipline but not if the same act was done by a differently credentialed person.

The UDA was passed with the express legislative intent to strengthen and consolidate disciplinary and licensure procedures for licensed health professions. The UDA further provides that all new health professions fall under it, ensuring that no new profession can be created and disciplined in a vacuum separate from all other health professions³⁹

The UDA provides clear authority, enforcement actions, and procedures for taking disciplinary actions. It also clearly defines what is considered unprofessional conduct (e.g. violations of state or federal laws, failure to cooperate with the disciplining authority, and misuse of substances) and applies that standard across professions. This ensures there are minimum standards to which every health professional, regardless of scope, is held..⁴⁰

The UDA also directs the department to create uniform procedural rules⁴¹, and directs the secretary of health to review and coordinate rules for any health profession board or commission.⁴² This ensures uniformity and consistency in rule as well.

The department regulates 85 health care professions. These professions range in their scope of practice but the disciplinary actions that can be taken all fall under the UDA. This provides for equity across professions. Regardless of the profession, each licensee is subject to the same enforcement actions and the same appeal process. The department also has clear processes, with progressive steps and sanctioning schedules, to follow in order to take disciplinary action.⁴³

⁴² RCW 18.130.065

⁴³ WAC 246-16-800 through WAC 246-16-890

³⁸ RCW 18.130

³⁹ RCW 18.130.010

⁴⁰ RCW 18.130.180

⁴¹ RCW 18.130.095

The UDA provides the department with the authority to;

- grant or deny a license,
- revoke or suspend a license,
- restrict or limit practice,
- require completion of remedial education,
- monitor practice,
- censure,
- impose conditions of probation,
- issue fines,
- require correction actions, or
- allow the surrender of a license in lieu of other sanctions.⁴⁴

All costs associated with compliance of the orders are the responsibility of the license holder.⁴⁵ These actions are governed by <u>chapter 34.05 RCW</u>.

The UDA also allows for alternatives to formal action, as well as the ability to summarily (immediately) suspend or restrict a license. The language used in SHB 2426 mirrored the show cause process for the immediate suspension of a license. 46

Stakeholder Engagement

The department hosted a stakeholder meeting on August 20, 2020 to present the information contained in this report, including background information on SHB 2426, the review of current statutes, and the additional research conducted by the department. The meeting included representatives from the various facility types this review affects. Stakeholders were asked several questions to gain their insight on the project.

What should we be paying attention to as we start this project?

Stakeholders stated that as the department takes on this project, we need to recognize the difference between the need for SHB 2426 and this project. Most facilities are doing a good job, and if the department is going to move toward more enforcement, then there needs to be a balance between enforcement and technical assistance.

Stakeholders asked that there be continued stakeholder engagement, as this is a complex issue with a lot of facilities. Stakeholders asked that the department and stakeholders review and understand all intended and unintended consequences.

They also asked that as the department moves forward, that there be transparency about expectations, and recognition of the department's role in helping facilities to be

⁴⁴ RCW 18.130.050, RCW 18.130.055

⁴⁵ RCW 18.130.160

⁴⁶ RCW 71.12.710

successful. They also asked that the department be aware of the increased costs that could come with increased inspections and enforcement actions.

What are the benefits of consistent facility regulation policies?

Stakeholders said that with the same standards for enforcement actions, licensees would know the expectations and there would be standardized expectations for patient care. Health care can be very complex, and health systems can own and operate multiple facility types. Having a common approach across facility types would help with compliance. Having more tools and a range of enforcement options could help encourage compliance, could be a benefit for staff members who are providing technical assistance for multiple programs, and could streamline the process of facility inspections. In turn this could make it easier for a facility to achieve compliance.

Are there areas where differentiation is necessary or good?

Stakeholders said the department needs to recognize that there may not be a one-size-fits-all model. For example, psychiatric hospitals are different from acute care hospitals, and birth centers are different from hospitals with birthing units.

There are different facility types with varying scopes of practice, and uniformity may not necessarily apply.

What are your hopes and fears about this effort?

As the department moves forward, stakeholders said we need to keep in mind the problem we are trying to address, and challenged us to consider whether we are trying to fix something that is not broken.

They indicated concerns about the regulatory and financial burden that could be borne by the smaller facility types, especially the cost to licensees when the department acts on unlicensed operations. They said we also need to recognize that smaller facilities do not have the legal resources as some of the larger facilities, and increased enforcement could disproportionately affect them.

Stakeholders hope that any uniform act would lead to increased transparency about what would lead to a statement of deficiency versus an enforcement action. If the department is going to use more enforcement tools, then there needs to be consistency around inspections.

Stakeholders also hope that the department will continue to have a strong consulting role, educating and advising so that a licensee can be successful.

Finally, stakeholders hope that there would be an appeals process when the facility does not agree with the action taken by the department.

Conclusion and Next Steps

The review of health care facility enforcement laws conducted by the department shows the current variability in available enforcement actions, as well as circumstances in which action can be taken. Long-term care facilities in Washington have a more similar (although not uniform) enforcement framework, and a broader array of enforcement tools than many facility types regulated by the department. More than half of the states included in this review have uniform laws governing health care facility enforcement. All 14 states reviewed have the authority to take progressive enforcement action (e.g., fines, limitations on admissions) in addition to the ability to suspend, revoke, or deny a license.

Discussion with health care facility stakeholders revealed they see benefits to a uniform approach to enforcement, but also some risks. The types of health care facilities regulated by the department vary in size and type of services delivered. We must give careful consideration to these differences, the effect of potential changes on cost to licensees, and the need to maintain technical assistance to support licensee compliance.

Over the coming year, the department will continue discussions with stakeholders about the concept of a uniform approach to health care facility enforcement, and will develop legislative recommendations. The department will report these recommendations to the legislature by December 31, 2021.

Appendix A – DOH Current State Enforcement Matrix

RCW	WAC	License Type	Available Action	Deny	Suspend	Revoke	Modify/ Conditions	Fines
18.46.050	246-329	Birthing Centers	deny suspend revoke	Х	X	Х		
<u>18.64.165</u>	246-945-005	manufacturer wholesaler pharmacy shopkeeper itinerant vendor peddler poison distributor health care entity precursor chemical distributor	Refuse Suspend revoke	X	х	х		
18.64.390	246-945-005	Nonresident Pharmacy	deny suspend revoke fine \$1000 per violation	Х	X	Х		X
70.41.130	246-320-011	Hospital	deny suspend revoke modify a license	Х	X	X	Х	
70.41.425	-	Hospital - Nurse Staffing	civil penalty of \$100 per day					Х
70.42.120	246-338-100	Medical Test Site	Deny	Х				
70.42.130	246-338-100	Medical Test Site	Conditions				Х	
70.42.140	246-338-100	Medical Test Site	Suspend		Χ			
70.42.150	246-338-100	Medical Test Site	Revoke			Χ		
70.42.160	246-338-100	Medical Test Site	Penalties - \$10,000 per violation in addition or in lieu of other actions					X
-	246-338-050	Medical Test Site	Discontinue certain testing & POC				Х	

RCW	WAC	License Type	Available Action	Deny	Suspend	Revoke	Modify/ Conditions	Fines
70.127.170	246-335-345	In-Home Service Agencies	deny restrict condition modify suspend revoke Penalties - \$1000 per violation Request refund	X	X	X	X	X
70.127.200	<u>N/A</u>	Unlicensed In- Home	injunction					
70.127.213	<u>N/A</u>	Unlicensed In- Home	cease and desist					
70.230.070	246-330-020	Ambulatory Surgical Facilities	Deny Suspend Revoke Cease & Desist Penalties - \$1000 per violation	х	х	х	X	х
-	246-330-030	ASF - Cease and Desist Operating without a license						
71.12.500	-	Private Establishments	Suspend Modify Revoke		X	X	X	
71.12.590	-	Private Establishments	Revoke			Χ		
71.12.595	-	Private Establishments	Suspend		X			
-	<u>246-322-025</u>	Psychiatric Hospitals			Summarily Suspend			
-	246-324-020	Chemical Dependency/Alcoh ol			Summarily Suspend			
-	246-337-021	Residential Treatment Facility			Summarily Suspend			
71.24.037	<u>246-341-</u> <u>0335</u>	Behavioral Health Agency	Suspend Modify Limit Restrict Refuse to approve Revoke	X	X		X	

Appendix B – Detailed Summary of 14 State Review

Colorado does not have an explicit uniform act; however, it does have a general power and duties of the department statute that covers all facilities. This statute includes the authority to enforce standards for all health care facilities, including "other facilities of a like nature, except those wholly owned and operated by any governmental unit or agency."⁴⁷ The Colorado Department of Public Health and Environment conducts announced and unannounced surveys, and can issue a suspension, revocation, annulment or modification of license. 48 It also has the authority to issue a provisional license when a health care entity fails to fully conform to the applicable statutes and regulations but the Colorado Department of Public Health and Environment determines the entity is making a substantial good faith attempt to comply.⁴⁹

Florida has a uniform enforcement authority statute, which grants the Florida Department of Health the authority to enforce rules for the protection of public health.⁵⁰ The Agency for Health Care Administration, within the department, can deny, modify, suspend or revoke a license whenever the agency finds there has been a substantial failure to comply with the laws or rules established by the chapter.⁵¹ The agency inspects and investigates facilities for initial licensure as well as for life safety, and charges a fee for these inspections.⁵² The agency is given general enforcement authority to adopt rules establishing the reasonable and fair minimum standards.⁵³ A fine can be assessed for operating a facility without a license, for violations of the laws or rules established by the chapter, or for failing to provide information. The agency may also impose an immediate moratorium on elective admissions to a facility when it presents a threat to public health or safety.⁵⁴

Idaho regulates various health care facilities, but it does not have a uniform statute. All facilities are regulated under Title 39 Health and Safety Hospitals but the facility-specific laws are under individual chapters within the title. The licensing agency can deny or revoke any license when conditions exist that endanger the health or safety of any resident.⁵⁵ The licensing agency can issue a fine for the unlicensed operation of a facility.⁵⁶

Illinois regulates a variety of health care facilities but does not have a uniform statute. The Department of Public Health conducts inspections and investigations of the facilities it regulates. When the inspector determines that the continued operation of a facility constitutes an imminent and serious risk to the health or safety of the patients, the inspector is authorized to immediately close the facility.⁵⁷ The department must implement a reviewer performance improvement program for survey staff as well as implement continuing education programs.⁵⁸

⁴⁷ § 25-1.5-103(1)(a)(I)(A) ⁴⁸ § 25-1.5-103

⁵⁰ F.S.A. §381.0012 ⁵¹ F.S.A. §395.003 ⁵² F.S.A. §395.0161 ⁴⁹ 6 CCR1011-1:2-2.5

⁵⁴ F.S.A. §395.1065 ⁵⁵ I.C. §39-1306; I.C.

⁵⁷ 210 ILCS 5/9a 58 210 ILCS 85/9.5

The department may deny, suspend or revoke a license.⁵⁹ The department may also impose penalties on facilities for violations as well as for a failure to report patient deaths.⁶⁰

lowa regulates health care facilities including hospitals. Health care facilities are covered under <u>Chapter 135C</u>, hospitals under <u>Chapter 51</u>, and both are overseen by the Department of Inspections and Appeals. Health care facilities and hospitals can have their licenses denied, suspended, or revoked in any case where there has been a repeated failure to comply with the laws and rules established by the chapter. As an alternative to these actions the department may allow for the conditional operation for no more than a year while a facility addresses the issues.

Massachusetts Department of Public Health regulates numerous health care facilities but does not have a uniform statute. Enforcement options vary depending on the facility type but the ability to suspend, revoke or refuse to renew for cause applies to them all. In addition, hospitals can have specific parts of their license revoked. ⁶³ If a violation of law poses an imminent risk to the safety or proper care of patients, the license or specific admissions on a license can be suspended immediately upon issuance. ⁶⁴ The department may assess fines for deficiencies that are not corrected within a specified time. The fine is based on per deficiency and per day. ⁶⁵ Fines may also be assessed for the unlicensed operation of a facility. ⁶⁶

The Minnesota State Department of Health regulates hospitals, sanitariums, and "other institutions for the ... care of human beings." ⁶⁷ A uniform enforcement statute provides the rules, inspections and enforcement requirements for health care facilities. When deficiencies are found during an inspection the department will issue a correction order. If a deficiency remains uncorrected the department can charge a fine of \$1,000 for each deficiency not corrected. ⁶⁸ A license can also be denied, revoked, suspended, or not renewed. ⁶⁹ The Office of Health Facility Complaints is within the department to handle all complaints and investigations. ⁷⁰

The Montana Department of Public Health and Human Services regulates "any facility covered under chapter 5..." providing for a uniform enforcement statute.⁷¹ The department can bring an action for injunction against a facility.⁷² When the department finds that a facility has violated the provisions of the chapters, it can impose a civil penalty.⁷³ The department can also take administrative enforcement, which includes a notice to take necessary corrective action, including ceasing new admissions, relocating residents, or ceasing the violation within a reasonable period of time stated in the order.⁷⁴ If the department believes there is an immediate and serious threat to the health and safety of patients, a receiver may be appointed by the court.⁷⁵ The department may issue a provisional

135B.6

⁶² I.C.A. 135C.12 ⁶³ MGLA 111 §57D;

MGLA 111D §11; 105 CMR 130.130 ⁶⁴ 105 CMR 130.132

⁶⁵ MGLA 111 §51G(6)

⁶⁶ MGLA 111 §51K; MGLA 111 §56

⁶⁷ M.S.A. §144.50 ⁶⁸ M.S.A. §144.653 ⁶⁹ M.S.A. §144.55(6) ⁷⁰ M.S.A. §144A.53 ⁷¹ M.C.A 50-5-103; MC 50-5-101.

M.C.A 50-5-108
 M.C.A 50-5-112
 M.C.A 50-5-114
 M.C.A 50-5-115

⁵⁹ 210 ILCS 5/10f; 210 ILCS 85/7 ⁶⁰ 210 ILCS 5/10d; 210 ILCS 85/7 ⁶¹ I.C.A. 135C.10; I.C.A

license for less than one year of operation if it will not result in undue harm.⁷⁶ A license can be denied, suspended, revoked, or reduced to a provisional license.⁷⁷

New Jersey has a uniform administrative chapter that regulates the standards for licensure of health care facilities. This includes procedures for surveys, imposition of penalties, other enforcement actions or remedies, and the facility's rights to request a hearing.⁷⁸ The authority for this uniform chapter stems from the Health Care Facilities Planning Act, which provides the department with the ability to employ its licensing functions to enforce regulations.⁷⁹ The commissioner may impose a civil monetary penalty, curtail admissions, appoint a receiver or temporary management, reduce status to a provisional license, suspend or revoke a license, or order a cease and desist.⁸⁰ A summary suspension may be issued and take effect immediately. The facility is provided 72 hours to correct the violations.⁸¹ When a facility is on a provisional license status the department must withhold authorization of additional beds or services, notify the Certificate of Need Program, which may result in withholding of approval or denial, and notify any public agency that provides funding of the status.82

North Carolina regulates a variety of health care facilities that all fall under Chapter 131E, Health Care Facilities and Services; however, enforcement actions are separated out within the chapter to be specific to facility type. Facilities can have their license denied, suspended, revoked, annulled, withdrawn, recalled, canceled or amended in any case in which it finds a substantial failure to comply with the law or rules established under the chapter. Fines can be issued for the operation of a facility without a license. 83 The department can also suspend admissions of new patients or suspend specific services. When the department suspends admissions, it must provide consultation to correct the conditions that led to the suspension.⁸⁴

The Oregon Health Authority Public Health Division regulates all health care facilities under a uniform enforcement statute under <u>Chapter 441 Health Care Facilities</u>. The authority may asses a civil penalty, and deny, suspend, or revoke a license for a substantial failure to comply with the laws or rules established by the chapter. The authority may also restrict admissions or patients when it finds an immediate threat in a long-term care facility.⁸⁵ The authority may also take action for an injunction to prevent the establishment of a health care facility without a license.86 The authority may also charge a hospital a fee for additional surveys or investigations.87

The Tennessee State Department of Health licenses and regulates health care facilities, and a uniform enforcement statute declares that the department regulates and enforces all health care facilities. 88 The Board for Licensing Health Care Facilities has the authority to suspend or

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<sup>76</sup> M.C.A. 50-5-204
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⁷⁷ M.C.A 50-5-207

⁷⁸ N.J.A.C. §8:43E-1.1

⁷⁹ NJ ST 26:2H-1

⁸⁰ N.J.A.C. § 8:43E-3.1

⁸¹ N.J.A.C. § 8:43E-3.8

⁸² N.J.A.C. § 8:43E-3.10

⁸³ NC ST § 131E-78; §

¹³¹E-139; § 131E-148; § 131E-205

⁸⁴ NC ST § 131E-78

⁸⁵ ORS 441.030

⁸⁷ ORS 441.021

revoke a license for violations of the laws or rules established by the chapter. The board may also impose sanctions, and establish a structure and associated penalties in rule, or place a facility on probation.⁸⁹ The department may seek an injunction or assess civil penalties for operating a facility without a license. 90 Suspension of admissions can be imposed. When this is done a special monitor must be appointed, and the facility is responsible for the cost of the special monitors.91

The Utah Department of Health regulates health care facilities under a uniform act known as the Health Care Facility Licensing and Inspection Act. Within the department is a health care facility committee that is responsible for rules, licensing, advising on enforcement, and providing technical assistance. 92 The department is responsible for enforcing the rules, conducting inspections, and assisting the committee. 93 The department may issue a statement of violations with a time frame for correction, deny or revoke a license, restrict or prohibit new admissions, place a department representative as a monitor, assess administrative penalties, or issue a cease-and-desist order. The cost of a monitor can be assessed to the facility. 94 A license can be restored after being revoked only after an inspection determines the issues have been corrected. 95 The department may issue a provisional or conditional license, which is in substantial compliance if the interests of the public will not be jeopardized. 96 If the department finds that conditions represent a clear hazard to public health the facility can be immediately closed.97

The Virginia Department of Health regulates medical care facilities and services. This is done through the Office of Licensure and Certification. There is not a uniform enforcement statute but all facilities are covered under Title 32.1 Chapter 5. Regulation of Medical Care Facilities and Services separated into individual articles. A license can be suspended or revoked when a licensee fails to comply with the laws and rules established by the chapter. 98 A certification can also be revoked. Suspension of a license must be for an indefinite time. A suspension can be completely or partially restored if the violations are corrected and the public will not be jeopardized. 99 A penalty may be imposed for failure to abide by the rules and laws surrounding balanced billing practices. 100 Administrative sanctions or initiations of court proceedings may also be used to ensure prompt correction of violations.

89 TN ST §68-11-207

⁹⁴ TN ST §68-11-221, UT ⁹⁰ TN ST §68-11-213 ST §26-21-11

91 TN ST §68-11-221 95 UT ST §26-21-12 ⁹² UT ST §26-21-5 93 UT ST §26-21-6

⁹⁶ UT ST §26-21-13 97 UT ST §26-21-14

98 VA ST §32.1-135; §32.1-162.6; §32.1-

162.13

99 VA ST § 32.1-135

¹⁰⁰ VA ST § 32.1-137.07