



Agency Recommendation Summary

The Department of Health (department) requests funds to develop a stronger enforcement approach to address health care facility noncompliance and take immediate action when there is risk of patient harm. The department’s authority to enforce health care facility licensing standards is often limited to suspending, revoking, or denying a facility license. In many facility types, the department lacks intermediate enforcement tools (e.g., fines) to correct non-compliance and lacks authority to take swift action to protect patients when there is immediate risk of serious harm. This proposal gives the department authority to use a wider array of enforcement tools to address noncompliance, take immediate action when there is immediate risk of patient harm, and better protect patients by strengthening our ability to ensure safe care in health care facilities.

Fiscal Summary

Fiscal Summary <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
Staffing						
FTEs	0.2	7.7	3.95	9.8	9.8	9.8
Operating Expenditures						
Fund 001 - 1	\$58	\$318	\$376	\$462	\$462	\$924
Fund 001 - 7	\$0	\$1,040	\$1,040	\$1,618	\$1,618	\$3,236
Fund 02G - 1	\$0	\$220	\$220	\$220	\$220	\$440
Fund 202 - 1	\$0	\$17	\$17	\$25	\$25	\$50
Total Expenditures	\$58	\$1,595	\$1,653	\$2,325	\$2,325	\$4,650
Revenue						
001 - 0597	\$0	\$1,040	\$1,040	\$1,618	\$1,618	\$3,236
Total Revenue	\$0	\$1,040	\$1,040	\$1,618	\$1,618	\$3,236

Decision Package Description

For many types of health care facilities the department regulates, the authority to address noncompliance with licensing requirements and protect patients from harm is limited to suspension, revocation, or denial of a facility’s license. The department can either take severe enforcement action or no enforcement action. There are no intermediate options (e.g., fines) to remedy noncompliance in a more targeted and nuanced manner. There is wide variability in available enforcement actions across facility types, as well as the circumstances under which enforcement action can be taken. This creates inconsistency and uncertainty for regulated facilities.

In addition, the current enforcement options generally do not allow the department to quickly address conditions in facilities that pose immediate risk of grave harm to patients, including severe injury, severe impairment, or death (i.e., “immediate jeopardy”). When such conditions are found, the department must file a notice of intent to suspend (or revoke) a license which initiates a legal proceeding that takes many months to resolve. In the meantime, the conditions posing serious risk to patients may persist.

Finally, many of the facility types don’t have an option to address unlicensed practice and there is not consistency in language for those that do.

In the last biennium, the legislature took action to strengthen the department’s enforcement authority for private psychiatric and acute care hospitals. Agency-request legislation for psychiatric hospitals passed in 2020 (SHB 2426), creating new intermediate enforcement tools such as the authority to stop placement of patients and impose fines and conditions on a license when there are repeat violations of licensing standards. The legislation also gave the department the authority to take summary action (e.g., summarily suspend a license) when conditions in psychiatric hospitals pose immediate jeopardy to patients. Lastly, the legislation directed the department to make facility inspection and investigation documents available to the public on the web, to include enforcement action and notices of resolutions. In the 2021 session, the legislature passed 2SHB 1148 which extended nearly identical enforcement provisions to acute care hospitals.

SHB 2426 directed the department to conduct a review of health care facility statutes to identify opportunities to standardize enforcement requirements across facility types and develop recommendations for a Uniform Facility Enforcement Act for consideration in the 2021 legislative session. The department was delayed two years in making this legislative proposal by the COVID-19 public health emergency.

The department’s proposed solution is to create a common health care facility enforcement framework that authorizes use of additional intermediate-level intervention tools for repeat violations and options to address immediate jeopardy in health care facilities the department regulates. This solution provides the department the ability to take actions that are appropriate to the facility and type and severity of violation, work with facilities to ensure access as well as patient safety, act sooner if the violation places the health and safety of patients in immediate jeopardy and address unlicensed operation of a facility when appropriate. The department proposes adding the following tools:

- Reasonable conditions on a license,
- Fines,
- Limited stop service (prohibits a facility from providing a specific category of services),
- Stop placement (prohibits new admissions to the facility due to a violation that is not contained to a specific category of patients or location in the facility),
- Limited stop placement (prohibits a facility from admitting patients due to a violation contained to a specific category of patients or location in a facility),
- Cease and desist orders (direct a facility operating without a license to stop practice and may include a fine), and
- Injunction (provides authority for the attorney general to maintain an action to enjoin a facility from practicing until a license is issued)

The proposed legislation builds upon the expanded enforcement authority and tools passed by the legislature for psychiatric and acute care hospitals. It will protect patients by strengthening the department’s ability to ensure regulated facilities are providing safe care for Washingtonians. It increases clarity, consistency, and predictability for facilities and health service providers, making it easier to comply with regulations. The proposal provides a more targeted and nuanced enforcement approach that centers on patients’ safety and access to quality care.

The table below shows our proposed recommendations by facility type. An “X” in the box indicates adding authority (or modifying existing authority) for the specified enforcement action for that facility type.

Facility Type	Reasonable Conditions	Limited Stop Placement	Stop Placement	Limited Stop Service	Fines	Cease & Desist Orders/Injunctions (unlicensed practice)
Birthing Centers Chapter 18.46 RCW	X		X	X	X	X
Medical Test Sites Chapter 70.42 RCW				X		X
In-Home Service Agencies Chapter 70.127 RCW	X		X*	X	X	X
Ambulatory Surgical Facilities Chapter 70.230 RCW	X		X	X	X	X
Residential Treatment Facilities Chapter 71.12 RCW	X	X	X	X	X	X
Behavioral Health Agency Chapter 71.24 RCW	X	X	-	X	X	
Pharmacies and other entities the Pharmacy Quality Assurance Commission regulates** Chapter 18.64 RCW	X				X	X

**For In-Home Service Agencies, stop placement applies only to hospice care centers.*

***The Pharmacy Quality Assurance Commission is proposing additional tools (e.g., plans of correction, statements of deficiency) to allow the commission to better address patient safety risks.*

This funding package will support the costs to the department of implementing the legislation including:

- One-time costs of rulemaking for each facility type. These are anticipated to be 18-month rulemaking projects that include workshops, public hearings, and AAG support.
- Ongoing costs to use the new tools for repeat violations, immediate jeopardy situations, and unlicensed practice, including additional time required for using these new tools, such as inspector and supervisor time to draft and issue the required documents and confirming correction of violations.
- Costs for contractor change order requests to configure additional inspection types, case nature (allegations) and tracking of duplicate deficiencies in our new licensing system under development (the Health Care Enforcement and Licensing Management System (HELMS)). The department expects HELMS to go live in the fall of 2023.

Ongoing administrative costs associated with processing enforcement cases and subsequently posting of inspection and investigation enforcement documents.

Initially, the department focused on creating a Uniform Facilities Enforcement Act, modeled on the Uniform Disciplinary Act for licensed health care providers. During stakeholder engagement it became clear that, due to significant differences in the type of services provided across facility types, as well as major operational differences, a standard approach could result in disproportionate impacts to some facilities, and potentially closures of facilities that would impact patient access to care. The department and regulated community agreed that a uniform framework would allow us to standardize enforcement across facility types while allowing flexibility to tailor specific enforcement tools to the unique needs of each facility type. This would allow health care delivery to continue as safely and seamlessly as possible, depending on the situation.

We are proposing this legislation now because we have completed the review of facility statutes directed in SHB 2426, identified opportunities to consolidate and standardize licensing and enforcement requirements across all types of health care facilities the department regulates, and worked with stakeholders on recommendations for a Uniform Health Care Facility Enforcement Act. The legislature required the department to produce recommendations for legislation for 2021 session. Due to the COVID-19 public health emergency, the department was delayed two years in proposing this legislation.

Taking no action would further delay addressing the need for a more targeted and nuanced approach to enforcing licensing standards in health care facilities as well as the need for authority to take swift action when conditions in facilities pose immediate risk of patient harm.

Assumptions and Calculations

Expansion, Reduction, Elimination or Alteration of a current program or service:

N/A

Detailed Assumptions and Calculations:

The department will require staff to accomplish the following activities:

- Conduct rulemaking including multiple workshops for each facility type,
- Implement changes to the Health Care Enforcement and Licensing Management System (HELMS) to account for new types of enforcement actions,
- Conduct investigations and inspections when repeat violations are found for a licensee, including travel expenses to support this activity,
- Manage complaints throughout the investigation and enforcement process,
- Coordinate with other state agencies (e.g., Health Care Authority and Department of Children, Youth, and Families) on relocation of patients when a stop placement is ordered,
- Provide staff attorney support to enforcement actions and coordinate with the Office of the Attorney General (AGO),
- Provide supervisory and management oversight when exercising these new enforcement tools
- Provide administrative support to staff engaged in this work, and
- Provide administrative and communications support to inform the public of enforcement actions.

The department also projects increased costs for legal services from AGO.

Workforce Assumptions:

Workforce Assumptions FY24 Projections Only					
FTE	Job Classification	Salary	Benefits	Startup Costs	FTE Related Costs
0.0	NURSING CONSULTATION ADVISOR	\$2,000.00	\$1,000.00	\$0.00	\$0.00
0.0	WMS02	\$5,000.00	\$2,000.00	\$0.00	\$0.00
0.0	WMS03	\$2,000.00	\$1,000.00	\$0.00	\$0.00
0.0	HEALTH SERVICES CONSULTANT 1	\$1,000.00	\$0.00	\$0.00	\$0.00
0.1	HEALTH SERVICES CONSULTANT 4	\$11,000.00	\$4,000.00	\$1,000.00	\$1,000.00
0.0	IT SYSTEM ADMINISTRATION - JOURNEY	\$1,000.00	\$0.00	\$0.00	\$0.00
0.0	IT BUSINESS ANALYST - JOURNEY	\$1,000.00	\$0.00	\$0.00	\$0.00
0.0	IT QUALITY ASSURANCE - JOURNEY	\$1,000.00	\$0.00	\$0.00	\$0.00
0.2		\$24,000.00	\$8,000.00	\$1,000.00	\$1,000.00

Strategic and Performance Outcomes

Strategic Framework:

Results Washington

This proposal supports the Governor's Results Washington healthy and safe communities by allowing the department to act quickly to address situations that place patients in immediate jeopardy of serious harm. It supports efficient, effective, and accountable government by creating tools that allow the department to act quickly in situations that place patients in immediate jeopardy.

Department of Health Transformational Plan

This proposal supports the department's Transformational Plan priority, II. Health Systems and Workforce Transformation by ensuring equitable access to behavioral health facilities and preventing possible patient harm due to facility noncompliance.

Performance Outcomes:

- Continued access to services in facilities through the ability to use enforcement tools appropriate to the type and severity of the violation
- Options for collaboration with facilities to address compliance issues when they don't risk immediate jeopardy for patients
- Safer patients through the ability to address immediate jeopardy situations quickly
- Few unlicensed facilities through the addition of cease and desist orders and injunctions to stop them from operating.

Equity Impacts

Community outreach and engagement:

The department conducted community outreach and engagement with these populations by sharing the proposal through email and inviting them to stakeholder meetings August 17-18 to respond to questions and hear their input. The only comments we received were from industry representatives and license holders, which has been incorporated into the current draft where appropriate.

Disproportional Impact Considerations:

We are not aware of any target populations or communities not included or would be marginalized or disproportionately impacted by this proposal. We did not receive input from the communities we engaged.

Target Populations or Communities:

Having the ability to take fast action to address issues that place patients in immediate jeopardy will increase patient safety in health care facilities and particularly benefit:

- Communities of color, Asian/Pacific Islander, Latinx/Hispanic communities, and Native American/Alaska Native populations. These populations use alternatives to hospitals like birthing centers at a higher rate because of variation in quality and a higher likelihood of dying of pregnancy-related causes, structural racism, and implicit bias.
- LGBTQIA+ populations. The rate of suicide attempts is four times greater for queer youth than that of heterosexual youth in America, and LGBTQIA+ individuals are 2.5 times more likely to experience depression, anxiety, and substance misuse compared with heterosexual individuals (APA).

Other Collateral Connections

Puget Sound Recovery:

N/A

State Workforce Impacts:

N/A

Intergovernmental:

Other state agencies including HCA, DSHS, DCYF, and DOC, as well as county and city governments, have an interest in assuring that licensed health care facilities are operating in accordance with minimum licensing standards that are regulated by DOH. Some of these agencies, notably DSHS and DOC, operate health care facilities licensed by the department and could be impacted by the bill if inspections or investigations revealed compliance issues. We plan to engage them on this proposal.

Stakeholder Response:

See attachment

State Facilities Impacts:

N/A

Changes from Current Law:

- Birthing center regulation
 - Amending RCW 18.46.010 and 050 to add definitions, reasonable conditions, stop placement, limited stop service, and fining authority.
 - Amending RCW 18.46.130 to align injunction language with the other facility types.
 - Adding a new section for authority to issue cease and desist orders for unlicensed practice.
- Medical test site regulation
 - Amending RCW 70.42.010 and 130 and added a new section to add definitions, limited stop service, and clarifications to align language with the other facility types.
 - Amended RCW 70.42.180 to align injunction language with the other facility types.
 - Adding a new section for authority to issue cease and desist orders for unlicensed practice.
- In-home services agency regulation
 - Amending RCW 70.127.010 and 170 to align enforcement authority language with the other facility types.
 - Adding two new sections to add reasonable conditions, stop placement, limited stop service, and fining authority.
 - Amending RCW 70.127.213 to align cease and desist language with the other facility types.
- Ambulatory surgical facility regulation
 - Amending RCW 70.230.010 and 070 to add definitions, reasonable conditions, limited stop service, stop placement, and fining authority.
 - Adding a new section for authority to issues cease and desist orders for unlicensed practice.
- Private establishment regulation
 - Amending RCW 71.12.710, 455, and 500 to add reasonable conditions, limited stop placement, stop placement, limited stop service, fining authority, and align existing language with the other facility types (and change outdated terminology throughout the chapter).
 - Adding new section for authority to issue cease and desist orders for unlicensed practice.
- Behavioral health agency regulation
 - Amending RCW 71.24.025, 037, 020, and adding a new section to add reasonable conditions, limited stop placement, limited stop service, and fining authority.
 - Amending RCW 70.38.025 and 260 to change “psychiatric hospital” to “behavioral health hospital” related to certificate of need regulations and amending RCW 70.170.020 to make this change related to charity care regulations.
- Pharmacy and pharmacy-regulated entity regulation
 - Amending pharmacy regulations - RCW 18.64.011, 165, and adding new sections to add statement of deficiency, plan of correction (these are not in the other facility proposed language because they already use these tools), fining authority, and cease and desist orders.
 - Amending pharmaceutical manufacturer regulation - RCW 69.45.080 to add statement of deficiency, plan of correction, and fining authority.
 - Amending humane society/animal control agency regulations - RCW 69.50.310 to add reasonable conditions, statement of deficiency, plan of correction, and fining authority.
 - Amending analytical laboratory regulation – RCW 69.50.302 to add reasonable conditions, statement of deficiency, plan of correction, and fining authority.
 - Amending precursor chemical distributor regulation - RCW 69.43.010 to.

Amending poison distributor and manufacturer regulations – RCW 69.38.140 and 060 to add reasonable conditions, statement of deficiency, plan of correction, and fining authority.

Legal or Administrative Mandates:

N/A

Reference Documents

[NEW - UFEF - FinancialCalculator_2023-25_ver24.1 - UPDATED 8-4-22 \(1\).xlsm](#)
[UFEF stakeholder list.xlsx](#)

IT Addendum

Does this Decision Package include funding for any IT-related costs, including hardware, software, (including cloud-based services), contracts or IT staff?

No

Objects of Expenditure

Objects of Expenditure <i>Dollars in Thousands</i>	Fiscal Years		Biennial	Fiscal Years		Biennial
	2024	2025	2023-25	2026	2027	2025-27
Obj. A	\$29	\$888	\$917	\$1,226	\$1,226	\$2,452
Obj. B	\$11	\$350	\$361	\$478	\$478	\$956
Obj. C	\$8	\$0	\$8	\$0	\$0	\$0
Obj. E	\$7	\$269	\$276	\$494	\$494	\$988
Obj. G	\$0	\$31	\$31	\$54	\$54	\$108
Obj. J	\$1	\$0	\$1	\$0	\$0	\$0
Obj. T	\$2	\$57	\$59	\$73	\$73	\$146

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