WSR 24-05-079
PROPOSED RULES
DEPARTMENT OF AGRICULTURE
[Filed February 21, 2024, 7:44 a.m.]

Supplemental Notice to WSR 23-03-045 [23-23-145].

Preproposal statement of inquiry was filed as WSR 23-03-045.

Title of Rule and Other Identifying Information: Chapter 16-309 WAC, Cannabis laboratory accreditation standards program.

Hearing Location(s): On April 9, 2024, at 1:00 p.m., via Microsoft Teams meeting. Join on your computer, mobile app, or room device https://teams.microsoft.com/l/meetup-join/19%3ameeting_MGFhMjllMWYtZjRhYi00ZDNmLWI4MWMtM2E0ZmIxZTU2NTAy%40thread.v2/0?context=%7b%22Tid%22%3a%2211d0e217-264e-400a-8ba0-57dcc127d72d%22%2c%22Oid%22%3a%22838c55c7-c187-44ae-8de0-2be684ce5d4a%22%7d, Meeting ID 275 870 779 25, Passcode 49xZ8h; or call in (audio only) +1 564-999-2000, Phone Conference ID 590 850 398#.

Date of Intended Adoption: April 16, 2024.

Submit Written Comments to: Gloriann Robinson, Rules Coordinator, P.O. Box 42560, Olympia, WA 98504-2560, email wsdarulescomments@agr.wa.gov, fax 360-902-2092, by April 9, 2024.

Assistance for Persons with Disabilities: Contact Trecia Ehrlich, cannabis programs manager, phone 360-584-3711, TTY 800-833-6388, email tehrlich@agr.wa.gov, by April 2, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: This proposed rule creates a new chapter of rule that is intended to expand the laboratory quality standards first created by the Washington state liquor and cannabis board (WSLCB) as required by HB 1859. To complete the mandate of HB 1859, the department is proposing the following rules:

(1) Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-050 through 16-309-080).

(2) Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).

(3) Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).

(4) Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).

(5) Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).

(6) Establishing facilities and equipment maintenance criteria for the laboratory (chapter 16-130 WAC).

(7) Establishing method performance criteria for laboratory testing (WAC 16-309-140).

(8) Establishing quality control and method performance criteria specific to each required test: Water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through 16-309-210).

(9) Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing (WAC 16-309-160, 16-309-190, and 16-309-220).

(10) Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by WSLCB (WAC 16-309-230).

(11) Creating laboratory computers and information system requirements (WAC 16-309-240).

(12) Establishing method validation criteria for laboratory testing (WAC 16-309-2640).

(13) Establishing a process by which laboratories can submit their own methods for approval (WAC 16-309-250).

(14) Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).

(15) Establishing certificate of analysis (CoA) report requirements (WAC 16-309-280).

(16) Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).

(17) Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

The proposed rules are developed in collaboration with WSLCB and the department of health (DOH). As such, both agencies are heavily involved with this rule. Since the interagency team is required to consider the recommendations made by the cannabis science task force (CSTF) on the development of appropriate laboratory quality standards for cannabis product testing laboratories, the department of agriculture (WSDA) will also coordinate rule development with the members of the task force which includes members of the cannabis scientific community.

Reasons Supporting Proposal: HB 1859 created an interagency coordination team for cannabis laboratory quality standards. The team consists of WSDA, WSLCB, and DOH. WSDA is the designated lead agency for the team and must provide all necessary administrative support.

WSDA must establish and maintain cannabis testing laboratory quality standards by rule. The cannabis testing laboratory quality standards must include, but are not limited to: Approved methods for testing cannabis for compliance with product standards established by rule by WSLCB or DOH; method validation protocols; and performance measures and criteria applied to testing of cannabis products.

On November 22, 2023, WSDA filed a CR-102 with proposed rule language of the laboratory standards which incorporated all components recommended by the CSTF. On December 28, 2023, WSDA held a public meeting in which stakeholders expressed concern primarily related to the required methods embedded and referenced in rule, as well as some of the costs associated with the new standards. Based on the comments received, WSDA determined that substantive changes were needed to the rule language and that they would proceed to file a supplemental CR-102 in order to have more time to take stakeholder comments into consideration.

From December 2023 to February 2024, WSDA offered multiple updated drafts for review, and one-on-one meetings with laboratories who had engaged in the initial CR-102 feedback process. Areas in which laboratories offered cost mitigation strategies were considered and incorporated when possible. Changes that were identified as "substantive" to the scientific rigor of the standard were discussed between scientists at all three participating agencies (WSDA, WSLCB, and DOH) in order to ensure consultation across a larger number of scientists.

The most substantive change made was extracting the methods from the rule and instead requiring that laboratories use a method that had undergone the method approval process by WSDA. The previously required methods were edited and will exist as a list of "pre-approved" methods; a process has been provided in rule by which laboratories can

submit their own methods for approval. WSDA also provided additional definitions and clarity in rule related to how methods are used and validated.

Statutory Authority for Adoption: RCW 15.150.030; HB 1859.

Statute Being Implemented: Chapter 15.150 RCW.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: WSDA, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Trecia Ehrlich, 1111 Washington Street S.E., Olympia, WA 98504, 360-584-3711.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. WSDA is not a listed agency under RCW 34.05.328 (5)(a)(i).

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does impose more-than-minor costs on businesses.

Small Business Economic Impact Statement (SBEIS)

Chapter 16-309 WAC

Cannabis Testing Laboratory Quality Standard

SECTION 1: **Describe the proposed rule, including: A brief history of the issue; an explanation of why the proposed rule is needed; and a brief description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.**

Background and Overview: Cannabis products sold in Washington state are required to be tested for harmful substances and for cannabinoid concentration. The science required to develop adequate testing protocols has been slow to meet industry needs. In 2019, Washington enacted HB 2052, which established and directed the cannabis science task force (CSTF) to recommend laboratory standards to be used in support of accrediting cannabis testing laboratories in Washington state. In June 2020, the department of ecology published a report of laboratory quality standards for testing cannabis plants and products created by CSTF; this report recommended the creation of an interagency cooperative team led by WSDA (the department) in coordination and consultation with WSLCB and DOH.

In response, the legislature passed HB 1859, which required the department to establish and maintain cannabis testing laboratory quality standards by rule. The cannabis testing laboratory quality standards must include but are not limited to: Approved methods for testing cannabis for compliance with product standards established by rule by WSLCB or DOH; method validation protocols; and performance measures and criteria applied to the testing of cannabis products. WSDA cannabis laboratory analysis standards program (CLASP) is responsible for creating and establishing these standards.

On November 22, 2023, the department filed a CR-102 of the laboratory standard which incorporated all components recommended by CSTF. On December 28, 2023, the department held a public meeting in which stakeholders expressed concern primarily related to the state of the required methods embedded and referenced in rule, as well as some of the costs associated with the new standards. After the public hearing,

the department determined that they would proceed to file a supplemental CR-102 in order to have more time to take stakeholder comments into consideration. The most substantive change made was extracting the methods from the rule, and instead requiring that laboratories use a method that had undergone the method approval process by the department. The previously required methods were edited and will exist as a list of "pre-approved" methods, and a process has been provided in rule by which laboratories can submit their own methods for approval. The department also provided additional definitions and clarity in rule related to how methods are used and validated. During this time, the department offered multiple updated drafts for review, and one-on-one meetings with laboratories who had engaged in the initial CR-102 feedback process. Areas in which laboratories offered cost mitigation strategies were considered and adopted when possible. Changes that were identified as "substantive" to the scientific rigor of the standard were discussed between scientists at all three participating agencies, WSDA, WSLCB, and DOH, in order to ensure consultation across a larger number of scientists. As several changes did create significant cost mitigation strategies, and multiple laboratories were able to provide the department with more specific financial data in our second round of engagement, we also have updated our initial SBEIS in order to reflect the additional data and cost mitigation strategies that were provided.

Proposed Rule: As required by HB 1859, the department is establishing cannabis testing laboratory quality standards under chapter 16-309 WAC, which include:

(1) Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-050 through 16-309-080).

(2) Requiring SOP criteria for all laboratory testing (WAC 16-309-090).

(3) Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).

(4) Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).

(5) Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).

(6) Establishing facilities and equipment maintenance criteria for the laboratory (chapter 16-130 WAC).

(7) Establishing method performance criteria for laboratory testing (WAC 16-309-140).

(8) Establishing quality control and method performance criteria specific to each required test: Water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through 16-309-210).

(9) Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing (WAC 16-309-160, 16-309-190, and 16-309-220).

(10) Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by WSLCB (WAC 16-309-230).

(11) Creating laboratory computers and information system requirements (WAC 16-309-240).

(12) Establishing method validation criteria for laboratory testing (WAC 16-309-2640).

(13) Establishing a process by which laboratories can submit their own methods for approval (WAC 16-309-250).

(14) Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).

(15) Establishing certificate of analysis (CoA) report requirements (WAC 16-309-280).

(16) Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).

(17) Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

Probable Compliance Costs and Professional Services Requirements: As standards rise, so does the cost of compliance. Cannabis testing laboratories will need to spend more time completing quality control and quality assurance steps to ensure the quality of the data being produced. This will be paired with an increased usage of solvents and standards from chemical manufacturers.

Probable compliance costs for businesses may be accrued from changing personnel to meet new personnel requirements; purchasing of reagents and consumables from laboratory suppliers to meet new and changing testing requirements; increased hours of operation; and purchasing of new instrumentation to meet new and changing method performance requirements, method validation requirements, standardized methods requirements, and proficiency testing requirements.

While there will be added costs for the industry to come into compliance; both the expenses and associated work needed to meet the department's regulations will be contingent upon each of the laboratories' current operations. The department has adapted the proposed regulations from a variety of leading scientific industry standards and thus laboratories currently operating at or near these industry standards will not incur expenses as high as a laboratory operating further away from those standards.

The proposed rule does not require professional services. A laboratory may choose to begin or continue to use professional services for maintenance of computer information systems, maintenance of security systems, and facilitation of lab-to-lab sample transfers; however, it will not be mandatory.

There are currently eight laboratories in Washington state providing cannabis testing services.

SECTION 2: **Identify which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS) codes and what the minor cost thresholds are.**

NAICS Code (4, 5 or 6 Digit)	NAICS Business Description	Number of Businesses in Washington	Minor Cost Threshold = 1% of Average Annual Payroll	Minor Cost Threshold = 0.3% of Average Annual Revenue
541380	Testing Laboratories	8	$8,577.31	$4,842.86

* Data source: 2020 Employment Security Department.
** Data source: 2020 Department of Revenue.

SECTION 3: **Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule, including: Cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.**

The rule making to establish chapter 16-309 WAC has undergone two separate trajectories: An initial path from January - December 2023, and an amended/iterative course between December 2023 - February 2024.

Throughout the initial trajectory, the department, in collaboration with stakeholders, researched and discussed probable costs that laboratories may expect to incur with the "then-current" rule language and methods. While probable costs of compliance were generally dependent upon the laboratories' methods, instrumentation, equipment, and personnel, the following cost areas were researched and identified:

Anticipated Costs to Laboratories, Generally - Original Rule-Making Proposal *(January - December 2023 Assessment)*	
1.	Matrix blanks/spikes requirements along with the number of controls has increased. While the current WSLCB rules require that laboratories use "appropriate matrix blank and controls," the new rules elaborate on how many. Cost for spiking standards and matrix could range between $10,000 - $50,000 per year depending on the laboratory's current processes.
2.	The proposed rule increases storage requirements from the current WSLCB rule from three years to five years. Laboratories may see a cost in hard-copy storage or storage of electronic documents. Estimates range between $360 - $5,000 per year.
3.	The proposed rule requires lab personnel conducting high complexity testing have a Bachelor of Science degree. Should a laboratory need to hire an additional scientist, costs could range between $0 and $90,000 per year. Most labs would not need to hire additional staff as they likely already have highly experienced analysts qualified to perform high complexity testing. ***Note:*** Please see Section 6 for available cost mitigations.
4.	The proposed rule requires that specific types of analytical instrumentation be used for different testing methods. From the information we have received, all laboratories have the instrumentation to perform the testing required. The proposed rule does not require the purchasing of any new analytical instrumentation and laboratories may arrange for a sample to be transferred to another lab for testing if they are unable to perform the method with their current instrumentation.
5.	The proposed rule requires refrigerated storage of samples if they were not processed within seven days. This concerned labs about the need to purchase additional refrigerators or freezers to store standards and samples. From the information we have received, all laboratories have current refrigerator(s) and/or freezer(s) necessary for the storage of standards and samples. Cost of a laboratory grade refrigerator or freezer could range from $0 - $10,000 each. ***Note:*** This requirement has since been removed. Please see Section 6.
6.	The proposed rule requires a photo record to perform the foreign matter inspection in addition to a written record to document test results. Some laboratories may need to purchase some type of camera or system to meet this requirement. Cost of equipment capable of capturing photos could range from $50 to $500.
7.	The proposed rule requires annual validation of each testing method. This requirement could increase the use of standards, solvents, personnel, and equipment. Costs would be between $2,000 - $10,000 per year.
8.	The proposed rule sets more quality control and quality assurance standards, which increases the possibility that a laboratory may need to repeat or redo work to meet data quality standards. Any repetition of work increases costs without increasing revenue. Quality assurance failures can be as simple as a reinjection ($5) to a more complex need, such as instrument maintenance ($25,000).

Based on feedback provided during the initial public hearing on December 28, 2023, the department decided to make substantial revisions to the rule language to incorporate concerns shared by the impacted laboratories.

In addition to the feedback provided both during and following the first public hearing, the department has since conducted several stakeholder meetings and question and answer (Q&A) webinars to provide general rule language clarification, as well as to better understand any economic concerns related to compliance. The expenses and associated work needed to meet the department's proposed regulations, however, will be contingent upon each of the labs' current operations and procedures. That is, laboratories currently operating at or near accepted scientific benchmarks will not incur expenses as high as a laboratory operating further away from those standards.

Following a series of collaborative assessments and discussions conducted between December 2023 - February 2024, the department redetermined that laboratories affected by the proposed rule may experience increased costs of compliance related to the following fields of testing: (1) Water Testing, (2) Cannabinoid Concentration Analysis, (3) Foreign Matter Inspection, (4) Residual Solvent Testing, (5) Pesticide Testing, (6) Heavy Metals Testing, (7) Microbiological Testing (Culture), (8) Microbiological Testing (Immunoassay), (9) Microbiological Testing (Polymerase Chain Reaction (PCR)), and (10) Microbiological Testing (Mycotoxins).

A laboratory's potential costs of compliance for the above referenced tests are as follows:

1. Water Testing - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument Calibration	$0.03	$0.03	$0.00
Standards and Controls	$0.11	$0.11	$0.00
Reagents and Consumables	$1.87	$1.87	$0.00
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $3.00 $4.15 $4.15	 $3.00 $4.15 $4.15	 $0.00 $0.00 $0.00
Preparation, Sanitation, and Disposal	$0.11	$0.11	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *water testing:* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.00

The department does not anticipate any significant cost increases for any of the laboratories in Washington state due to the new regulations pertaining to *water testing*. Based on discussion and feedback provided from industry representatives, the department had confirmed its notion that laboratories will likely not incur any additional costs beyond current operations and procedures as it relates to *water testing*.

Water testing is a moderate complexity test meaning the method validation is minor. A lab would only have to show the instrument is performing according to the manufacturer's expectations. This would only require running six to 10 standard samples to verify unless the manufacturer has a greater requirement.

(3.1)(a) Water Testing - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Initial Setup Verification **(Required)**	N/A	~$1,000.00	~$1,000.00
Reverification based on: (1) Implementing a New Instrument, (2) Moving Instrument to New Location, (3) Instrument Repair, or (4) Instrument Recalibration.	" "	~$100.00 - $500.00	~$100.00 - $500.00
Modifying Existing Method or Instrument for Each Matrices	" "	~$100.00 - $500.00	~$100.00 - $500.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

At minimum, a laboratory offering *water testing* services will incur an initial setup verification expense of ~$1,000.00. Beyond this one-time cost, if a laboratory decides to (1) implement a new instrument, (2) move instrument to a new location, (3) have the instrument repaired, or (4) recalibrate the instrument, then a "reverification cost" will be incurred estimated between ~$100.00 - $500.00. Further, if a laboratory is modifying an existing method or instrument for *water testing*, they may also expect to incur costs ranging between ~$100.00 - $500.00.

2. Cannabinoid Concentration Analysis - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards and Controls	$0.76 - $1.50	$107.00	$105.50 - $106.24
Reagents and Consumables	$0.36 - $0.60	$5.70	$5.10 - $5.34
Personnel (i) Tester (ii) Reviewer	 $0.94 $1.06	 $2.50 $3.40	 $1.56 $2.34
Preparation, Sanitation, and Disposal	$0.3 [0.03] - $1.50	$0.03 - $1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *cannabinoid concentration analysis*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			**Safe Range** $2,806.60 - $3,355.48 **Maximum** $2,806.60 - $7,025.00

The department anticipates cost increases for laboratories due to the new regulations related to *cannabinoid concentration analysis*. The expenses and associated work needed to meet the department's regulations will be contingent upon each of the laboratories' current operations. That is, laboratories currently operating at or near accepted scientific benchmarks will not incur expenses as high as a laboratory operating further way from those standards.

The most significant cost increase identified by the department, as related to *cannabinoid concentration analyses*, is a direct result of the regulated timing for the spiking of a cannabinoid matrix spike. Laboratories currently spiking a cannabinoid matrix spike post-extraction will need to make procedural changes (following review of dynamic ranges, etc.) to ensure they are able to spike a cannabinoid matrix spike pre-extraction for compliance. This departmental decision was based on the determination that there is insufficient data to support whether post-extraction spikes can adequately monitor the extraction process.

While the laboratories' need to spike a cannabinoid matrix spike pre-extraction poses as an area for increased costs, the department has researched and determined that cost mitigations are available by utilizing a customer's sample. In essence, laboratories may run a customer sample in duplicate to replace the matrix spike duplicate. Laboratories would still incur typical costs for running the customer sample, that is, costs for methanol, injection, etc., but would be able to forego the matrix spike duplicate requirement and only need to spike one matrix per batch.

(3.2)(a) Cannabinoid Concentration Analysis - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	**Minimum** • $5,948.00 **Mean** • $7,024.00 **Maximum** • $8,100.00	**Minimum** • $8,640.00 **Mean** • $11,820.00 **Maximum** • $15,000.00	**Safe Range** • $2,692.00 - $4,796.00 **Maximum** • $6,900.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	**Safe Range** • $2,692.00 - $4,796.00 **Maximum** • $2,692.00 - $6,900.00	**Safe Range** • $2,692.00 - $4,796.00 **Maximum** • $2,692.00 - $6,900.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

(3.2)(b) Cannabinoid Concentration Analysis - Instrument Calibration:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument Calibration **Note:** Costs are based per calibration; costs were found to be incalculable per sample. "Labor" includes preparation, review, and documentation.	**Frequency** • 2-4 times/yr. **Standards** • $3,000.00 per calibration **Consumables** • $30.00 per calibration **Labor** • $135.00 per calibration	**Frequency** • 12 times/yr. **Standards** • $36,000.00 **Consumables** • $360.00 **Labor** • $1,620.00	**Frequency** • 8-10 times more/yr. **Standards** • $24,000.00 - $30,000.00 **Consumables** • $240.00 - $300.00 **Labor** • $1,080.00 - $1,350.00

In sum, the department recognizes that the proposed rule will impose additional costs to laboratories related to *cannabinoid concentration analyses* and other fields of testing. With this, the department has both considered requests and made concessions, where feasible and legal, without adversely impacting the *cannabis laboratory accreditation standards program's* objectives or Washington's scientific merit.

3. Foreign Matter Inspection - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument	$0.00	$0.00 - $500.00, if needed	$0.00 - $500.00, if needed
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $0.00 - $1.25 $0.00 - $8.33 $0.00 - $2.00	 $0.00 - $1.25 $0.00 - $8.33 $0.00 - $2.00	 $0.00 $0.00 $0.00
Preparation, Sanitation, and Disposal	$0.00 - $1.50	$0.00 - $1.50	$0.00

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Total expected increase to a laboratory's existing cost(s) per sample for *foreign matter inspection*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			No cost increases so long as camera/phone with magnification/resolution to document presence of foreign matter is on hand.

The department does not anticipate any significant cost increases for any of the laboratories due to the proposed regulations related to *foreign matter inspection*. Based on discussion and feedback provided from laboratories, the department has confirmed its evaluation that *foreign matter inspection* will likely not cause laboratories to incur any additional costs beyond their current operations. Should a camera need to be purchased to meet the department's proposed regulations, the department has identified several ≤ $50.00 digital cameras sufficient for *foreign matter inspection* purposes. These adequate budget friendly options are available at major retailers such as Amazon, Best Buy, Target, and Walmart.

4. Residual Solvent Testing - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards and Controls	$0.58 - $1.00	**Minimum** • $0.83 If subsample mass ~0.04g and no extraction required **Maximum** • $20.00 - $25.00 if sample mass ~0.2g and extraction required	**Minimum** • $0.83 - $1.00 If subsample mass ~0.04g and no extraction required **Maximum** • $19.00 - $24.00 if sample mass ~0.2g and extraction required
Reagents and Consumables	$3.50 - $4.00	$4.10 - $10.00	$0.60 - 6.00
Personnel (i) Tester (ii) Reviewer	 $0.78 - $5.00 $1.06 - $10.33	 $2.18 - $10.00 $3.40 - $12.50	 $1.40 - $9.22 $2.17 - $11.44
Preparation, Sanitation, and Disposal	$0.02	$0.02	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *residual solvent testing*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			**~.04g Subsample Mass** $5.00 - $27.66 **.2g Sample Mass** $23.17 - $44.66

(3.4)(a) Residual Solvent Testing - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	**Minimum** • $5,585.00 **Mean** • $6,935.00 **Maximum** • $8,285.00	**Minimum** • $5,585.00 **Mean** • $17,792.50 **Maximum** • $30,000.00	**Minimum** • $0.00 **Mean** • $10,857.50 **Maximum** • Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	$0.00 If a laboratory is operating within the Minimum, Maximum, or Mean range. Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.	$0.00 If a laboratory is operating within the Minimum, Maximum, or Mean range. Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

(3.4)(b) Residual Solvent Testing - Instrument Calibration:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Instrument Calibration **Note:** Costs are based on per calibration; costs were found to be incalculable per sample. "Labor" includes preparation, review, and documentation.	**Frequency** • 2-4 times/yr. **Standards** • $300.00 **Consumables** • $17.00 **Labor** • $59.00	**Frequency** • 12 times/yr. **Standards** • $300.00 **Consumables** • $17.00 **Labor** • $59.00	**Frequency** • 8-10 more times **Standards** • $2,400.00 - $3,000.00 **Consumables** • $270.00 **Labor** • $1,215.00

The department anticipates cost increases for the laboratories due to the new regulations pertaining to *residual solvent testing*. As previously noted, the expenses and associated work needed to meet the department's regulations will be contingent upon each of the lab's current operations. Laboratories at or near leading scientific benchmarks will not incur expenses as high as those operating further from those standards.

The department recognizes that the proposed rule will impose additional costs to laboratories related to *residual solvent testing* and other fields of testing. In assessing the areas for potential cost mitigations related to *residual solvent testing*, the department fielded requests regarding the removal of the sample mass requirement. The

department took the inquiry into consideration but was unable to offer concessions in the matter. The department made this decision because the removal of the sample mass requirement would significantly minimize the scientific integrity and merit of *residual solvent testing*, and through causation, would then reduce laboratory credibility which adversely affects consumer protections.

5. Pesticide Testing: Based on discussion, research, and provided feedback between the department and industry, it was determined that laboratories may incur minimal costs related to *pesticide testing*.

Current Cost: Cost for two lots of pesticide standards: $1,000.00 - $1,100.00 every ~6 months.

Expected Cost: Due to the small volume of standard required to prepare calibrators and controls, coupled with the compounds' stability after cracking an ampule, the department does not anticipate any of the laboratories to incur costs beyond their current operations and procedures. Additionally, if a laboratory adheres to widely accepted scientific standards calling for weekly, or frequent, pesticide method calibrations, the department does not expect for laboratories to incur any additional costs to comply with the regulations related to *pesticide testing* calibration workflow and requirements.

(3.5)(a) Pesticide Testing - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	N/A - Labs are currently not required to revalidate their methods	$0.00 - $25,000.00	$0.00 - $25,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	$0.00 If a laboratory is operating within the Minimum, Maximum, or Mean range. Without a current cost to support the maximum, the dept. cannot calculate the expected increase to a laboratory's existing cost if they operate within that range.	**Dept. Calculation** **Staff Time:** $250.00 - $2,000.00 (Assuming ~5 - 40 hours @ 50/hr) **New Matrix:** $0.00 - $50.00 **Standards:** $50.00 - $200.00 (Assuming 10 spikes per mod. @ $5.00 - $20.00 per) **Minimum:** $300.00 **Mean:** $1,275.00 **Maximum:** $2,250.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

As previously noted, there will be added costs for the industry to come into compliance; however, the range of expenses and associated work needed to meet the department's regulations will be contingent upon the laboratories' current operations. The department has adopted these regulations with leading scientific industry standards in mind and thus laboratories currently operating at or near these benchmarks

will not incur as expenses as high as a laboratory operating further way from those standards.

6. Heavy Metals Testing: Through research and collaborative discussion between the department and laboratories, it was determined that laboratories that offer *heavy metals testing* will likely not incur any additional costs beyond their current operations and procedures. Generally, *heavy metals testing* analyses warrant calibration with every batch that is tested. Further, this testing utilizes both stable and inexpensive standards and the number of required compounds is minimal. Thus, a laboratory should not expect to incur any additional or increased costs beyond their current workflow and requirements because of the department's proposed rule language.

7. Microbiological Testing (Culture Method) - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards and Controls	$0.05	$0.05	$0.00
Reagents and Consumables	$2.20	$2.20	$0.00
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter Personnel (High Range) (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $2.50 $8.33 $2.00 $2.50 $8.33 $2.00	 $2.59 $8.62 $2.60 $2.83 $9.03 $2.00	 $0.09 $0.29 $0.60 $0.34 $0.70 $0.00
Preparation, Sanitation, and Disposal	$1.50	$1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *microbiological testing (culture method)*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.98 - $1.04

Based on extensive research and dialogue between the department and laboratories, it was determined that the only noteworthy cost increase relates to an additional two to three hours of analyst time per day to capture pictures of all controls and samples. For laboratories testing 50 - 80 samples per day, an expected increase to their existing *microbiological testing (culture method)* daily costs may range from $52.00 - $78.00, meaning a per sample increase of $0.98 - $1.04.

(3.7)(a) Microbiological Testing (Culture Method) - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	N/A - Labs are currently not required to revalidate their methods.	$1,000.00	$1,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Modifying Existing Method or Instrument for Each Matrices	" "	N/A - No need to control for matrix interference, and thus, there should be no added cost.	N/A - No need to control for matrix interference, and thus, there should be no added cost.

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

8. Microbiological Testing (Immunoassay Method) - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards and Controls	N/A	$2.22	$2.22
Reagents and Consumables	$7.28	$8.88	$1.60
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	$3.32 $8.33 $2.00	$5.25 $12.50 $2.00	$1.93 $4.17 $0.00
Preparation, Sanitation, and Disposal	$1.00	$5.00	$4.00
Total expected increase to a laboratory's existing cost(s) per sample for *microbiological testing (immunoassay method)*: **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$13.92

Beyond costs that have been identified in the table above, the department, with industry input, has also identified that there may be slight cost increases resulting from the spill and handling instructions. As mentioned previously, should a laboratory's operations be at or near widely accepted scientific benchmarks, the costs incurred from this expense subject should be minimal, if any.

(3.8)(a) Microbiological Testing (Immunoassay Method) - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	N/A - Labs are currently not required to revalidate their methods.	$5,000.00 - $10,000.00	$5,000.00 - $10,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	N/A	$5,000.00 - $10,000.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

As previously noted, there will be added costs for the industry to come into compliance; however, the range of expenses and associated work needed to meet the department's regulations will be contingent upon the laboratories' current operations. The department has adopted these regulations with leading scientific industry standards in mind and thus laboratories currently operating at or near these benchmarks will not incur as expenses as high as a laboratory operating further way from those standards.

9. Microbiological Testing (Polymerase Chain Reaction Method) - Per Sample:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Cost(s) with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Standards and Controls	$1.00	$1.00	$0.00
Reagents and Consumables	$25.00	$25.00	$0.00
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $4.50 $8.33 $2.00	 $4.50 $8.33 $2.00	 $0.00 $0.00 $0.00
Preparation, Sanitation, and Disposal	$1.50	$1.50	$0.00
Total expected increase to a laboratory's existing cost(s) per sample for *microbiological testing (polymerase chain reaction (PCR) method):* **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.00

Based on extensive research and dialogue between the department and industry representatives, it was determined that laboratories will likely not incur any noteworthy cost increases beyond their current operations and procedures related to *microbiological testing (polymerase chain reaction (PCR))*.

(3.9)(a) Microbiological Testing (Polymerase Chain Reaction) - Method Validation:

Expense Subject	Laboratory's Current Cost(s)	Laboratory's Perceived Costs w/ New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	N/A - Labs are currently not required to revalidate their methods.	$5,000.00	$5,000.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "	N/A	N/A

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

(3.10) Mycotoxin Testing (ELISA Method)

The department was unable to gather sufficient data from industry for (1) current costs and (2) perceived costs from the proposed regu-

lations related to *mycotoxin testing*. As a result, department staff conducted an independent cost analysis and furnished information to calculate an expected "*mycotoxin testing (ELISA Method) item costs*," "*mycotoxin testing (ELISA method) quality control items*," and "*researched costs relating to method validation and personnel*."

Utilizing the ELISA method, the department determined that a laboratory may expect to incur either the following or comparable *mycotoxin testing* costs:

Mycotoxin Testing (ELISA Method) Item Costs:

Microbial Flower (1g) Testing Item	Cost per Unit	Use per Sample	Total Cost
AgraQuant® Ochratoxin ELISA Test	$3.54	1	$3.54
AgraQuant® Total Aflatoxin ELISA Test	$3.54	1	$3.54
Whirl-Pak® Sterile Sample Bag	$0.29	1	$0.29
Methanol, ACS Reagent	$0.31	3.5	$1.09
Certified Filter Pipette Tip, 1-1000uL	$0.17	0.05	$0.01
Certified Filter Pipette Tip, 1-200uL	$0.14	3	$0.42
Total Testing Item Costs for Mycotoxin Testing (ELISA Method), Per Sample:			$8.89

Mycotoxin Testing (ELISA Method) Quality Control Item Costs:

Quality Control Items Positive and Negative Controls	Cost per Unit	Use per Batch	Total Cost
AgraQuant® Ochratoxin ELISA Test	$3.54	7	$24.77
AgraQuant® Total Aflatoxin ELISA Test	$3.54	7	$24.77
Whirl-Pak® Sterile Sample Bags	$0.29	2	$0.57
Methanol, ACS Reagent	$0.31	7	$2.19
Certified Filter Pipette Tip, 1-1000uL	$0.17	0.05	$0.01
Certified Filter Pipette Tip, 1-200uL	$0.14	21	$2.94
Aflatoxin Mix	$18.54	0.000004	$0.0001
10µg/mL Ochratoxin A in Methanol	$38.20	0.000004	$0.0002
Flower Matrix	$6.51	2	$13.02
Total quality control item costs for mycotoxin testing (ELISA method), per batch (20 samples):			$68.28

Department Researched Method Validation and Personnel Costs:

Expense Subject	Department Researched Current Cost(s)	Department's Perceived Cost Increase with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Personnel (i) Tester (ii) Reviewer (iii) Admin/Reporter	 $2.50 $8.33 $2.00	 $2.75 $8.33 $2.00	 $0.25 $0.00 $0.00
Department's expected increase to a laboratory's existing cost(s) per sample of *mycotoxin testing (ELISA method)*: This calculation omits the following: (1) Standards and controls costs, (2) reagents and consumables costs, and (3) any other costs associated with preparation, sanitation, and disposal. **Note:** *The department was unable to gather the number of samples per day for each test from laboratories. As a result, these estimates are unable to accurately create a monthly or yearly summary detailing the total increased costs for each field of testing.*			$0.25

Based on the department's research and cost analysis related to *mycotoxin testing (ELISA method)*, a laboratory may expect a cost increase of $0.25 on top of their existing per sample costs.

(3.10)(a) Mycotoxin Testing (ELISA Method) - Method Validation:

Expense Subject	Department Researched Current Cost(s)	Department's Perceived Cost Increase with New Regulatory Requirements	Expected Increase to Laboratory's Existing Cost(s)
Method Validation or Annual Method Revalidation **(Required)**	N/A - Labs are currently not required to revalidate their methods	$1,500.00	$1,500.00
Implementing a New or Original Test Method	" "	" "	" "
Implementing a New Instrument	" "	" "	Full Validation: " " If identical instrument validated in lab → Abbreviated validation = (33% - 50%) (Full Val.)
Modifying Existing Method or Instrument for Each Matrices	" "		**Dept. Calculation Staff Time:** $400.00 - $800.00 (Assuming ~8 - 16 hours @ 50/hr) **Reagents and Consumables:** ~$200.00
			Minimum: $600.00 **Mean:** $800.00 **Maximum:** $1,000.00

Note: Labs currently have method validation requirements prescribed in WAC 314-55-103(32), but the department is currently unable to determine the extent in which each method has been fully validated. As such, these *method validation* figures are estimates based on the laboratories' varying operational levels.

If a method validation is needed for *mycotoxin testing (ELISA method)*, laboratories may also expect to incur an additional $1,500.00 expense.

Throughout the discussions with the impacted laboratories, it was expressed that most increases in costs related to testing samples would be passed on to the growers (clients) submitting samples for testing. This increase in price to test samples could potentially result in loss of sales or revenue. As previously discussed, laboratories that are further away from operating under typical industry standards would experience greater increases to their operating costs and could also potentially experience the largest loss in sales and revenue as customers naturally tend to seek out the most cost-effective ways to operate their businesses.

SECTION 4: **Analyze whether the proposed rule may impose more-than-minor costs on businesses in the industry.**

Based on the data provided in Section 3, the proposed rule may impose more-than-minor costs on some businesses in the industry.

It is assumed that businesses will choose the least expensive options to maintain adequate testing laboratories and meet these new accreditation requirements. Businesses that choose to purchase expensive capital equipment, like analytical instruments, will likely do so because the equipment can be used to bring in additional revenue and uses.

Through assessments, surveys, and meetings, the department determined that laboratories currently have all the necessary instruments to provide their currently offered services. Businesses may have more-than-minor costs imposed on them even if they are able to continue us-

ing current equipment and utilize lab-to-lab transfers for testing. Businesses may exceed the minor cost threshold if they need to purchase equipment or hire additional scientist(s).

With per test method validations ranging from $1,000.00 - $30,000.00, it is also likely that this is an area where businesses will exceed the minor cost threshold. Similarly, annual instrument calibrations range from $3,000.00 - $30,000.00 and thus would cause a business to exceed the minor cost threshold.

Table 4.1 shows a range of estimated costs to run testing laboratories. These costs can be as low as $0.00 and as high as $400,000.00 for instrumentation to perform testing requirements. In some cases, these costs can be as low as $0.00 and as high as $90,000.00 to maintain proper controls, storage, equipment, consumables, or increased staffing.

Table 4.1: Summary of potential cost increases in relation to the minor cost threshold.

NAICS	541380
Industry Type	Testing Laboratories
Minor cost threshold**	$8,577.31
Cost for matrix blanks/spiking standards	$10,000.00 - $50,000.00
Cost for increased storage	$360.00 - $5,000.00
Costs for additional staff	$0.00 - $90,000.00
Cost for analytical instruments	$0.00 - $400,000.00
Cost for refrigeration storage	$0.00 - $10,000.00
Cost for camera equipment	$0.00 - $500.00
Cost for increased standards, solvents, personnel, and equipment	$2,000.00 - $10,000.00
Cost of reanalysis and reextraction work	$5.00 - $25,000.00

Sources: Census Bureau, WSLCB, DOH, WSDA.
* Minor cost thresholds calculated as 1% of average annual payroll.

SECTION 5: **Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.**

RCW 19.85.040(1) requires the department to compare the cost of compliance for small businesses with the cost of compliance for the 10 percent of businesses that are the largest businesses required to comply with the proposed rules using one or more of the following as a basis for comparing costs: (a) Cost per employee; (b) cost per hour of labor; or (c) cost per $100.00 of sales.

After several surveys and interviews conducted by the department, it was determined that all eight laboratories currently providing cannabis testing are considered small businesses with fewer than 50 employees.

Since there are no large businesses offering cannabis testing services in Washington, the department was not able to compare the costs of compliance for small businesses with the costs of compliance for large businesses.

Without any large businesses to compare costs of compliance with, the proposed rule is considered inherently disproportionate.

SECTION 6: **If the proposed rule has a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs cannot be reduced provide a clear explanation of why.**

RCW 19.85.030(2) requires consideration of the following methods of reducing the impact of the proposed amendment on small businesses:

(a) *Reducing, modifying, or eliminating substantive regulatory requirements:* The proposed rule eliminates the necessity for laboratories to be certified for multiple fields of testing. A laboratory will be able to specialize in one or a few tests that share instrumentation and personnel needs. This increased flexibility allows laboratories to do only the work they find profitable and allows them to outsource all other work required.

Additionally, the proposed rule allows for laboratories to engage in a method approval process should they deem that the methods provided by the department are uneconomical, or more expensive to validate than using their preexisting methods. In essence, this allows for laboratories to submit their current methods to the department, as it relates to the fields of testing described herein, and be notified whether their submitted method is acceptable or not.

Moreover, the amended proposed rule now allows for laboratories to potentially waive the academic requirements listed in WAC 16-309-050 through 16-309-070, which would presumably eliminate the need to hire additional staff. The academic requirement waivers are assessed by the accrediting authority on a case-by-case basis and are intended for a laboratory's current employee(s) that already function as a highly experienced analyst.

Further, the department decided to remove the refrigeration requirement listed under WAC 16-309-090. This decision may reduce the need for some of the laboratories to purchase new equipment so long as laboratories test the sample(s) they are in receipt of before seven days have elapsed. Laboratories that we talked to were already testing their samples below the seven-day mark, and therefore would receive the benefit of this change.

Lastly, laboratories may now run a customer sample in duplicate to replace the matrix spike duplicate. Laboratories would still incur typical costs for running the customer sample, that is, costs for methanol, injection, etc., but would be able to forego the matrix spike duplicate requirement and only need to spike one matrix per batch.

(b) *Simplifying, reducing, or eliminating recordkeeping and reporting requirements:* While the proposed rule increases the total time that records must be maintained from three years (WSLCB rule) to five years, the creation of hard copies of data and reports is not a requirement. The use of electronic data and storage of the electronic data is allowed and must be maintained for the minimum period described in the proposed rule. Electronic storage of records is generally less expensive than storage of hard copy records.

(c) *Reducing the frequency of inspections:* Inspections will be performed annually. The laboratories and the department agree this schedule is suitable as it is standard for accreditations across fields.

(d) *Delaying compliance timetables:* While the department sets and adopts the standards for accreditation, the current accrediting authority is responsible for compliance and enforcement of the standards. Delaying the compliance timetables is outside this rule making's scope. If the department becomes the accrediting authority, it plans to issue a separate policy statement delaying enforcement of these requirements until December 31, 2024.

(e) *Reducing or modifying fine schedules for noncompliance:* Currently, there are no scheduled fines for noncompliance. It is the in-

tent of this program to work with the laboratories to support compliance.

(f) *Any other mitigation techniques including those suggested by small businesses or small business advocates:* Conditions were added to allow nondegreed laboratory technicians to perform several of the tests, but not all. This may require some laboratories to hire degreed staff. A grandfather clause is included in the proposed rule, which may qualify some of the laboratory technicians to perform high complexity testing.

Through informed research and analysis, the department has considered all suggested cost mitigations for laboratories as it relates to the proposed rule. All cost mitigation requests reviewed by the department were both thoroughly analyzed and discussed by the interagency team. For inquiries that could not be put into effect, the department made these decisions by determining that their amendments and/or removal would significantly minimize the scientific integrity and merit of the cannabis testing laboratory quality standards. The department further determined that some of the requests would reduce laboratory credibility, which then negatively affects consumer protections and lowers the public's overall trust in government.

SECTION 7: **Describe how small businesses were involved in the development of the proposed rule.**

The department facilitated several opportunities for small businesses to be involved in the rule-making process. Before creation of the first draft of the proposed rule, the department arranged for meetings with all the laboratories as indicated in Table 1. The department shared the first draft of the rule with all eight impacted laboratories, with instructions for the laboratories to identify the probable costs to comply with the proposed rule, including: Cost of equipment, supplies, labor, professional services, and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue. Laboratories were also asked to identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule. The department arranged a video conference call with all eight impacted laboratories to discuss their feedback. The department revised the proposed rule to create a second draft and documented the changes made in a separate secondary document. The department shared the second draft of the proposed rule and secondary document with all eight impacted laboratories, asking for additional feedback. The department revised the second draft based on the feedback and has created a third and final version of the proposed rule amendment.

Based on the comments received during the public comment period and the public hearing held on December 28, 2023, the department determined that substantive changes were necessary to the proposed rule language to address the concerns that were provided. Over the following month, the department held one-on-one meetings with the heavily engaged laboratories. Following this round of meetings to solicit feedback from laboratories regarding the current regulations and cost implications, the department then decided to hold an open Q&A forum for laboratory representatives to voice any final concerns.

Table 1 - Stakeholder Engagement Interactions

Meeting with	Meeting Venue	Date	Discussion
Medicine Creek Analytics	In person	Thursday, February 2, 2023	Introduction to CLASP and next steps for lab standards.

Table 1 - Stakeholder Engagement Interactions			
Meeting with	Meeting Venue	Date	Discussion
Green Growers Labs	In person	Wednesday, February 22, 2023	Introduction to CLASP and next steps for lab standards.
True Northwest, Inc.	In person	Tuesday, April 4, 2023	Concerns with current cannabis laboratory regulations.
Integrity Labs	In person	Tuesday, April 11, 2023	Concerns with current cannabis laboratory regulations.
Treeline Analytics, LLC	In person	Friday, May 5, 2023	Introduction to CLASP and next steps for lab standards.
Capitol Analysis	Phone call	Friday, May 12, 2023	Concerns with current cannabis laboratory regulations.
Testing Technologies, Inc.	Phone call	Friday, May 26, 2023	Concerns with current cannabis laboratory regulations.
Confidence Analytics	Phone call	Friday, May 26, 2023	Concerns with current cannabis laboratory regulations.
All laboratories	Outbound email	Thursday, June 22, 2023	Requesting feedback on draft rule; inviting to video conference.
All laboratories	Video conference	Wednesday, June 28, 2023	Requesting feedback on draft rule.
Treeline Analytics, LLC	Inbound email	Monday, July 3, 2023	Response and comments on first draft.
True Northwest, Inc.	Inbound email	Wednesday, July 5, 2023	Response and comments on first draft.
Medicine Creek Analytics	Inbound email	Thursday, July 6, 2023	Response and comments on first draft.
Capitol Analysis	Inbound email	Friday, July 7, 2023	Response and comments on first draft.
All laboratories	Outbound email	Friday, July 21, 2023	Sent second draft of rules and responses to original questions and concerns.
Integrity Labs	Inbound email	Wednesday, July 26, 2023	Response and comments on second draft.
Treeline Analytics, LLC	Inbound email	Friday, July 28, 2023	Response and comments on second draft.
Confidence Analytics	Inbound email	Friday, July 28, 2023	Response and comments on second draft.
Capitol Analysis	Inbound email	Thursday, August 10, 2023	Follow up question on rule section.
Treeline Analytics, LLC	Video conference	Friday, January 26, 2024	Concerns with current cannabis laboratory regulations/cost implications.
Medicine Creek Analytics	Video conference	Wednesday, January 31, 2024	Concerns with current cannabis laboratory regulations/cost implications.
Confidence Analytics	Video conference	Thursday, February 1, 2024	Concerns with current cannabis laboratory regulations/cost implications.
All laboratories invited	Video conference	Monday, February 5, 2024 10 a.m.	Feedback and Q&A session.

Table 1 - Stakeholder Engagement Interactions			
Meeting with	Meeting Venue	Date	Discussion
All laboratories invited	Video conference	Monday, February 5, 2024 2 p.m.	Feedback and Q&A session.

SECTION 8: **Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule.**

The proposed rule should not cause job loss.

Some laboratories have indicated that the additional validation requirements will require more personnel hours. If laboratories need to hire one additional person to meet the requirements, then the proposed rule amendment may create up to eight new jobs.

A copy of the statement may be obtained by contacting Gloriann Robinson, Rules Coordinator, P.O. Box 42560, Olympia, WA 98504-2560, phone 360-902-1802, TTY 800-833-6388, email wsdarulescomments@agr.wa.gov.

February 21, 2024
Jessica Allenton
Assistant Director

OTS-4989.6

Chapter 16-309 WAC
CANNABIS LABORATORY ACCREDITATION STANDARDS PROGRAM

NEW SECTION

WAC 16-309-010 Purpose of chapter. Under the authority of chapter 15.150 RCW, the department adopts rules to establish and maintain quality standards for laboratories conducting analysis of recreational and medicinal cannabis. The standards are the elements used in the evaluation of a product's compliance with established product standards. These rules consist of method approval, method validation protocols, and performance measures and criteria applied to the testing of the product.

NEW SECTION

WAC 16-309-020 Definitions. "Accessioning" means the process of receiving and organizing samples for testing in a laboratory.

"Accreditation" means the formal recognition by the accrediting authority that a cannabis laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by the issuance of a written certificate, accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited.

"Accreditation year" means the one-year period as stated on the certificate of accreditation.

"Accrediting authority" means the recognized agency that has the authority to perform audits and inspections to assure laboratories meet the standards established in rule and will issue, suspend, or revoke accreditation to the laboratory.

"Accuracy" means the degree to which an analytical result corresponds to the true or accepted value for the sample being tested. Accuracy is affected by bias and precision.

"Action level" means the level of concern, decision point, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Aliquot" means a portion of a larger whole, especially a sample taken for chemical analysis or other treatment.

"Analyte" means the constituent or property of a sample measured using an analytical method.

"Analytical batch" means a group of samples, standards, and blanks which are analyzed together with the same method sequence and same lots of reagents and with the manipulations common to each sample within the same time period usually no more than 24 hours. Batch size is usually limited to instrument loading capacity.

"Analytical data" means the recorded qualitative and/or quantitative results of a chemical, physical, biological, microbiological, radiochemical, or other scientific determination.

"Analytical method" means a written procedure for acquiring analytical data.

"Autoclave" means a steam sterilizer device that is intended for use by a laboratory to sterilize biohazardous products by means of pressurized steam.

"Bias" means the difference between the expectation of the test result and the true value or accepted reference value. Bias is the total systematic error, and there may be one or more systematic error components contributing to the bias.

"Biohazardous" means products that are infectious, and sharps materials such as needles and broken glass.

"Biosafety cabinet (BSC)" means biocontainment equipment used in biological laboratories to provide personnel, environmental, and product protection.

"Blank" means a substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, system blanks, and field blanks. Response for target analytes must be less than 50 percent of the limit of quantitation.

"Board" means the Washington state liquor and cannabis board.

"Calibration" means determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.

"Calibration curve" means the functional relationship between instrument response and target analyte concentration determined for a series of calibration standards. The calibration curve is obtained by plotting the instrument response versus concentration and performing a regression analysis of the data.

"Calibration standard (CalS)" means a known amount or concentration of analyte used to calibrate the measuring/detection system. May be matrix matched for specific sample matrices.

"Cannabis laboratory analytical standards program (CLASP)" means the interagency coordination team for cannabis laboratory quality standards. The team consists of the department of agriculture (WSDA), the liquor and cannabis board (LCB), and the department of health (DOH). The WSDA is the designated lead agency for the team.

"Cannabis laboratory" or "laboratory" means a facility:

(a) Under the ownership and technical management of a single entity in a single geographical location;

(b) Where scientific determinations are performed on samples taken from cannabis plants and products; and

(c) Where data is submitted to the customer or regulatory agency, or other entity requiring the use of an accredited laboratory under provisions of a regulation, permit, or contractual agreement.

"Carryover" means residual analyte from a previous sample or standard which is retained in the analytical system and measured in subsequent samples. Also called memory.

"Certified reference material (CRM)" means a reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures.

Note: Standard reference material (SRM) is the trademark name of CRMs produced and distributed by the National Institute of Standards and Technology (NIST).

"Certifying scientist" means the person authorized by the scientific director to review the analytical results and issue the certificate of analysis for cannabis samples who has the education, training, and competencies to perform such duties. No certifying duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or testing.

"Clean room" means an isolated environment, strictly controlled with respect to: Airborne particles of viable and nonviable nature, temperature, humidity, air pressure, air flow, air motion, and lighting.

"Continuing calibration verification standard (CCV)" means one of the primary calibration standards used to verify the acceptability of an existing calibration.

"Control" means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

"Corrective action" means the process of identifying and eliminating the cause of a problem to prevent it from happening again.

"Cut-off concentration" means, in qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods).

"Decision point" means the level of concern, action level, cut-off, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample.

"Department" means the state of Washington department of agriculture when the term is not followed by another state designation.

"High complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a higher level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Initial calibration blank (ICB)" means an aliquot that consists of the same solvent used for the calibration standards, but without the analytes, analyzed following the initial calibration and prior to

quantitating any samples to verify the absence of instrumental interferences.

"Initial calibration verification (ICV)" means a second source standard that is used to verify the correctness of the primary source calibration curve. This standard is initially analyzed prior to sample analysis.

"Incubation" means the act of storing microorganisms at a predetermined temperature, for a predetermined amount of time, to allow for growth of microorganism colonies.

"Inoculation" means the act of introducing microbes into a culture media to induce reproductive growth.

"Interference" means a positive or negative response or effect on response produced by a substance other than the analyte. Includes spectral, physical, and chemical interferences which result in a less certain or accurate measurement of the analyte.

"Intermediate precision" means within-laboratory precision obtained under variable conditions, e.g., different days, different analysts, and/or different instrumentation.

"Internal standard (IS)" means a chemical added to the sample, in known quantity, at a specified stage in the analysis to facilitate quantitation of the analyte. Internal standards are used to correct for matrix effects, incomplete spike recoveries, etc. Analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard must have similar physiochemical properties to those of the analyte.

"Laboratory control sample (LCS)" means a portion of respective matrix blank that is spiked with known quantities of target analytes and processed as if it were a sample. The LCS is used to evaluate the accuracy of the methodology.

"Laboratory information management system (LIMS)" means a computer software system that is used to collect information about a sample, track results through the testing process, and disseminate the final results to the customer and regulating agency.

"Limit" means a point or level beyond which something does not or may not exceed or pass. Something that bounds, restrains, or confines to the utmost extent. Limits are used to define a specific concept in analysis. Decision points and action levels are examples of limits.

"Limit of detection (LOD)" means the minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the detection limit. When applied to the instrument capability it is known as an instrument detection limit (IDL) or when applied to the complete analytical method it is often referred to as the method detection limit (MDL).

"Limit of quantitation (LOQ)" means the minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision and accuracy. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and applies to the complete analytical method.

"Linearity" means the ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.

"Low complexity testing" means laboratory tests that require little to no expertise to perform the test due to the lack of complexity of the test methodology and the low risk of erroneous results. These tests require a low level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Matrix" means the material to be analyzed including, but not limited to, flower, trim, leaves, other plant matter, cannabis concentrate, cannabis infused, and edibles.

"Matrix blank" means a substance that closely matches the samples being analyzed with regard to matrix components. Ideally, the matrix blank does not contain the analyte(s) of interest but is subjected to all sample processing operations including all reagents used to analyze the test samples. The matrix blank is used to determine the absence of significant interference due to matrix, reagents, and equipment used in the analysis.

"Matrix effect" means an influence of one or more components from the sample matrix on the measurement of the analyte concentration or mass. Matrix effects may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte.

"Matrix spike (MS)" means an aliquot of a sample prepared by adding a known amount of analyte(s) to a specified amount of matrix. A matrix spike is subjected to the entire analytical procedure to establish if the method is appropriate for the analysis of a specific analyte(s) in a particular matrix. Also referred to as a laboratory fortified matrix.

"Matrix spike duplicate (MSD)" means a replicate of a sample that has known concentrations of analytes added to it. It is used to evaluate the precision and bias of a method for a specific sample matrix. A matrix spike duplicate is processed along with the same sample batch and follows the same sample preparation and analytical testing.

"Method" means a particular procedure that systematically describes how a cannabis test is performed and analyzed.

"Method validation" means the process of demonstrating or confirming that a method is suitable for its intended purpose. Validation criteria include demonstrating performance characteristics such as accuracy, precision, selectivity, limit of detection, limit of quantitation, linearity, range, ruggedness, and robustness.

"Method validation report" means documentation generated detailing the evidence which established the suitability of the method for its intended use.

"Moderate complexity testing" means laboratory tests that require a level of expertise to perform the test due to the complexity of the test methodology and the risk of erroneous results. These tests require a moderate level of scientific knowledge and experience, troubleshooting skills, and quality control checks.

"Parameter" means the combination of one or more analytes determined by a specific analytical method.

"Performance criteria" means defined, measurable performance characteristics of an analytical method or process-specific requirements for accuracy, precision, recovery, specificity (selectivity), sensitivity (limits of detection), inclusivity, exclusivity, linearity, range, and scope of application. Criteria may also be set by defining process (i.e., method validation protocols).

"Performance-based methods approach" means or conveys "what" needs to be accomplished, but not prescriptively "how" to do it. It is a measurement system based upon established performance criteria for accuracy and precision with use of analytical test methods. Under this measurement system, laboratories must demonstrate that a particular analytical test method is acceptable for demonstrating compliance. Performance-based method criteria may be published in regulations,

technical guidance documents, permits, work plans, or enforcement orders.

"Precision" means the closeness of agreement between independent test results obtained under specified conditions. This is described by statistical methods such as a standard deviation or confidence limit of test results. See also "random error." Precision can be further classified as repeatability, intermediate precision, and reproducibility.

"Preparation batch" means samples that are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents. A preparation batch consists of one to 20 samples (not including matrix blanks, LCS, matrix spikes and matrix duplicates) of the same matrix.

"Proficiency testing (PT)" means evaluation of the results from the analysis of samples, the true values of which are known to the supplier of the samples but unknown to the laboratory conducting the analyses.

"Proficiency testing provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking certification that is approved by the department and provides samples for use in PT testing.

"Qualitative analysis/method" means analysis/method in which substances are identified or classified on the basis of their chemical, biological, or physical properties. The test result is either the presence or absence of the analyte(s) in question.

"Quality assurance (QA)" means activities intended to assure that a quality control program is effective. A QA program is a totally integrated program for assuring reliability of measurement data.

"Quality assurance (QA) manual" means a written record intended to assure the reliability of measurement data. A QA manual documents policies, organization, objectives, and specific QC and QA activities.

"Quality control (QC)" means the routine application of statistically based procedures to evaluate and control the accuracy of analytical results.

"Quantitative analysis/method" means analysis/method in which the amount or concentration of an analyte may be determined (or estimated) and expressed as a numerical value in appropriate units with acceptable accuracy and precision.

"Random error" means component of measurement error that in replicate measurements varies in an unpredictable manner. See also "precision."

"Range" means the interval of concentration over which the method provides suitable accuracy and precision.

"Reagent blank" means reagents used in the procedure taken through the entire method. Reagent blanks are used to determine the absence of significant interference due to reagents or equipment used in the analysis.

"Recovery" means the proportion of analyte (incurred or added) remaining at the point of the final determination from the analytical portion of the sample measured. Commonly expressed as a percentage.

"Reference material" means a material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.

"Reference standard" means a standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived.

Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).

"Relative percent difference (RPD)" means the comparison of two quantities while taking into account the size of what is being compared as calculated:

percent RPD=|(sample - duplicate)|/((sample + duplicate)/2) * 100

"Repeatability (RSDr)" means precision obtained under observable conditions at a specific concentration/spike level where independent test results are obtained with the same method on identical test items in the same test facility by the same operator using the same equipment within short intervals of time.

"Representative matrix" means a cannabis matrix used to assess probable analytical performance with respect to other matrices, or for matrix-matched calibration, in the analysis of broadly similar cannabis products.

"Reproducibility (RSDR)" means precision obtained at a specific concentration/spike level under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.

"Ruggedness/robustness" means a measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

"Sample" means representative portion of material taken from a larger quantity of homogenate for the purpose of examination or analysis, which can be used for judging the quality of a larger quantity for the purpose of compliance.

"Sample package" means the sealed, tamper-resistant container (e.g., plastic bag, box, etc.) which contains the quality control sample and transportation manifest from grower or producer collection.

"Scientific director" means the individual with the proper education and training responsible for the overall laboratory operations, compliance, and training of personnel.

"Selectivity" means the extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Also known as specificity.

"Sensitivity" means the change in instrument response which corresponds to a change in the measured quantity (e.g., analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.

"Shipping container" means the container (e.g., box, mailer, bag) in which the collector, or laboratory has placed one or more sample packages for transport.

"SI" means the international system of units and more commonly known as the metric system. This is the international standard for measurement. Critical laboratory measurements must be traceable to this system.

"Signal to noise ratio (SNR)" means a measure that compares the level of desired signal of an analyte to the level of background noise from the instrument thus establishing the instrument's ability to differentiate between the two.

"Specificity" means the ability of a method to measure analyte(s) in the presence of components which may be expected to be present.

"Spike recovery" means the fraction of analyte remaining at the point of final determination after it is added to a specified amount of matrix and subjected to the entire analytical procedure. Spike recovery is typically expressed as a percentage. Spike recovery must be calculated for the method as written. For example, if the method prescribes using deuterated internal standards or matrix-matched calibration standards, then the reported analyte recoveries must be calculated according to those procedures.

"Spore bioindicators" means a biological indicator that is made up of a carrier material, on which bacterial spores with a defined resistance to the sterilization process have been applied.

"Standard operating procedures (SOP)" means a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

"Standard reference material (SRM)" means a certified reference material issued by the National Institutes of Standards and Technology (NIST) in the United States.

"Standard (solution)" means a solution containing a precisely known concentration of an element, analyte, or a substance.

"Sterilization" means a validated process used to render a product free of all forms of viable microorganisms.

"Stock standard" means a concentrated solution of method analyte(s) prepared in the laboratory from referenced and certified analyte standards, where available, or a concentrated solution of method analyte(s) purchased directly from a referenced and certified source, where available.

"Surrogate (SUR)" means a pure compound that shall not be found in any sample but is similar in nature to the compounds of interest. This compound is added to a sample in a known amount before processing to monitor method performance for each sample. It is quantified in a manner analogous to that used for the analytes. The SUR is useful in ensuring that there were no problems in sample preparation.

"Systematic error" means component of measurement error that in replicate measurements remains constant or varies in a predictable manner. This may also be referred to as bias.

"Target analytes" means those analytes required to be tested on samples by the laboratory as defined in WAC 314-55-102.

"Testing personnel" means those qualified on the basis of education, training, experience and demonstrated skills to perform analytical testing on cannabis, cannabis concentrates, and cannabis infused products.

"Uncertainty" means nonnegative parameter characterizing the dispersion of the values being attributed to the measured value.

"Unidirectional flow" means performing a standard operating procedure in a single direction to reduce the risk of microbiological contamination.

"Upper level of linearity (ULOL)" means the highest level at which an instrument can measure the concentration of a substance accurately within an acceptable measure of deviation.

"Validated methods" means the methods that have undergone validation.

"Validation (method)" means the process of demonstrating or confirming the performance characteristics through assessments of data quality indicators for a method of analysis.

NEW SECTION

WAC 16-309-030 Laboratory instructions. (1) A cannabis testing laboratory must be accredited by the accrediting authority prior to conducting quality assurance tests on any cannabis flower or products derived under chapter 69.50 RCW.

(a) Accredited labs must conspicuously display the accreditation letter received by the accrediting authority at the lab's premises in a location where a customer may observe it unobstructed in plain sight.

(b) The laboratory must maintain a list of all tests they are currently accredited to test.

(2) The laboratory must identify potential conflicts of interest among key personnel in the organization that have involvement or influence on the testing activities of the laboratory.

(a) The laboratory conducting third-party testing must be independent of other cannabis businesses and have no financial interest in another cannabis license, excluding multiple lab accreditations.

(b) If a potential conflict of interest is identified, the laboratory must notify the accrediting authority for review, determination, and resolution of the conflict.

(3) The customer's confidential information and proprietary rights must be protected by the laboratory. The laboratory must maintain policies and procedures to protect confidential information.

(4) Cannabis labs must report certificate of analysis test results both to the customer and directly to the board in the required format(s).

(5) The department, board, and or accrediting authority may require the laboratory to submit raw data and information related to testing. The laboratory must keep and maintain all raw data and testing information for a period of five years.

(6) Laboratories must conduct an internal audit of laboratory operations to verify compliance with the accreditation checklist within 60 days of their scheduled audit. This self-audit will be reviewed by the accrediting authority at their yearly laboratory audit.

NEW SECTION

WAC 16-309-040 Laboratory personnel. (1) The laboratory must have a training and retraining program for all personnel that is kept current and is documented and maintained with personnel records.

(2) The laboratory must maintain personnel files on all employees detailing their qualifications and duties for all positions that include:

(a) Resume of training and experience.

(b) Job description of current position.

(c) Copies of certificates.

(d) Copies of diploma(s).

(e) Training checklists which include what training was performed, who did the training, and when it was performed.

(f) Documentation of continuing education, if any.

(g) Documentation of demonstrated abilities and competencies.

(3) The laboratory must document the technical staff's competency for each method performed on a yearly basis demonstrating their abilities to perform their specific job functions. Completion must be signed and dated by the scientific director.

(a) Demonstration of competencies include performing instrument setup or maintenance, sample handling, extractions, testing on each instrument used, quality control acceptance, and reporting of results.

(b) Testing personnel must demonstrate acceptable performance on precision, accuracy, selectivity, reportable ranges, blanks, and unknown challenges through the use of proficiency samples or internally generated quality controls. Completion must be signed and dated by the scientific director.

(4) The laboratory must have a personnel organization chart showing the chain of command and responsibilities approved, initialed, and dated by the scientific director.

(5) The scientific director may delegate some responsibilities in their absence or for other management staff. The delegation must be in writing, indicating what functions are being delegated (i.e., quality control data review, assessment of competency, or review of proficiency testing performance), and the delegate must be qualified and approved by the scientific director.

(6) If the laboratory performs microbiological testing, at least one member of the laboratory staff must have a bachelor's degree in a biological or clinical laboratory science or medical technology from an accredited institution, or associate degree in a biological or clinical laboratory science or medical laboratory technology from an accredited institution. The scientific director may satisfy this requirement if they hold a biological or clinical laboratory science degree or medical technology from an accredited institution, as described in WAC 16-309-050.

(7) All staff must be properly trained and evaluated for proper test performance prior to starting sample testing and reporting results.

(8) The accrediting authority may waive the academic requirements listed in WAC 16-309-050 through 16-309-070, on a case-by-case basis, for highly experienced analysts. The accrediting authority may also waive the need for the specified training, on a case-by-case basis, for supervisors of laboratories associated with testing of cannabis and cannabis products.

(9) Laboratory testing personnel must be supervised by persons familiar with test methods and procedures.

(10) Supervisors of testing personnel must meet one of the qualifications for a scientific director or have at least a bachelor's degree in one of the natural sciences and three years of full-time laboratory experience in a regulated laboratory environment performing analytical scientific testing. A combination of education and experience may substitute for the three years of full-time laboratory experience.

(11) The laboratory must designate a quality assurance manager or officer with defined responsibilities for ensuring the quality system is implemented and followed. The QA manager must be a separate person from the scientific director.

(12) The laboratory must report to the accrediting authority any change in the status of the scientific director. A laboratory cannot be without a scientific director for more than 30 days.

NEW SECTION

WAC 16-309-050 Scientific director. (1) Each laboratory must employ a scientific director to ensure the achievement and maintenance of quality standards of practice who meets the following minimum qualifications:

(a) Must possess a doctorate in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of two years post-degree laboratory experience; or

(b) A master's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of four years of post-degree laboratory experience; or

(c) A bachelor's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of six years of post-education laboratory experience.

(2) The scientific director must have supervisory authority over all personnel involved with the accessioning, testing and storage of samples, and the reporting of results.

(3) The scientific director is not required to have direct supervisory authority over client service or IT personnel. However, they are responsible for ensuring laboratory compliance with chapters 314-55 and 246-70 WAC and this chapter, even if functions are performed by staff outside the cannabis laboratory (e.g., another department, off-site staff, corporate staff) ensuring that the confidentiality of reported results is maintained.

(4) The scientific director's responsibilities include, but are not limited to:

(a) Engaging in and responsible for the daily management of the laboratory;

(b) Establishing a training program for personnel;

(c) Ensuring that personnel are sufficiently trained;

(d) Ensuring that all personnel have demonstrated proficiency in assigned duties prior to working independently on customer cannabis samples;

(e) Ensuring that the standard operating procedures (SOP) manual is complete, current, available, signed, and followed by all personnel;

(f) Reviewing and approving any requests to modify analytical methods and documentation;

(g) Ensuring that all personnel are properly informed, and training documented when changes occur in the SOP;

(h) Ensuring that analytical methods are properly validated;

(i) Establishing a quality assurance program sufficient to legally and scientifically support results;

(j) Establishing acceptable performance limits for calibrators and controls;

(k) Ensuring that corrective action is taken in response to unacceptable QC performance or when other errors occur;

(l) Ensuring that results are not reported until after corrective actions have been taken and that the results provided are accurate and reliable;

(m) Fully understanding the function of the laboratory information management systems (LIMS) and other laboratory computer systems in sample receiving, accessioning, chain of custody, testing, and the review and reporting of results;

(n) Ensuring that the LIMS software and other software in the laboratory have been properly validated;

(o) Fully understanding the role of any external service providers and the functions of external information systems and computer systems in the laboratory's activities associated with cannabis testing;

(p) Ensuring that external information systems and software used by the laboratory have been properly validated;

(q) Ensuring that corrective actions are taken in response to issues identified in the inspection and proficiency testing (PT) phases of the program;

(r) Demonstrating knowledge of the cannabis regulatory documents and the cannabis laboratory analysis standards program.

NEW SECTION

WAC 16-309-060 Laboratory personnel performing high complexity testing. Personnel performing high complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have a bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution; or

(2) Must have an associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution; or

(3) Have education and training equivalents that includes at least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either:

(a) Twenty-four semester hours of medical, clinical, or chemical laboratory technology courses; or

(b) Twenty-four semester hours of science courses that include:

(i) Six semester hours of chemistry;

(ii) Six semester hours of biology; and

(iii) An additional 12 semester hours of chemistry, biology, or medical laboratory technology in any combination;

(c) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;

(d) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-070 Laboratory personnel performing moderate complexity testing. Personnel performing moderate complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:

(1) Have at least a high school diploma or equivalent;
(2) Have documented training to perform the test;
(3) Have the skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;
(4) Have the skills required to implement the quality control policies and procedures of the laboratory;
(5) Have the awareness of factors that influence test results;
(6) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;
(7) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-080 Laboratory personnel performing low complexity testing. Personnel performing low complexity testing must be qualified on the basis of education, training, experience and demonstrated skills, and must meet the following minimum requirements:
(1) Have at least a high school diploma or equivalent;
(2) Have training to perform the test;
(3) Be evaluated for competencies to perform the test by someone who is already qualified to perform the test;
(4) Be approved by the scientific director to perform the test.

NEW SECTION

WAC 16-309-090 Standard operating procedures. (1) The laboratory must have a complete and current standard operating procedures (SOP) manual that describes in detail all laboratory operations and ensures all samples are tested in a consistent manner using the same procedures.
(2) Copies of relevant sections of the SOP must be available to all staff in their work areas.
(3) The scientific director must review and show written approval of all sections of the SOP dating when they were implemented. An itemized list of changes and versions made within the last five years must be documented on a summary of changes sheet for each section.
(4) The SOP must include a safety manual, procedure, or policy that describes specific precautionary issues throughout the lab that makes employees aware of, and know how to safely maneuver through, the issue as described in the OSHA laboratory safety guidance document.
(5) The SOP must include a procedure for decontamination and cleaning of instruments, bench space, and ventilation and microbial hoods.
(6) The SOP must include testing procedures that include pertinent information for the scope and complexity of the procedure, including:
(a) Title that identifies the activity or procedure;
(b) Scope and principle;
(c) Sample requirements;
(d) Calibration and control preparation and usage protocol;
(e) Instrumentation, equipment, materials and supplies used;

(f) Instrument settings, data acquisition, system operation, parameters and conditions for testing;

(g) Procedure for sample preparation and testing;

(h) Results review and acceptability;

(i) Additional information, notes, safety requirements, and precautions to include calculations, interferences, limitations, background corrections, and proper disposal of lab waste including biohazardous waste and cannabis waste compliant with WAC 314-55-097; and

(j) References.

(7) The SOP must include a policy for the use of personal protective equipment (PPE) when working with samples, reagents, chemicals, or potential hazards in the workplace along with a written and documented system on the competency of personnel on how to handle chemical spills and the use of chemical spill kits.

(8) The SOP must include a policy for limiting access to controlled areas of testing, storage of samples, disposal of samples, and records. Personnel must be assigned limited access according to their job responsibilities.

(9) The SOP must include a policy or procedure informing employees how to interact with law enforcement should they request information or come on-site for regulatory issues.

(10) The SOP must include a policy or procedure that informs employees and staff what tasks need to be performed and what information or documents need to be gathered prior to an audit or inspection.

(11) The SOP must include information on the proper handling and disposal of used and unused samples once testing is completed.

(12) The SOP must include information on how employees can access medical attention for chemical or other exposures, including follow-up examinations, without cost or loss of pay.

(13) The SOP must include a record or log of any deviations from the SOP detailing the reason for the deviation, the date, and approval from the scientific director.

(14) The laboratory must maintain retired procedures for at least five years beyond the retirement date and must be able to reconstruct the procedures that were in effect when a given sample was tested.

NEW SECTION

WAC 16-309-100 Sampling and homogenization protocols. (1) Upon receipt, the laboratory must inspect each sample package and transportation manifest, assuring they meet the following minimum requirements:

(a) Each sample package must have a transportation manifest accompanying it to the laboratory.

(b) Each manifest must have the identifying information on it documented at the time of collection prior to sending it to the laboratory.

(c) Each manifest must have a unique sample identification number matching the label on the sample.

(d) The laboratory must reject samples when the sample ID number or label on sample container does not match the sample ID number or label on the manifest or when the container shows evidence of tampering.

(2) The laboratory must transfer samples to a secure, limited access area of the laboratory upon receipt for processing and analysis.

(3) Receipt of samples must be documented as to condition of the package, who took possession, and whether there were any unacceptable conditions.

(4) The laboratory must document all persons handling the original sample, aliquots, and extracts.

(5) The laboratory must establish the minimum volume or weight required to conduct all testing requested and any additional tests (i.e., repeat tests, differential tests, or reflex tests) that may be required.

(6) The laboratory must establish storage requirements for all sample types upon receipt at the lab.

All samples received for residual solvent testing must have an aliquot placed in an enclosed container that minimizes the evaporation of any solvents that may be present as soon as possible upon receipt.

(7) Samples that do not undergo initial testing within seven days of arrival at the laboratory must be placed in a secure temperature-controlled storage until testing.

(8) Samples must be handled in a way that avoids cross-contamination during aliquoting and handling by keeping other samples closed and out of the immediate vicinity. Analyte standards must be handled in areas separate from sample preparation areas.

(9) It is not acceptable to reuse any labware that comes into contact with samples or aliquots until after proper cleaning. Labware, equipment, and surfaces must be properly cleaned between each sample preparation or handling.

(10) All disposable pipettes/sample measuring devices can be used only once and must be discarded after use to prevent the possibility of cross-contamination.

(11) Aliquots must be labeled with a unique identifier assigned to the sample both with a barcode and in human-readable form, or just in human-readable form.

(12) When multi-well plates are used for testing, the laboratory must ensure the correct sample is aliquoted into the correct plate well and map the location of each sample on the plate.

(13) The laboratory must have a system to easily retrieve and track samples that are maintained in storage.

(14) Laboratories must ensure sample homogenization is appropriate for each test method performed.

NEW SECTION

WAC 16-309-110 Security. (1) Laboratories must control and document access into operation areas (e.g., accessioning, data entry, sample handling, analytical, certification), along with sample storage areas, and records storage areas during both operating and nonworking hours.

(2) Individuals who do not have routine duties in secured areas (with the exception of auditors and emergency personnel) must be escorted, and their entries and exits must be properly documented (i.e., date, time of entry and exit, purpose of visit, and authorized escort).

(3) If a laboratory uses external service provider(s) to perform services on the laboratory's behalf (i.e., records storage, software service provider, or cloud service providers), the laboratory must show due diligence in verifying that the service provider has proce-

dures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform. The laboratory is responsible for ensuring the external service provider is in compliance with applicable requirements.

(4) Samples must be stored in a limited access, secured area.

(5) Only personnel who are assigned to the limited access, secured area can have unescorted access.

(6) Samples may be transported outside a secured area if they are in the custody of an authorized individual who is moving them to another secured location.

(7) Laboratories must maintain physical custody of samples and are not allowed to delegate sample storage to external service providers.

(8) Original hard copy records for reported samples must be maintained in a secure room, area, or file cabinet at all times suitable to prevent damage or deterioration and to prevent loss.

(9) Laboratories may use off-site record storage locations or services if they meet the limited access and security requirements listed above.

(10) The laboratory must establish a system to ensure records are protected from loss or accidental destruction. This could include backup copies of electronic records, cloud storage, or off-site secured storage of back up tapes or disks.

(11) The laboratory must establish a procedure for documenting record retrieval, removal, and disposal assuring destruction is only allowed on records held past the five-year storage requirement.

(12) The laboratory must establish a procedure for securing documents past the five-year storage requirement when specifically requested by the accrediting authority or for legal purposes.

NEW SECTION

WAC 16-309-120 Quality control and assurance. (1) The laboratory must develop and maintain an extensive quality control (QC) program which involves the concurrent analysis of calibrators and controls with samples to demonstrate if the analytical system is operating within defined tolerance limits and that random and systematic errors can be identified in a timely manner.

(2) Laboratories must use controls that evaluate the performance of the sample prep and analytical instrument(s) in each preparation batch and must monitor the results of those samples within each batch and across batches for methods that include:

(a) A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.

(b) A CCV above the cutoff or decision point but below the upper limit of linearity. Using a calibrator from the initial calibration is an acceptable CCV.

(c) A matrix spike (MS) and matrix spiked duplicate (MSD) at least every 20 samples per matrix for high complexity tests.

(d) If a matrix is not available, a representative matrix may be used and must be spiked at a concentration above the action limit with the target analytes. This is also known as a laboratory control sample (LCS).

(e) A laboratory control sample (LCS) may be used in place of a continuing calibration verification (CCV)(but not as a replacement for

a failing CCV) for methods where the calibration goes through the same process as the LCS.

(f) A sample duplicate and a singular matrix spike is acceptable, when a matrix spike duplicate is not used, for each preparation batch.

(3) Positive control materials must be processed in the same manner and included with the test sample batches through the entire testing process. This does not include the ICV or CCV.

(4) Calibration curves must be verified from a second source including, but not limited to, an ICV. Laboratories must use a standard obtained from a second manufacturer if available for purchase. Laboratories may use a separate lot prepared independently by the same manufacturer if a standard obtained from a second manufacturer is unavailable for purchase. The ICV must include all required analytes for each analysis performed.

(5) Laboratories must use reference standards that are traceable to a primary standard through a certificate of analysis, when possible.

(6) Laboratories must use surrogate analytes or internal standards for all high complexity testing. Internal standard response must be within 50-200 percent of the response of a midpoint ICAL standard.

(7) The use of quality control material must determine the accuracy and precision of all required analytes in each analyses performed.

(8) For any method in which quality control acceptance criteria is not defined, the criteria must not exceed 30 percent.

(9) New lots of reagents, calibrators, and control material must be validated against a currently validated calibration or method before it is put into service.

(10) All control results must be documented in a manner to allow the laboratory to detect instrument or process failure and to identify trends or bias.

(11) Quality control results must be reviewed by a qualified analyst and must meet the acceptance limits prior to reporting out sample results.

(12) Cumulative quality control records must be reviewed by the individual responsible for oversight of the laboratory's QC program on a regular basis so that they can detect assay problems, trends, shifts, and bias.

(13) The laboratory must have procedures describing corrective action to be taken and take action when cumulative control results show evidence of problems. Control records must include documentation of the specific problem noted and documented evidence of the corrective actions to resolve the problem.

(14) The laboratory must use notebooks, logbooks, or other electronic means of communicating with staff regarding issues, problems, or communications between shifts.

(15) The laboratory must have a quality assurance manual, policy, or procedure to identify operational procedures, organization objectives, functional activities, and quality control activities designed to achieve quality goals desired for operation of the lab.

(16) The laboratory must designate a quality manager who, irrespective of other duties and responsibilities, must have defined responsibility and authority for ensuring that the quality system is implemented and followed. The quality manager must have direct access to the highest level of management at which decisions are made on laboratory policy or resources.

(17) The laboratory's quality assurance plan must measure meaningful data throughout laboratory processes that establish thresholds or limits for the indicators to trigger evaluation of the services if not met. Meaningful indicators established within the laboratory can be qualitative or quantitative and may be related to structure, processes, or outcome of the service involved.

(18) The quality assurance data must be reviewed by the scientific director on an ongoing basis that allows timely identification of problems to catch trends or issues early enough to make changes.

(19) The laboratory must maintain documentation and tracking of failed samples and batches like all other data and must make them available when requested.

(20) Instruments that use a multipoint curve must be calibrated using a minimum of a four-point curve with the first calibrator at the LOQ. No blanks can be used as a point unless required by the manufacturer. The linear correlation determination (r^2) must be ≥ 0.9950 or the correlation coefficient (r) must be ≥ 0.9975, unless otherwise specified in a CLASP-approved method. Linear regression with $1/x$ or no weighting must be used. Forcing the curve through zero is not allowed.

(21) To ensure the quality of data for mass spectrometry methods, the laboratory must:

(a) Perform mass spectrometric tuning at relevant frequencies or at the frequency specified by the manufacturer.

(b) Ensure method performance by comparing transitions and retention times between duplicated controls, calibrators, and samples.

(c) Use an internal or external standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies.

(d) Have a detailed procedure for the manual integration of any peaks, including the review of automated integration and adjustments.

(e) Maintain all information necessary for reconstruction of the data.

(22) To ensure the quality of data for an immunoassay method, the laboratory must:

(a) Ensure functionality of new test kits and reagent lots by utilizing positive and negative controls.

(b) Ensure absorbance intensity is within the acceptable range as defined by the manufacturer.

(c) Challenge the linearity of the calibration curve by using:

(i) Different levels of positive controls to challenge the low and high end of the corresponding curve assuring results are reliable throughout the whole range of the curve;

(ii) A negative or blank control to demonstrate the assay's ability to distinguish a positive from a negative and to perform without interference or contamination.

(d) Perform second source verification by utilizing a control separate from calibration material:

(i) For multianalyte assays, calibration curves and controls must be specific for each analyte;

(ii) Control analytes with similar chemical properties as the target analyte may be used.

(23) The laboratory may verify expired neat analytical standards if the standard is recertified by the vendor and new documentation is obtained or the standard is verified by comparison to unexpired neat standard. The response factors must be within 10 percent to be considered fit for purpose. Verified expired standards must be recorded in the verification logs.

(24) The laboratory may only report quantitative results that are above the limit of quantification and below the upper limit of linearity.

(25) The laboratory must use at minimum reagent grade acids and bases, ultra-high purity grade gases, Type II water, and analytical quality materials in the preparation of standards and sample processing.

(26) Laboratory records must be legible and in ink or computerized system. Documents must be signed and dated. Changes must be initialed and dated, and there must be evidence of periodic review.

(27) When corrective action is needed, the laboratory must identify and document the issue, determine a plan for corrective actions, evaluate the results from the plan, and ensure that sample results are not reported until after the corrective actions have provide accurate and reliable results.

NEW SECTION

WAC 16-309-130 Facilities, equipment, and maintenance. (1) Facilities where laboratory testing is performed must be designed for dealing with preanalytical, analytical, and postanalytical functions.

(2) The laboratory must monitor, control, and record environmental conditions as required by the relevant specifications, methods, and procedures where they influence the quality of the results. Due attention must be paid to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as necessary to the technical activities concerned.

(3) Laboratories recycling solvents by roto-evaporator or similar equipment must have a procedure for evaluating recycled solvent performance prior to use in testing. This must be applied any time the laboratory recycles solvents.

(4) The laboratory must have space for the number of personnel and separation of work areas.

(5) The arrangement of space must allow for workflow, sampling, lab space, office space, and break areas.

(6) The laboratory must have eyewash stations, safety showers, and sinks within the laboratory in areas where exposure to corrosive chemicals or substances may occur. Eyewash facilities must be no greater than 10 seconds unobstructed travel distance from the area in the laboratory where hazardous chemicals are present.

(7) The laboratory must have chemical spill kits on-site and placed in locations that are well-labeled and easily available to personnel.

(8) The laboratory must have adequate electrical outlets, unobstructed, single-use, multiplug adaptors with surge control; single-use extension cords; ground fault circuit interrupters near wet areas.

(9) The laboratory must have sufficient numbers and types of safety equipment to minimize personnel exposure to biological hazards and toxic materials. There must be vacuum traps, ventilation for fume hoods and around solvent use or storage of solvents or waste. There must be storage cabinets for flammable solvent, acids, and bases. There must be vented hoods for any microbiological analysis (i.e., Class II Type A biosafety cabinets as applicable).

(10) The laboratory must assign a unique identifier to distinguish the individual test instrument and software version used. Each

test result must be traceable back to the instrument used at the time of testing.

(11) The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer at minimum and perform preventive maintenance and check critical operating characteristics of each instrument used in the testing process. Records must be retained for all instruments and equipment.

(12) For automated liquid handling equipment performing quantitative aliquoting, the laboratory must check the accuracy and precision of each system, perform a contamination check, and monitor and detect system issues or failures (e.g., drips or leaks, short sampling, bubbles, or air gaps in reagent dispensing lines) on a regular basis.

(13) The laboratory must verify the accuracy and precision of each pipette or pipetting device prior to placing it into service. Each device must be rechecked at least every six months. If the pipette or pipetting device is used to make measurements at different volumes, accuracy and precision must be checked at each volume used. Devices that do not meet stated precision and accuracy criteria must be removed from service.

(14) The laboratory must check and record temperatures on temperature sensitive devices (e.g., water baths, heating blocks, incubators, ovens, refrigerators, freezers, and refrigerated centrifuges) on a daily or when used basis. The laboratory must establish acceptance ranges to ensure proper storage conditions for samples, calibrator and control materials, test materials, and to ensure correct analytical conditions according to manufacturer and procedure requirements. Temperature records must be complete and clearly document the date and individual performing the check, and the laboratory must document corrective actions taken to address unacceptable temperature readings.

(15) Analytical balances must be mounted in accordance with manufacturer's instructions. They must be serviced and checked periodically over the relevant weight range using ANSI/ASTM Classes 1-3 or equivalent weights.

(16) The laboratory must verify instrument and equipment performance prior to initial use, after major maintenance or service, and after relocation to ensure that they run within defined tolerance limits and according to expectations.

(17) Instrument maintenance records and function check documents must be reviewed by technical supervisory staff or the scientific director at least monthly.

(18) Instruments that do not meet performance specifications must be placed out of service and labeled as "Not in Use" until it has been repaired and shown by verification that it will perform correctly.

(19) Laboratories must demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.

(20) Laboratories must have breakrooms separate from the laboratory and ensure that food is not kept in refrigerators that have specimens, chemicals, or other laboratory related materials.

NEW SECTION

WAC 16-309-140 Method performance criteria. (1) Accredited labs may reference samples for testing by subcontracting fields of testing to another accredited laboratory.

(2) Laboratories must maintain the integrity of the sample by testing samples on an "as is" or "as received" basis before sample prep unless otherwise specified in rules.

(3) Laboratories may use historical calibrations for high complexity testing as long as it is supported by analytical data through quality control results. Historical calibrations cannot extend past 30 days.

(4) The samples fail quality control testing if the results exceed the limits indicated in WAC 314-55-102.

(5) Sample results are positive for the analyte being tested if their results are greater than or equal to the decision point or cut-off limits as indicated in WAC 314-55-102.

(6) Sample results are to be reported out in the number of digits and units of measure described in WAC 314-55-102.

(7) Laboratories may be accredited to conduct the following fields of testing:

Field of Testing	Level of Complexity
water activity	low
cannabinoid concentration analysis	high
foreign matter inspection	low
microbiological testing	
culture method	moderate
immunoassay method	moderate
polymerase chain reaction (PCR) method	high
residual solvent testing	high
mycotoxin testing	
enzyme-linked immunosorbent assay (ELISA) method	moderate
liquid chromatography with tandem mass spectrometry (LC-MS/MS) method	high
pesticide testing	high
heavy metals testing	high

NEW SECTION

WAC 16-309-150 Water activity testing. (1) Water activity (a_w) analysis is intended to quantitatively report out the presence of water in the sample.

The laboratory must run two continuing calibration verifications at levels bracketing the action limit concentration at the beginning of each day of testing.

(2) One sample must be run in duplicate with difference in values of 80 percent - 120 percent as a quality control specimen.

(3) The laboratory must monitor and record temperature and humidity daily or when testing is performed.

(4) The laboratory must calibrate the a_w instrument when:

(a) The instrument has been physically moved from one location to another.

(b) The instrument has been cleaned.
(c) The manufacturer's instruction manual recommends.

NEW SECTION

WAC 16-309-160 Cannabinoid concentration analysis. (1) Cannabinoid concentration analysis, previously known as potency, is intended to quantitate and accurately report cannabinoids above the lower limit of quantitation as described in WAC 314-55-102.

(2) Laboratories must use a method approved by the department to analyze cannabinoids.

(3) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(4) ICV, CCV, and surrogate must meet a minimum of 80-120 percent recovery for each analyte.

(5) LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(6) Sample and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(7) Chromatographic performance must be described in method and must include, but is not limited to, the following criteria:
(a) Tailing factor less than 2.0;
(b) Column performance resolution greater than 1.0;
(c) Retention time shift less than two percent.

NEW SECTION

WAC 16-309-170 Foreign matter inspection. (1) The laboratory must analyze not less than 30 percent of the total representative sample of cannabis and cannabis products prior to sample homogenization to determine whether foreign material is present.

(2) The laboratory must report the result of the foreign material test by indicating "pass" or "fail."

(3) The laboratory must use a microscope with photographic capabilities or a camera with magnification or resolution to document the presence of foreign matter. Magnification will only be required when something is identified and the picture without magnification does not allow identification of the foreign matter.

(4) The laboratory must document the observation with a detailed description of any foreign matter and photograph the sample supporting the report.

(5) The foreign matter inspection must be performed in a clean and sanitary location that prevents contamination or degradation prior to other testing.

NEW SECTION

WAC 16-309-180 Microbiological testing. (1) Microbiological testing is intended to accurately measure qualitative, semi-quantitative, or quantitate results, and report microorganisms incurred

through the production and processing of cannabis and cannabis products.

(2) The laboratory must have a microbiological testing SOP that contains a detailed description of the preparation of any material that does not come as a working stock (i.e., culture media, master mix, spiked controls).

(3) The laboratory may use either culture-based testing methods, immunoassay methods, molecular assay methods, or a combination of culture-based, immunoassay, and molecular assay methods for microbiological testing.

(4) Quality control must be performed on each new media lot, PCR reagent lot, or kit lot used. For molecular assays, DNA controls must be included with each analytical run and internal amplification controls (IACs) must be included with each individual reaction.

(a) Acceptability criteria for all calibration and QC materials such as controls, spikes, and blanks, must be defined, as well as the action to be taken when results are outside control limits. The laboratory must set controls at relevant limits around the decision points for the microbial assay(s) as defined above.

(b) Positive and negative controls must be included in all microbial assay tests. Quality controls must be analyzed in the same manner as samples.

(i) The laboratory must use control organisms that represent the target organism. Controls for the confirmation of a target, such as salmonella or Shiga toxin-producing *E. coli* (STEC), must be as similar as possible to the presumptive organism.

(ii) The laboratory must maintain documentation of quality control organisms and ensure purity of the control organism is maintained by limiting the number of cell divisions from the original culture.

(5) The laboratory must have a record of all microbial quality control and sample results. If the laboratory does not use equipment capable of recording and printing results (i.e., a PCR instrument or plate reader), then the laboratory must photograph all microbial quality control and sample results for recordkeeping.

(6) The laboratory must have a procedure in place which must specify any safety requirements or precautions unique to the microbial assay(s) used, including:

(a) Biohazard labels on equipment used to store biohazardous materials and waste such as restricted areas, refrigerators, and waste receptacles;

(b) Performing microbial assay(s) in either a Class II biosafety cabinet (BSC) or a designated clean room;

(c) Sterilization of biohazardous waste, including any materials that have come into contact with control organisms, either by autoclave or by chemical disinfectants;

(d) For safety reasons, biosafety level (BSL) 1 organisms for salmonella and STEC may be used as control organisms.

(e) Lab-prepared media must be sterilized by autoclave and undergo a quality control check for sterility before use.

Sterilization by autoclave must be documented using materials such as autoclave tape, and autoclave functionality must be tested using materials such as spore bioindicators.

(7) The laboratory must have a procedure and training for shipping and receiving bacterial enrichments, organisms, or presumptive positive samples. Biohazardous shipping and receiving training must be documented.

(8) The laboratory must perform microbial analysis in a unidirectional (i.e., one way) manner to reduce possible contamination of microbial test materials.

(a) For molecular microbial assays, the laboratory must use materials to reduce contamination such as reaction tubes that are RNAase-free and DNAase-free and use aerosol barrier pipette tips.

(b) For culture-based testing methods, all samples and controls must initiate incubation within 10 minutes of inoculation.

(9) For qualitative methods, all results must be reported as qualitative designations such as "detected," "not detected," "positive," or "negative." For quantitative methods, the laboratory may only report results that are above the limit of quantification and below the upper limit of linearity.

(10) The laboratory may not report colony-forming units (CFU) counts with greater than two significant figures.

NEW SECTION

WAC 16-309-190 Residual solvent testing. (1) Residual solvent analysis is intended to accurately quantitate and report solvent residue left behind from product processing.

(2) Laboratories must use a method approved by the department to analyze residual solvents.

(3) Methanol and any other solvent listed in WAC 314-55-102 must not be used in any preparation or analysis procedure for residual solvent testing.

(4) Upon receipt of a sample at a laboratory, the sample treatment must follow the method requirements for preservation and storage.

(5) When an extraction solvent is used in method it must be an organic solvent that is capable of accomplishing the dilution of the sample while still able to meet the quality control requirements of this method and regulatory requirements, and is NOT a required analyte per regulations. The selected solvent must be specifically cited in a lab's standard operating procedure(s).

(6) Subsampling and homogenization protocols must be specified in the approved method(s) to include:

(a) The lab must analyze at least 0.2 grams of sample per residual solvents analysis.

(b) Upon receipt of sample, the portion of the sample that is to be used for residual solvents analysis must be stored to minimize solvent evaporation.

(c) Homogenization of residual solvent samples by the lab is prohibited unless necessary due to sample composition. If homogenization is necessary, steps must be taken to minimize evaporative loss.

(7) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(8) The ICV must meet a minimum of 80-120 percent recovery for each analyte.

(9) CCV, surrogate, LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(10) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

NEW SECTION

WAC 16-309-200 Mycotoxin testing. (1) Mycotoxin testing is intended to accurately measure semi-quantitative or quantitate results, and report mycotoxins incurred through the production and processing of cannabis and cannabis products.

(2) For semi-quantitative or qualitative methods, the laboratory may report negative results. The limit of detection must be equal to or less than the analyte limit. Positive detections must be confirmed and reported using a quantitative method.

(3) For quantitative methods, the laboratory may only report numerical results that are above the limit of quantification and below the upper limit of linearity.

(4) The analytical processes for mycotoxin testing must include the following:

(a) A matrix negative and a matrix positive for each sample matrix tested per batch;

(b) Matrix positive controls at relevant levels above the decision point;

(c) The laboratory must perform a second-source calibration verification (ICV) above the decision point concentration.

(5) For high complexity testing, additional quality control is required.

(a) ICV, CCV, and surrogate must meet a minimum of 70-130 percent recovery for each analyte.

(b) Matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(c) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(6) Analyze matrix spike duplicates or sample duplicates at a frequency of one in 20 samples per matrix, per sample extraction or preparation method, to measure repeatability and precision of the mycotoxin assay(s).

(7) Mass spectrometry testing criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

(8) The laboratory must have procedures that include the following:

(a) Special safety precautions required for handling mycotoxin standards;

(b) Mycotoxin standards may only be opened and used within a certified fume hood;

(c) A mycotoxin spill cleanup procedure must be included;

(d) The laboratory must ensure stability of mycotoxin standards;

(e) A detailed description of how potentially hazardous waste is disposed of.

NEW SECTION

WAC 16-309-210 Pesticide testing. (1) Pesticide testing is intended to accurately quantitate and report pesticides incurred through the production and processing of cannabis and cannabis products.

(2) Pesticide standards and stock solutions must be prepared in an area separate from samples.

(3) Laboratories must use a method approved by the department to analyze pesticides.

(4) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(5) ICV, CCV, and surrogate must meet a minimum of 70-130 percent recovery for each analyte.

(6) LCS and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(7) Sample and matrix duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(8) Mass spectrometry confirmation criteria.

(a) A minimum of three structurally significant ions (meeting the three to one signal to noise ratio) are required for confirmation. If instrument conditions or ionization techniques limit the number of ions available, the laboratory may request a deviation from the department in order to report results under these conditions.

(b) The confidence limits of the relative abundance of structurally significant ions and precursor-to-product ion transitions used for single ion monitoring and multiple reaction monitoring must be ± 30 percent (relative) when compared to the same relative abundances observed from a standard solution injection made during the same analytical run.

NEW SECTION

WAC 16-309-220 Heavy metals testing. (1) Heavy metals testing is intended to accurately quantitate and report metals incurred through the production and processing of cannabis and cannabis products.

(2) Analytical standards and solutions must be National Institutes of Standards (NIST) traceable or equivalent.

(3) The ICP-MS must be tuned each day of analysis using a tuning solution containing elements representing all of the mass regions of interest.

(4) Instruments must be calibrated every day of testing using a minimum of a four-point curve (no blanks can be used as a point).

(5) Laboratories must use a method approved by the department to analyze heavy metals.

(6) A stabilizer must be added during sample preparation to stabilize mercury through the acid digestion and analysis. The stabilizer must be at the same level in the calibration standards as the samples.

(7) An internal standard (IS) must be added and analyzed in all calibration standards and samples.

(8) Spectral interference checks (SIC) must be used to verify that the interference levels are corrected by the instrument's data system. The SIC must contain known amounts of interfering elements that will demonstrate the magnitude of interference and test for any corrections.

(9) An initial calibration verification (ICV) and initial calibration blank (ICB) must be analyzed each day of testing.

(a) The ICB is analyzed after the ICV and must not contain target analytes.

(b) The ICV must meet a minimum of 70-130 percent recovery for each analyte.

(10) Laboratories must limit batch size to 20 samples in a preparation batch not including quality controls.

(11) CCV, surrogate, LCS, and matrix spike samples must meet a minimum of 70-130 percent recovery for each analyte.

(12) Sample duplicates and matrix spike duplicates must have a relative percent difference (RPD) value of less than 20 percent.

(13) Sample concentrations that exceed the highest calibration standard must be diluted and reanalyzed to fall within the linear calibration range.

NEW SECTION

WAC 16-309-230 Other analytes. Should a laboratory test for analytes beyond the analytes required in chapter 314-55 or 246-70 WAC, they must adhere to the following guidelines:

(1) Additional test results must be identified as analytes outside the scope of accreditation on the certificate of analysis.

(2) Additional analytes that are tested using methods that also include required analytes for compliance must meet similar requirements for testing and reporting.

(3) Additional analytes that are tested using methods that do not include required analytes for compliance must be validated and tested using standards established in this chapter.

NEW SECTION

WAC 16-309-240 Laboratory computers and information systems. (1) The laboratory must have computer systems and software for sample tracking throughout the laboratory's possession from receipt of the samples through testing, reporting, and disposal.

(2) The laboratory must maintain a system security plan (SSP) for each information system used, including corporate systems and external service provider systems.

(3) The laboratory must have security controls (i.e., management, operations, and technical controls) in place to protect the confidentiality, integrity, and availability of the system and its information.

(4) If the laboratory contracts with an external service provider such as a cloud service provider, the laboratory must show due diligence in verifying that the service provider has procedures in place to protect the confidentiality, integrity, and availability of data for the services that they will perform on behalf of the laboratory.

(5) The laboratory must protect any internal computer systems (e.g., desktops, servers, instrument computers) against electrical power interruptions and surges that can contribute to data loss.

(6) The laboratory must protect any internal computer systems from spyware, viruses, malware, and other attacks through the use of firewalls and by maintaining software security updates.

(7) The laboratory must validate and document changes made to computer systems, software, interfaces, calculations, and security measures prior to implementing for use on samples.

(8) Software testing must include performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.

(9) The laboratory must have a signed contract or agreement with any external service providers that includes the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

NEW SECTION

WAC 16-309-250 Method approvals. (1) Laboratories must use an agency approved method for cannabinoid concentration, pesticides, residual solvents, and heavy metals testing. A list of approved analytical and preparative methods are available on the agency's website (https://agr.wa.gov/departments/cannabis/cannabis-lab-analysis-program). If a laboratory wants to use a method not currently on the approved agency list of methods, the lab can submit a method for approval.

(2) Laboratories must, at a minimum, do the following for a new method approval:

(a) Laboratories must submit a method approval form with their required method documentation and method validation data emailed to the department at cannabis@agr.wa.gov.

(b) Receive written approval from the department of the validated method for use on customer samples.

(3) The initial method review and approval may take 30 days. The department may request revisions, clarifications, and/or additional data to review the method.

(4) Laboratories will receive notification via email about the status of the method. Approved methods will be added to the agency website for public access.

(5) Laboratories with denied methods will be provided with a detailed synopsis of why the method was insufficient.

(6) Methods submitted to the WSDA for approval must include a standard operating procedure that documents the following:

(a) A title that indicates the type of procedure being conducted (i.e., pesticides, residual solvents, cannabinoid concentration, or heavy metals).

(b) A document control number, date, and revision number.

(c) Approval signatory and date.

(d) A table of contents and page numbering.

(e) A section that documents the revision history for the method.

(f) A definitions section that includes a definition of terms, acronyms, and abbreviations used in the methods.

(g) A section that outlines the purpose, range, limitations (including limit of quantitation and limit of detection), intended use of the method, and target analytes.

(h) A summary section that includes an overview of the method procedure and quality assurance.

(i) An interference section that identifies known or potential interferences that may occur during use of the method and describes ways to reduce or eliminate these interferences.

(j) A safety section that describes special precautions needed to ensure personnel safety during the performance of the method.

(k) A section for equipment, supplies, reagents, and standards that are required to perform the method.

(l) A section that provides requirements and instructions for collecting, preserving, and storing samples.

(m) A quality control section that cites the procedures and analyses required to document the quality of data generated by the method and includes corrective actions for out-of-control data. This section must also describe how to assess data for acceptance based on quality control measures.

(n) A calibration and standardization section that describes the method or instrument calibration and standardization process and the required calibration verification.

(o) A procedure section that describes the sample processing and instrumental analysis steps of the method and provides detailed instructions to analysts.

(p) A section that provides instructions for analyzing data, equations, and definitions of constants used to calculate final sample analysis results.

(q) A method performance section that provides method performance criteria, including precision or bias statements regarding detection limits and sources or limitations of data produced using the method.

(r) A pollution prevention and waste management section that describes aspects of the method that minimizes or prevents pollution and the minimization and proper disposal of waste and samples.

(s) A section for references that lists source documents and publications that contain ancillary information.

(t) A section that contains all the tables, figures, diagrams, example forms for data recording, and flowcharts. This section may also contain validation data references in the body of the method.

(7) Methods must be validated and laboratories must submit method validation documentation as detailed in WAC 16-309-260.

(8) Should the department determine a method has become obsolete or invalid, it may retire the approved method after providing six months notice.

NEW SECTION

WAC 16-309-260 Method validations. (1) Laboratories must perform method validation studies prior to implementing a new or original test method, implementing an approved method, implementing a new instrument, or modifying an existing method or instrument for each matrices tested.

(2) The records must include sufficient information to allow for a comprehensive review of the studies performed. Laboratories must have criteria for acceptance of study data, for agreement of replicate study samples, and for defining true outlier values. Study samples for quantitative methods must meet the same qualitative criteria (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) used for samples. The laboratory's acceptance criteria must be described in the SOP and in the study summary.

(3) Laboratories must perform reverification studies on an annual basis at minimum on high complexity nonreagent methods. Reverification studies are designed to verify that the existing LOD, LOQ, and ULOL values are still valid and do not require laboratories to analyze the same number of samples that are required for full validation studies.

(4) If the laboratory modifies an existing test method or instrument parameter that affects the performance of the method, the revised method must be re-validated prior to use. If the modification is relatively minor, the validation studies may be focused on those parameters that have been affected.

(5) Validations must include linearity, precision, accuracy, LOD, LOQ, ULOL, carryover, selectivity/interference, and matrix effects. unless defined specifically below.

(6) The laboratory must characterize the linearity of a method based on replicate analysis (i.e., a minimum of three replicates at each concentration) of samples of at least six concentrations. The concentrations must be distributed above and below the cutoff for the test.

(7) The laboratory must characterize the precision of a method based on replicate analysis, at least 20 results total. Analysis must be at significant concentrations around the cutoff/decision point and expected range. At least three replicates at each concentration must be analyzed. Precision studies must be performed on multiple days and in multiple batches in order to assess intra-batch and inter-batch variability.

(8) The laboratory must characterize the accuracy (expressed as bias) of a method by calculating the percent difference between the analyzed sample results and the target concentrations. Accuracy studies must be performed on multiple days and in multiple batches to assess intra-batch and inter-batch variability.

(9) The laboratory must characterize the LOD of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOD must be experimentally determined and supported by analytical data. The laboratory can choose to artificially set the LOD at the established LOQ if the LOQ is at least 25 percent below the decision point limit.

(10) The laboratory must characterize the LOQ of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOQ of a method must be determined and supported by analytical data and must be at least 25 percent below the decision point limit.

(11) The laboratory must characterize the ULOL of a method by a series of replicates with increasing concentrations (i.e., a minimum of three replicates at each concentration). Laboratories may select a value at the upper end of the dynamic range for a method, but it must be determined and supported by analytical data.

(12) The laboratory must investigate the potential of carryover of a method from one sample to another during testing by analyzing highly concentrated samples followed by negative samples (i.e., without the analyte of interest) and evaluate the negative samples for carryover. Positive samples that follow a sample at carryover concentrations must be reinjected or reextracted to eliminate carryover concerns.

(13) The laboratory must investigate the day-to-day precision using positive and negative samples assuring the ruggedness of the testing method provides good reproducibility over a period of at least five days.

(14) The laboratory must investigate the selectivity and interferences of a method by testing commonly encountered compounds and compounds that are structurally similar that could potentially interfere with the method at higher concentrations. Laboratories may accept manufacturer studies of immunoassay products if the study was performed using cannabis-focused compounds.

(15) The laboratory must investigate any possible matrix effect by evaluating the potential for components of the sample matrix to either suppress or enhance the ionization of the analytes of the compound(s) of interest and internal standard(s). Studies must include the evaluation of at least five different lots of products (i.e., flower from five different plants or from five different plant lots).

(16) When dilution of a sample is necessary to keep the result concentration within the range of linearity, the laboratory must conduct dilution integrity studies to document that the dilution does not affect the method's performance. These consist of precision/accuracy studies using samples at the dilution specified in the procedure.

(17) The laboratory must perform a parallel study when a new instrument or a new/revised procedure is implemented where results from the revised/new method or new instrument are compared to results from the existing method/instrument.

(18) The laboratory must perform a positive/negative differentiation study when validating a qualitative test by analyzing positive and negative samples that have been verified by a quantitative method to assess the assay's ability to differentiate positive and negative samples. The laboratory may analyze a combination of positive and negative controls, proficiency test (PT) samples or previously tested samples. The laboratory must analyze a minimum of five positive samples at differing concentrations and five negative samples (i.e., 10 results total).

(19) The laboratory must verify extraction efficiency assuring their method can sufficiently extract out the analyte of interest from the sample matrix.

(20) Records for validation and periodic reverification studies must be organized in a format to facilitate a comprehensive review and, at a minimum, the records must include:

(a) A stated purpose;

(b) Description of test method(s);

(c) Identity of the instrument(s) used for the study;

(d) A listing of the instrument parameters used for the study;

(e) A description of the study samples;

(f) A summary of the statistical data collected to characterize the assay;

(g) A discussion;

(h) A summary with conclusions; and

(i) All raw analytical data from the samples analyzed in the study.

(21) The laboratory must use the same criteria for acceptance of study data (e.g., the same retention time, mass ratio, internal standard abundance, and chromatography criteria) as used for the daily samples.

(22) The laboratory must maintain the original assay validation study records for methods in production for an indefinite period. Validation and reverification study records must be made available at the time of inspection or upon request. Labs are required to maintain records for retired methods for five years.

(23) All immunoassay and qualitative assay methods must be properly validated prior to use with samples and supported with the following studies:

(a) Linearity;

(b) Precision and accuracy around the cutoff;

(c) Selectivity;

(d) Carryover;

(e) A parallel study using the existing and new/revised procedures;

(f) Positive/negative sample differentiation studies.

(24) All quantitative assays must be properly validated prior to use with samples and supported with the following studies:

(a) Determination of LOQ, LOD, and ULOL;

(b) Precision/accuracy around the cutoff;

(c) Carryover;

(d) Selectivity/interference;

(e) For an assay validation: Method parameters including ion selection;

(f) For full instrument validation: Instrument parameter optimization;

(g) For LC-MS, and LC-MS/MS methods: Matrix effects;

(h) For assays using a new technology: Parallel studies of PT samples and customer samples (e.g., when validating a technology different from the existing method);

(i) For assays using an extraction: Extraction efficiency must be determined; and

(j) Hydrolysis efficiency (if sample preparation includes a hydrolysis step).

(25) An abbreviated instrument validation must be performed prior to implementing an additional instrument of an exact model that has been validated by the laboratory. The laboratory must perform the following studies:

(a) Determination of the LOQ, LOD, and ULOL;

(b) Carryover evaluation;

(c) Instrument parameter optimization; and

(d) For LC, LC-MS, and LC-MS/MS methods: Evaluation of matrix effects.

NEW SECTION

WAC 16-309-270 Proficiency testing. The laboratory must participate in an approved proficiency testing (PT) program that reflects the best available science as determined by the accrediting authority.

NEW SECTION

WAC 16-309-280 Reports. (1) All sample test results must be supported by analytical data and all analytical data must have a documented review, once reviewed by an analyst, and once reviewed by a certifying scientist prior to being reported.

(2) Laboratories must report results as either "negative," "none detected," "pass/fail," or the numeric concentration equal to or above

the decision point or cutoff of the required analytes tested as indicated in rules.

(3) For the purpose of reporting, decision points or cutoff limits have been written in WAC 314-55-102 to the number or significant digits that laboratories are expected to use when reporting results.

(4) If the result is above the established ULOL, the laboratory must dilute the sample and retest to bring the results within the linear range of the test, unless allowed differently in the guidelines.

(5) The concentration of a diluted primary sample prior to applying the dilution factor must be above the concentration of the lowest calibrator or control in the batch.

(6) At a minimum, the computer generated COA reports for samples going to the customer must contain:

(a) A title: "Certificate of Analysis" or "Test Report";

(b) Laboratory name, lab ID number, and address;

(c) Unique identification of the test report certificate and on each page an identification in order to ensure that the page is recognized as a part of the COA, and a clear identification of the end of the report;

(d) The name, address, and license number of the customer;

(e) Date of sample collection;

(f) Sample identification number from transportation manifest;

(g) Sample/matrix type (flower, concentrate etc.);

(h) Product/sample name and category;

(i) Amount of sample received;

(j) Date received by laboratory;

(k) Name of certifying scientist;

(l) Date reported by the laboratory;

(m) Results of each test performed to include name of test, results, measurands (i.e., mg/g), cutoffs, and instrument/method of testing used;

(n) A statement to the effect that the results relate only to the items tested.

(7) Laboratories must use the analyte terminology and abbreviations specified by rules to ensure consistency in reporting and interpretation of test results.

(8) Laboratories must not release any cumulative or individual test result prior to the completion of all analysis by the lab for that sample.

(9) Any amendments to a COA after the original issuance must include a statement for the reason issued like "Corrected Report," "Supplement to COA (to include COA number)," or an equivalent form of wording.

(10) When it is necessary to issue a completely new COA, it must be uniquely identified and contain a reference to the original that it replaces (i.e., reprint).

(11) All records must include the identity of personnel performing the aliquoting, sample preparation, calibration, testing of samples and controls, and review of results.

(12) Observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific task.

(13) When mistakes occur in records, each mistake must be lined out, not erased, or made illegible or deleted, and the correct value entered alongside. All such alterations or corrections to records must be signed or initialed and dated by the person making the correction.

(14) All entries to hard copy laboratory records must be made using indelible ink. No correction fluid or tape may be used on laboratory data records.

NEW SECTION

WAC 16-309-290 Procurement controls. (1) The laboratory must have procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables must exist for the purchase, receipt, storage, and disposition of expired materials.

(2) The laboratory must ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned.

(3) New lots or materials received outside of expected environmental conditions must be documented and validated before use.

(4) Reagents and standards must be inspected, dated, and initialed upon receipt, and upon opening.

(5) Calibration standards and analytical reagents must have an expiration or reevaluation date assigned.

(6) Standards and solutions must be identified with lot number or other assigned unique identifier to trace back to preparation documentation.

(7) Prospective suppliers must be evaluated and selected on the basis of specified criteria.

(8) Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

NEW SECTION

WAC 16-309-300 Subcontracting. (1) The laboratory must notify the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials under chapters 69.50 RCW and 314-55 WAC.

(2) The laboratory must maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with chapter 314-55 WAC for the work in question.

(3) When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information must be forwarded to laboratory management for corrective action.

WSR 24-06-014
PROPOSED RULES
HEALTH CARE AUTHORITY
[Filed February 26, 2024, 3:30 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-17-101.

Title of Rule and Other Identifying Information: WAC 182-550-2600 Inpatient psychiatric services.

Hearing Location(s): On April 9, 2024, at 10:00 a.m. The health care authority (HCA) holds public hearings virtually without a physical meeting place. To attend the virtual public hearing, you must register in advance https://us02web.zoom.us/webinar/register/WN_2cVZ3hp9Tjm5l1WnaQYOmQ. If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing.

Date of Intended Adoption: No sooner than April 10, 2024.

Submit Written Comments to: Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, email arc@hca.wa.gov, fax 360-586-9727, by April 9, 2024, by 11:59 p.m.

Assistance for Persons with Disabilities: Contact Johanna Larson, phone 360-725-1349, fax 360-586-9727, telecommunication[s] relay service 711, email Johanna.larson@hca.wa.gov, by March 29, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: HCA is amending this section to replace outdated terms such as "residential support network (RSN)" and "mental health designee," to delete references to the department of mental health, and to update language regarding authorization and certification for inpatient psychiatric care consistent with the current managed care and administrative services organization structure. HCA is also making changes to align with RCW 74.09.520(13), which requires HCA to provide a hospital payment for apple health clients who meet the criteria for discharge from a hospital stay to certain facilities but who cannot be discharged because placement is unavailable. This revision provides for the payment of medically necessary ancillary services to be billed by and paid to the hospital separately.

Reasons Supporting Proposal: See purpose.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Statute Being Implemented: RCW 41.05.021, 41.05.160.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: HCA, governmental.

Name of Agency Personnel Responsible for Drafting: Jason Crabbe, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-9563; Implementation and Enforcement: Yvonne Keller, P.O. Box 42730, Olympia, WA 98504-2730, 360-725-9993.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 does not apply to HCA rules unless requested by the joint administrative rules review committee or applied voluntarily.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Scope of exemption for rule proposal:

Is fully exempt.

February 26, 2024
Wendy Barcus
Rules Coordinator

OTS-5189.1

AMENDATORY SECTION (Amending WSR 19-18-026, filed 8/28/19, effective 9/28/19)

WAC 182-550-2600 Inpatient psychiatric services. (1) The medicaid agency((~~, on behalf of the mental health division (MHD), regional support networks (RSNs) and prepaid inpatient health plans (PIHPs),~~)) or the agency's designee pays for covered inpatient psychiatric services for ((~~a voluntary or involuntary inpatient psychiatric admission of an~~)) eligible Washington apple health ((~~client, subject to the limitation and restrictions in this section and other published rules~~)) clients.

(2) The ((~~following~~)) definitions ((~~and abbreviations and those~~)) found in chapter 182-500 WAC and WAC 182-550-1050 apply to this section ((~~(where there is any discrepancy, this section prevails):~~

~~(a) "Authorization number" refers to a number that is required on a claim in order for a provider to be paid for providing psychiatric inpatient services to a Washington apple health client. An authorization number:~~

~~(i) Is assigned when the certification process and prior authorization process has occurred;~~

~~(ii) Identifies a specific request for the provision of psychiatric inpatient services to a Washington apple health client;~~

~~(iii) Verifies when prior or retrospective authorization has occurred;~~

~~(iv) Will not be rescinded once assigned; and~~

~~(v) Does not guarantee payment.~~

~~(b) "Certification" means a clinical determination by an MHD designee that a client's need for a voluntary or involuntary inpatient psychiatric admission, length of stay extension, or transfer has been reviewed and, based on the information provided, meets the requirements for medical necessity for inpatient psychiatric care. The certification process occurs concurrently with the prior authorization process.~~

~~(c) "IMD" See "institution for mental diseases."~~

~~(d) "Institution for mental diseases (IMD)" means a hospital, nursing facility, or other institution of more than sixteen beds that is primarily engaged in providing diagnosis, treatment, or care of people with mental diseases, including medical attention, nursing care, and related services. The MHD designates whether a facility meets the definition for an IMD.~~

~~(e) "Involuntary admission" refer to chapters 71.05 and 71.34 RCW.~~

~~(f) "Mental health division (MHD)" is the unit within the department of social and health services (DSHS) authorized to contract for and monitor delivery of mental health programs. MHD is also known as the state mental health authority.~~

~~(g) "Mental health division designee" or "MHD designee" means a professional contact person authorized by MHD, who operates under the direction of a regional support network (RSN) or a prepaid inpatient health plan (PIHP).~~

~~(h) "PIHP" see "prepaid inpatient health plan."~~

~~(i) "Prepaid inpatient health plan (PIHP)" see WAC 388-865-0300.~~

~~(j) "Prior authorization" means an administrative process by which hospital providers must obtain an MHD designee's for a client's inpatient psychiatric admission, length of stay extension, or transfer. The prior authorization process occurs concurrently with the certification process.~~

~~(k) "Regional support network (RSN)" see WAC 388-865-0200.~~

~~(l) "Retrospective authorization" means a process by which hospital providers and hospital unit providers must obtain an MHD designee's certification after services have been initiated for a Washington apple health client. Retrospective authorization can be before discharge or after discharge. This process is allowed only when circumstances beyond the control of the hospital or hospital unit provider prevented a prior authorization request, or when the client has been determined to be eligible for Washington apple health after discharge.~~

~~(m) "RSN" see "regional support network."~~

~~(n) "Voluntary admission" refer to chapters 71.05 and 71.34 RCW.~~

~~(3) The following department of health (DOH)-licensed hospitals and hospital units are eligible to be paid for providing inpatient psychiatric services to eligible Washington apple health clients, subject to the limitations listed:~~

~~(a) Medicare-certified distinct part psychiatric units;~~

~~(b) State-designated pediatric psychiatric units;~~

~~(c) Hospitals that provide active psychiatric treatment outside of a medicare-certified or state-designated psychiatric unit, under the supervision of a physician according to WAC 246-322-170; and~~

~~(d) Free-standing psychiatric hospitals approved as an institution for mental diseases (IMD).~~

~~(4) An MHD designee has the authority to approve or deny a request for initial certification for a client's voluntary inpatient psychiatric admission and will respond to the hospital's or hospital unit's request for initial certification within two hours of the request. An MHD designee's certification and authorization, or a denial, will be provided within twelve hours of the request. Authorization must be requested before admission. If the hospital chooses to admit the client without prior authorization due to staff shortages, the request for an initial certification must be submitted the same calendar day (which begins at midnight) as the admission. In this case, the hospital assumes the risk for denial as the MHD designee may or may not authorize the care for that day.~~

~~(5) To be paid for a voluntary inpatient psychiatric admission:~~

~~(a) The hospital provider or hospital unit provider must meet the applicable general conditions of payment criteria in WAC 182-502-0100; and~~

~~(b) The voluntary inpatient psychiatric admission must meet the following:~~

~~(i) For a client eligible for Washington apple health, the admission to voluntary inpatient psychiatric care must:~~

~~(A) Be medically necessary as defined in WAC 182-500-0070;~~

~~(B) Be ordered by an agent of the hospital who has the clinical or administrative authority to approve an admission;~~

~~(C) Be prior authorized and meet certification and prior authorization requirements as defined in subsection (2) of this section. See subsection (8) of this section for a voluntary inpatient psychiatric admission that was not prior authorized and requires retrospective authorization by the client's MHD designee; and~~

~~(D) Be verified by receipt of a certification form dated and signed by an MHD designee (see subsection (2) of this section). The form must document at least the following:~~

~~(I) Ambulatory care resources available in the community do not meet the treatment needs of the client;~~

~~(II) Proper treatment of the client's psychiatric condition requires services on an inpatient basis under the direction of a physician (according to WAC 246-322-170);~~

~~(III) The inpatient services can reasonably be expected to improve the client's level of functioning or prevent further regression of functioning;~~

~~(IV) The client has been diagnosed as having an emotional or behavioral disorder, or both, as defined in the current edition of the Diagnostic and Statistical Manual of the American Psychiatric Association; and~~

~~(V) The client's principle diagnosis must be an MHD covered diagnosis.~~

~~(ii) For a client eligible for both medicare and a Washington apple health program, the agency pays secondary to medicare.~~

~~(iii) For a client eligible for both medicare and a Washington apple health program and who has not exhausted medicare lifetime benefits, the hospital provider or hospital unit provider must notify the MHD designee of the client's admission if the dual eligibility status is known. The admission:~~

~~(A) Does not require prior authorization by an MHD designee; and~~

~~(B) Must be under medicare standards.~~

~~(iv) For a client eligible for both medicare and a Washington apple health program who has exhausted medicare lifetime benefits, the admission must have prior authorization by an MHD designee.~~

~~(v) When a liable third party is identified (other than medicare) for a client eligible for a Washington apple health program, the hospital provider or hospital unit provider must obtain an MHD designee's authorization for the admission.~~

~~(6) To be paid for an involuntary inpatient psychiatric admission:~~

~~(a) The involuntary inpatient psychiatric admission must be under the admission criteria specified in chapters 71.05 and 71.34 RCW; and~~

~~(b) The hospital provider or hospital unit provider:~~

~~(i) Must be certified by the MHD under chapter 388-865 WAC;~~

~~(ii) Must meet the applicable general conditions of payment criteria in WAC 182-502-0100; and~~

~~(iii) When submitting a claim, must include a completed and signed copy of an Initial Certification Authorization form Admission to Inpatient Psychiatric Care form, or an Extension Certification Authorization for Continued Inpatient Psychiatric Care form.~~

~~(7) To be paid for providing continued inpatient psychiatric services to a Washington apple health client who has already been admitted, the hospital provider or hospital unit provider must request from an MHD designee within the time frames specified, certification and authorization as defined in subsection (2) of this section for any of the following circumstances:~~

~~(a) If the client converts from involuntary (legal) status to voluntary status, or from voluntary to involuntary (legal) status as described in chapter 71.05 or 71.34 RCW, the hospital provider or hospital unit provider must notify the MHD designee within twenty-four hours of the change. Changes in legal status may result in issuance of a new certification and authorization. Any previously authorized days under the previous legal status that are past the date of the change in legal status are not billable;~~

~~(b) If an application is made for determination of a patient's Washington apple health eligibility, the request for certification and prior authorization must be submitted within twenty-four hours of the application;~~

~~(c) If there is a change in the client's principal ICD-10-CM diagnosis to an MHD covered diagnosis, the request for certification and prior authorization must be submitted within twenty-four hours of the change;~~

~~(d) If there is a request for a length of stay extension for the client, the request for certification and prior authorization must be submitted before the end of the initial authorized days of services (see subsections (11) and (12) of this section for payment methodology and payment limitations);~~

~~(e) If the client is to be transferred from one community hospital to another community hospital for continued inpatient psychiatric care, the request for certification and prior authorization must be submitted before the transfer; or~~

~~(f) If a client who has been authorized for inpatient care by the MHD designee has been discharged or left against medical advice prior to the expiration of previously authorized days, a hospital provider or hospital unit provider must notify the MHD designee within twenty-four hours of discharge. Any previously authorized days past the date the client was discharged or left the hospital are not billable.~~

~~(8) An MHD designee has the authority to approve or deny a request for retrospective certification for a client's voluntary inpatient psychiatric admission, length of stay extension, or transfer when the hospital provider or hospital unit provider did not notify the MHD designee within the notification time frames stated in this section. For a retrospective certification request before discharge, the MHD designee responds to the hospital or hospital unit within two hours of the request, and provides certification and authorization or a denial within twelve hours of the request. For retrospective certification requests after the discharge, the hospital or hospital unit must submit all the required clinical information to the MHD designee within thirty days of discharge. The MHD designee provides a response within thirty days of the receipt of the required clinical documentation. All retrospective certifications must meet the requirements in this section. An authorization or denial is based on the client's condition and the services provided at the time of admission and over the course of the hospital stay, until the date of notification or discharge, as applicable.~~

~~(9) To be paid for a psychiatric inpatient admission of an eligible Washington apple health client, the hospital provider or hospital unit provider must submit on the claim form the authorization (see subsection (2)(a) for definition of prior authorization and retrospective authorization).~~

~~(10) The agency uses the payment methods described in WAC 182-550-2650 through 182-550-5600, as appropriate, to pay a hospital~~

~~and hospital unit for providing psychiatric services to Washington apple health clients, unless otherwise specified in this section.~~

~~(11) Covered days for a voluntary psychiatric admission are determined by an MHD designee utilizing MHD approved utilization review criteria.~~

~~(12) The number of initial days authorized for an involuntary psychiatric admission is limited to twenty days from date of detention. The hospital provider or hospital unit provider must submit the Extension Certification Authorization for Continued Inpatient Psychiatric Care form twenty-four hours before the expiration of the previously authorized days. Extension requests may not be denied for a person detained under ITA unless a less restrictive alternative is identified by the MHD designee and approved by the court. Extension requests may not be denied for youths detained under ITA who have been referred to the children's long-term inpatient program unless a less restrictive alternative is identified by the MHD designee and approved by the court.~~

~~(13) The~~)).

(3) To be paid for an inpatient psychiatric admission, the hospital provider or hospital unit provider must meet the requirements for payment including the applicable general conditions of payment criteria in WAC 182-502-0100.

(4) When billing the agency directly for Washington apple health clients not enrolled in an agency-contracted managed care organization (MCO) plan, hospitals may use the expedited prior authorization (EPA) process for inpatient psychiatric services that require authorization when the EPA criteria is met.

(a) To meet the EPA criteria, the inpatient admission must:

(i) Be medically necessary;

(ii) Have psychiatric needs as the focus of treatment and not have an acute medical condition;

(iii) Not have a less-restrictive placement available; and

(iv) Be approved or ordered by the professional in charge of the facility.

(b) If the EPA criteria is not met, a hospital may request prior authorization from the agency or the agency's designee.

(5) Authorization of elective, nonemergency, or emergency-related poststabilization services by an agency-contracted MCO plan are subject to federal rules, including 42 C.F.R. 438.114 and 438.210.

(6) When clients enrolled in an agency-contracted MCO plan are involuntarily detained or committed under chapter 71.05 or 71.34 RCW, the stay must be treated as either an emergency or poststabilization service, and authorization must follow the rules found in 42 C.F.R. 438.114.

(7) When a hospital or hospital unit bills the agency directly, the agency pays the administrative day rate and pays for pharmacy services ((~~and~~)), pharmaceuticals, and medically necessary ancillary services, as determined by the agency, for any authorized days that meet the administrative day definition in WAC 182-550-1050 when ((~~all the following conditions are met:~~

~~(a) The client's legal status is voluntary admission;~~

~~(b) The client's condition is no longer medically necessary;~~

~~(c) The client's condition no longer meets the intensity of service criteria;~~

~~(d)~~)) less restrictive alternative treatments are not available, posing a barrier to the client's safe discharge((~~; and~~

~~(e) The hospital or hospital unit and the MHD designee mutually agree that the administrative day is appropriate.~~

~~(14) The hospital provider or hospital unit provider will use the MHD approved due process for conflict resolution regarding medical necessity determinations provided by the MHD designee.~~

~~(15) In order for an MHD designee to implement and participate in a Washington apple health client's plan of care, the hospital provider or hospital unit provider must provide any clinical and cost of care information to the MHD designee upon request. This requirement applies to all Washington apple health clients admitted for:~~

~~(a) Voluntary inpatient psychiatric services; and~~

~~(b) Involuntary inpatient psychiatric services, regardless of payment source.~~

~~(16) If the number of days billed exceeds the number of days authorized by the MHD designee for any claims paid, the agency will recover any unauthorized days paid~~)).

(8) The agency may review paid claims and recoup any improperly paid claims, including determining whether the client did not meet EPA criteria or other conditions of payment. See WAC 182-502-0230 and chapter 182-502A WAC.

WSR 24-06-034
PROPOSED RULES
HEALTH CARE AUTHORITY
[Filed February 29, 2024, 7:46 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-01-131.

Title of Rule and Other Identifying Information: WAC 182-550-4000 Payment method—Out-of-state hospitals and 182-550-4500 Payment method—Ratio of costs-to-charges (RCC).

Hearing Location(s): On April 9, 2024, at 10:00 a.m. The health care authority (HCA) holds public hearings virtually without a physical meeting place. To attend the virtual public hearing, you must register in advance https://us02web.zoom.us/webinar/register/WN_2cVZ3hp9Tjm5l1WnaQYOmQ. If the link above opens with an error message, please try using a different browser. After registering, you will receive a confirmation email containing information about joining the public hearing.

Date of Intended Adoption: No sooner than April 10, 2024.

Submit Written Comments to: Rules Coordinator, P.O. Box 42716, Olympia, WA 98504-2716, email arc@hca.wa.gov, fax 360-586-9727, by April 9, 2024, by 11:59 p.m.

Assistance for Persons with Disabilities: Contact Johanna Larson, phone 360-725-1349, fax 360-586-9727, telecommunication[s] relay service 711, email Johanna.larson@hca.wa.gov, by March 29, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: HCA is removing references to the hospital outpatient RCC payment method due to the discontinuation of this payment method.

Reasons Supporting Proposal: See purpose.

Statutory Authority for Adoption: RCW 41.05.021, 41.05.160.

Statute Being Implemented: RCW 41.05.021, 41.05.160.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: HCA, governmental.

Name of Agency Personnel Responsible for Drafting: Jason Crabbe, P.O. Box 42716, Olympia, WA 98504-2716, 360-725-9563; Implementation and Enforcement: Melissa Craig, P.O. Box 45500, Olympia, WA 98504-5500, 360-725-0938.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 does not apply to HCA rules unless requested by the joint administrative rules review committee or applied voluntarily.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Scope of exemption for rule proposal:

Is fully exempt.

February 29, 2024
Wendy Barcus
Rules Coordinator

OTS-5176.1

AMENDATORY SECTION (Amending WSR 14-12-047, filed 5/29/14, effective 7/1/14)

WAC 182-550-4000 Payment method—Out-of-state hospitals. This section describes the payment methods the agency uses to pay hospitals located out-of-state for providing services to eligible Washington apple health clients. This section does not apply to hospitals located in any of the designated bordering cities listed in WAC 182-501-0175. Payment methods that apply to bordering city hospitals, including critical border hospitals, are described in WAC 182-550-3900. See also WAC 182-501-0180, health care services provided outside the state of Washington - General provisions, and WAC 182-502-0120, payment for health care services provided outside the state of Washington.

(1) Emergency hospital services.

(a) For inpatient hospital claims for emergency services provided in out-of-state hospitals, the agency:

(i) Pays using the same methods used to pay in-state hospitals as specified in this chapter; and

(ii) Calculates the payment using the lowest in-state inpatient hospital rate corresponding to the payment method.

(b) For outpatient hospital claims for emergency services provided in out-of-state hospitals, the agency pays an out-of-state hospital using the following methods:

(i) The agency's outpatient prospective payment system (OPPS) described in WAC 182-550-7000; and

(ii) The maximum allowable fee schedule method described in WAC 182-550-6000. When the maximum allowable fee schedule method is used, the agency limits payment to the lesser of the:

(A) Billed charges; or

(B) Calculated payment amount((~~; and~~

~~(iii) The hospital outpatient RCC payment method described in WAC 182-550-4500. When using the RCC payment method, the agency pays the lowest in-state hospital outpatient RCC, excluding weighted costs-to-charges (WCC) rates that are paid to in-state critical access hospitals~~)).

(2) Nonemergency hospital services.

(a) The agency pays for:

(i) Contracted and prior authorized nonemergency hospital services according to the contract terms whether or not the hospital has signed a core provider agreement; and

(ii) Nonemergency hospital services authorized by the agency after the fact (subsequent to the date of admission, if the client is still at the out-of-state hospital, or after the services have been provided) according to subsections (1) and (3) of this section.

(b) The agency does not pay for:

(i) Nonemergency hospital services provided to a Washington apple health client in a hospital located out-of-state unless the hospital is contracted and prior authorized by the agency or the agency's designee for the specific service provided to a specific client; and

(ii) Unauthorized nonemergency hospital services are not paid by the agency. See WAC 182-501-0182.

(3) The agency makes claim payment adjustments including, but not limited to, client responsibility, third-party liability, and medicare. All applicable adjustments are factored into the final hospital payment amount.

AMENDATORY SECTION (Amending WSR 23-20-048, filed 9/28/23, effective 10/29/23)

WAC 182-550-4500 Payment method—Ratio of costs-to-charges (RCC). (1) The medicaid agency pays hospitals using the ratio of costs-to-charges (RCC) payment method for services exempt from the following payment methods:

(a) Ambulatory payment classification (APC);
(b) Diagnosis-related group (DRG);
(c) Enhanced ambulatory patient group (EAPG);
(d) Per case;
(e) Per diem; and
(f) Maximum allowable fee schedule.

(2) The agency:

(a) Determines the payment for((~~:~~ ~~(i)~~)) inpatient claims by multiplying the hospital's inpatient RCC by the allowed covered charges for medically necessary services((~~; and~~

~~(ii) Outpatient claims by multiplying the hospital's outpatient RCC by the allowed covered charges for medically necessary services~~)).

(b) Deducts from the amount derived in (a) of this subsection:
(i) All applicable adjustments for client responsibility;
(ii) Any third-party liability;
(iii) Medicare payments; and
(iv) Any other adjustments as determined by the agency.

(c) Limits the RCC payment to the hospital's usual and customary charges for services allowed by the agency.

(3) The agency uses the RCC payment method to calculate the following:

(a) Payment for the following services:
(i) Organ transplant services (see WAC 182-550-4400 (4)(h));
(ii) Hospital services provided at a long-term acute care (LTAC) facility not covered under the LTAC per diem rate (see WAC 182-550-2596); and
(iii) Any other hospital service identified by the agency as being paid by the RCC payment method; and

(b) Costs for the following:
(i) High outlier qualifying claims (see WAC 182-550-3700); and
(ii) Hospital services provided in hospitals eligible for certified public expenditure (CPE) payments under WAC 182-550-4650(5).

(4) When directed by the legislature to achieve targeted expenditure levels, as described in WAC 182-550-3000(8), the agency may apply an inpatient adjustment factor to the inpatient RCC payments made for the services in subsection (3) of this section.

(5) This section explains how the agency calculates each in-state and critical border hospital's RCC. For noncritical border city hospitals, see WAC 182-550-3900. The agency:

(a) Divides adjusted costs by adjusted patient charges. The agency determines the allowable costs and associated charges.

(b) Excludes agency nonallowed costs and nonallowed charges, such as costs and charges attributable to a change in ownership.

(c) Bases the RCC calculation on data from the hospital's annual medicare cost report (Form 2552) and applicable patient revenue reconciliation data provided by the hospital. The medicare cost report must cover a period of 12 consecutive months in its medicare cost report year.

(d) Updates a hospital's inpatient RCC annually after the hospital sends its hospital fiscal year medicare cost report to the centers for medicare and medicaid services (CMS) and the agency. If medicare grants a delay in submission of the CMS medicare cost report to the medicare fiscal intermediary, the agency may determine an alternate method to adjust the RCC.

(e) Limits a noncritical access hospital's RCC to one point zero (1.0).

(6) For a hospital formed as a result of a merger (see WAC 182-550-4200), the agency combines the previous hospital's medicare cost reports and follows the process in subsection (5) of this section. The agency does not use partial year cost reports for this purpose.

(7) For newly constructed hospitals and hospitals not otherwise addressed in this chapter, the agency annually calculates a weighted average in-state RCC by dividing the sum of agency-determined costs for all in-state hospitals with RCCs by the sum of agency-determined charges for all hospitals with RCCs.

WSR 24-06-049
PROPOSED RULES
DEPARTMENT OF
CHILDREN, YOUTH, AND FAMILIES
[Filed March 1, 2024, 1:33 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-15-092.

Title of Rule and Other Identifying Information: Guardianship assistance program (GAP) and extended guardianship assistance program (EGAP), chapter 110-85 WAC.

The department of children, youth, and families (DCYF) will be creating new GAP and EGAP chapter 110-85 WAC and other related rules related to the GAP and EGAP. New rules are needed to establish eligibility, application, and program standards consistent with the 42 U.S.C. 673 to ensure guardianship subsidy payments comply with the guidelines for expenditures for federal grant monies for relatives and state monies for other nonrelated guardians. These rules will clarify the application process, eligibility and program standards, and the process for adjudicating denied applications.

The following WAC in the new GAP and EGAP chapter will be created:

LEGAL BASIS, PURPOSE, AND DEFINITIONS: WAC 110-85-0010 Legal basis for the department's guardianship assistance program (GAP) and extended guardianship assistance program (EGAP), 110-85-0020 Purpose, and 110-85-0030 Definitions.

SUBSIDY AND ELIGIBILITY: WAC 110-85-0040 Subsidy that may be available to guardians through GAP and 110-85-0050 Eligibility criteria for GAP.

GAP APPLICATION AND AGREEMENT PROCESS: WAC 110-85-0060 Submitting the GAP application, 110-85-0070 GAP application process, 110-85-0080 GAP agreement purpose, 110-85-0090 GAP agreement requirements, 110-85-0100 Factors that determine the amount of the GAP cash payment, and 110-85-0110 Effective date of the GAP agreement.

NONRECURRING GUARDIANSHIP EXPENSES: WAC 110-85-0120 Reimbursement for nonrecurring guardianship expenses and 110-85-0130 Reimbursement process.

GAP AGREEMENT MODIFICATION, SUSPENSION, AND TERMINATION: WAC 110-85-0140 Modification of GAP agreement, 110-85-0150 Suspension of GAP agreement subsidy, 110-85-0160 Circumstances to terminate the GAP agreement, and 110-85-0170 Guardian's right to an administrative hearing.

SUBSIDY RELATED QUESTIONS: WAC 110-85-0180 GAP subsidies and other financial programs to meet the children's and youth's basic needs, 110-85-0190 Duty to inform the department of a family's change in circumstance, 110-85-0200 Guardianship family resides in or moves to another state, 110-85-0210 EGAP agreement and subsidy program, 110-85-0220 Transferring GAP subsidy to a subsequent successor guardian, 110-85-0230 GAP subsidies and residential treatment placement services, and 110-85-0240 GAP subsidy and out-of-home placement.

EXTENUATING CIRCUMSTANCES: 110-85-0250 Extenuating circumstances.

Hearing Location(s): On April 9, 2024, telephonic. Make oral comments by calling 360-972-5385 and leaving a voicemail that includes the comment and an email address or physical mailing address where DCYF will send its response. Comments received through and including April 9, 2024, will be considered.

Date of Intended Adoption: April 10, 2024.

Submit Written Comments to: Rules coordinator, email dcyf.rulescoordinator@dcyf.wa.gov, https://dcyf.wa.gov/practice/policy-laws-rules/rule-making/participate/online, by April 9, 2024.

Assistance for Persons with Disabilities: Contact rules coordinator, phone 360-902-7956, email dcyf.rulescoordinator@dcyf.wa.gov, https://dcyf.wa.gov/practice/policy-laws-rules/rule-making/participate/online, by April 2, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The new rules will create and clarify the GAP application process, eligibility requirements, program standards, and the process for adjudicating denied applications. The new rules will also provide the eligibility criteria for the EGAP.

Reasons Supporting Proposal: See purpose.

Statutory Authority for Adoption: RCW 74.13.062 and 13.36.090.

Statute Being Implemented: RCW 74.13.062 and 13.36.090.

Rule is necessary because of federal law, 42 U.S.C. 673.

Name of Proponent: DCYF, governmental.

Name of Agency Personnel Responsible for Drafting: Geene Delaplane, Olympia, Washington, 360-688-0391; Implementation and Enforcement: DCYF, statewide.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. DCYF is not among the agencies listed as required to comply with RCW 34.05.328 (5)[(a)](i). Further, DCYF does not voluntarily make that section applicable to the adoption of this rule.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules relate only to internal governmental operations that are not subject to violation by a nongovernment party; and rules adopt, amend, or repeal a procedure, practice, or requirement relating to agency hearings; or a filing or related process requirement for applying to an agency for a license or permit.

Is exempt under RCW 19.85.025(4).

Scope of exemption for rule proposal:

Is fully exempt.

March 1, 2024
Brenda Villareal
Rules Coordinator

OTS-5162.2

Chapter 110-85 WAC
GUARDIANSHIP ASSISTANCE PROGRAM (GAP) AND EXTENDED GUARDIANSHIP ASSISTANCE PROGRAM (EGAP)

LEGAL BASIS, PURPOSE, AND DEFINITIONS

NEW SECTION

WAC 110-85-0010 Legal basis for the department's guardianship assistance program (GAP) and extended guardianship assistance program (EGAP). The legal basis for the department's GAP and EGAP are:

(1) RCW 13.36.090;
(2) RCW 74.13.031;
(3) RCW 74.13.062;
(4) 42 U.S.C. § 671-675;
(5) 45 C.F.R. § 205.10;
(6) 45 C.F.R. § 1355; and
(7) 45 C.F.R. § 1356.

NEW SECTION

WAC 110-85-0020 Purpose. GAP was established as a subsidy to support the care of children or youth entering into a guardianship under chapter 13.36 RCW or RCW 11.130.215. GAP encourages guardianship for children or youth in the legal custody of public or tribal child welfare agencies for whom permanency would not be an option if support for the child or youth was not available.

NEW SECTION

WAC 110-85-0030 Definitions. The following definitions apply to this chapter:

"Applicant" means individuals or couples applying for GAP on behalf of a child or youth for whom the individual or couple plans to be guardians.

"Department" or **"DCYF"** means the department of children, youth, and families.

"Extended guardianship assistance program" or **"EGAP"** means the department's extended guardianship assistance program (EGAP), for eligible youth 18 through 20 years of age.

"Extenuating circumstances" means a finding by an administrative law judge or a review judge that one or more qualifying conditions or events occurred that erroneously prevented an otherwise eligible child or youth from receiving a GAP subsidy before the guardianship was established.

"GAP" means the department's guardianship assistance program (GAP), for eligible children and youth birth to their 18th birthday.

"Guardians" means the individuals or couples who have been appointed by a court as a legal guardian of the child or youth in a chapter 13.36 RCW or RCW 11.130.215 guardianship. The term includes a coguardian, but does not include a guardian ad-litem.

"Guardianship" means a guardianship pursuant to chapter 13.36 RCW or a limited guardianship of a minor pursuant to chapter 11.130 RCW or equivalent laws of another state or a federally recognized Indian tribe.

"Guardianship assistance program agreement" or **"GAP agreement"** means a written contract between the guardian and the department that identifies the terms and conditions of the agreement and specific subsidy, per WAC 110-85-0040, available to the guardian.

"Guardianship assistance program cash payment" or **"GAP cash payment"** means the monthly cash payment paid by the department to the guardian on behalf of the child or youth pursuant to a guardianship assistance program agreement.

"Indian children" means any unmarried and unemancipated Indian person who is under age 18 and is, as determined by the Indian child's tribe or tribes, one of the following:

(a) A member of an Indian tribe; or

(b) Is eligible for membership in an Indian tribe.

"Medical services" means services covered by medicaid and administered by the state medical assistance administration.

"Negotiation" means the process when the department and the applicant attempt to reach an agreement on the terms of the GAP agreement.

"Nonrecurring guardianship expenses" means expenses directly related to the cost of establishing the chapter 13.36 or 11.130 RCW guardianship of a dependent child or youth.

"Relatives" means the same as defined in RCW 13.36.020(5), described in RCW 74.15.020(2) and 11.130.010(32), or caregivers of Indian children or youth who are defined by their tribal code or custom as relatives or extended family.

"Resident state" means the state in which the child or youth physically resides for purposes of their medicaid eligibility. In some cases, this may be different from the state of the guardian's legal residence.

"Subsidy" is a benefit given to an individual by DCYF including, but not limited to, cash payments and payment for services.

"Successor guardian" means an individual who has become the child's or youth's guardian due to the death or incapacity of the original guardian and was named in the GAP agreement.

"Title IV-E administering agency" means DCYF and federally recognized tribes with federally approved Title IV-E plans pursuant to section 471 of the Social Security Act or an approved operational agreement with DCYF.

SUBSIDY AND ELIGIBILITY

NEW SECTION

WAC 110-85-0040 Subsidy that may be available to guardians through GAP. GAP may provide guardians the following subsidy:

(1) Reimbursement for nonrecurring guardianship finalization expenses;

(2) Cash payments as negotiated by the guardian and the department;

(3) Medical services through the medicaid program; and

(4) Evidence based programs contracted by the department to help stabilize the child or youth in the guardianship home if the department determines the programs are pertinent to the needs of the child or youth and family.

NEW SECTION

WAC 110-85-0050 Eligibility criteria for GAP. (1) In order for children or youth to be eligible for GAP, they must be:

(a) Under 18 years old when the department and the applicant sign the GAP agreement and the order establishing the guardianship is entered by the court;

(b) A dependent of a Title IV-E administering agency or federally recognized tribe located in Washington state; and

(c) Placed for at least six consecutive months with the prospective guardian who has been fully licensed and receiving foster care maintenance payments for at least six consecutive months.

(2) The department must not use applicants' income as a basis to determine the children's or youth's eligibility for GAP. However, the department will consider the applicant's income and other financial circumstances when determining the amount of the GAP cash payments.

GAP APPLICATION AND AGREEMENT PROCESS

NEW SECTION

WAC 110-85-0060 Submitting the GAP application. Applicants must complete the GAP application and worksheet and submit the completed paperwork to the department prior to the finalization of the guardianship in court.

NEW SECTION

WAC 110-85-0070 GAP application process. The department will review applications and determine if the child or youth and applicant meet the eligibility requirements. If the eligibility requirements are met, the department must:

(1) Provide the applicant with the application and worksheet used to negotiate the amount of GAP subsidy;

(2) Verify the eligibility criteria in WAC 110-85-0050 continues to be met;

(3) Negotiate the GAP cash payment amount with the applicant;

(4) Complete the GAP agreement and request the applicant's signature on the agreement; and

(5) Provide a copy of the signed agreement to the applicant.

NEW SECTION

WAC 110-85-0080 GAP agreement purpose. (1) The purpose of the GAP agreement is to define terms of financial and medical assistance provided to qualified applicants by DCYF on behalf of eligible children or youth.

(2) The GAP agreement is a binding agreement between guardians and the department that identifies the terms and conditions that DCYF and the guardian must follow.

NEW SECTION

WAC 110-85-0090 GAP agreement requirements. The GAP agreement must be signed by the applicant and the department before the court establishes the guardianship and must include the following:

(1) The amount of any GAP cash payment the department must make to the guardian on behalf of the child or youth;

(2) A statement that includes:

(a) The child or youth is eligible for medical services through medicaid;

(b) GAP subsidy will continue as long as the child or youth is eligible, regardless of where the guardianship family resides;

(c) A change in the guardianship family's circumstances or the child's or youth's needs may warrant further renegotiation and adjustment of the GAP cash payment as mutually agreed by the guardian and the department and the terms of the agreement may be modified under the requirements of WAC 110-85-0140;

(d) The basis for termination or suspension of subsidy under the agreement; and

(e) The name of a successor guardian in the event of the guardian's incapacity or death.

NEW SECTION

WAC 110-85-0100 Factors that determine the amount of the GAP cash payment. (1) The amount of the GAP cash payment is determined by negotiations between the applicant and the department based on the following factors:

(a) The child's or youth's needs and the applicant's circumstances. The agreed GAP cash payment and applicant's resources should combine to cover the child's or youth's current and anticipated ordinary and special needs projected over the period of the GAP agreement.

(b) The applicant's foster care maintenance payment level is based on the level they were receiving prior to the guardianship.

(c) The GAP monthly subsidy amount cannot exceed the following statutory caps for foster care maintenance payments for the child or youth if they had remained in foster care during the same period:

(i) Infants and children birth through age four may receive up to 80 percent of the foster care maintenance payment.

(ii) Children age five through nine may receive up to 90 percent of the foster care maintenance payment.

(iii) Children or youth age 10 to 18 may receive up to 95 percent of the foster care maintenance payment.

(d) The family circumstances including, but not limited to:

(i) Size, including the identified child or youth for whom the guardianship applies;

(ii) Normal living expenses;

(iii) Income;

(iv) Guardianship family's financial resources; and

(v) Additional miscellaneous expenses related to the child or youth.

(2) The department must not consider previously approved child care, medical related expenses, or exceptional costs when calculating the GAP subsidy amount.

(3) Under no circumstances may the amount of the GAP cash payment exceed the statutory cap for the maintenance payment, under RCW 74.13A.047. DCYF has adopted the percentage caps in adoption support under RCW 74.13A.047.

NEW SECTION

WAC 110-85-0110 Effective date of the GAP agreement. The GAP agreement must be signed prior to entry of the order establishing guardianship. The agreement takes effect on the date the court enters an order establishing the guardianship.

NONRECURRING GUARDIANSHIP EXPENSES

NEW SECTION

WAC 110-85-0120 Reimbursement for nonrecurring guardianship expenses. (1) The department will reimburse some or all of the guardian's nonrecurring guardianship expenses associated with establishing the guardianship and as specified in the agreement up to $2,000 per child or youth.

(2) The department will reimburse for the following nonrecurring guardianship expenses:

(a) Court costs associated with establishing the guardianship;

(b) Attorney fees directly related to finalizing a guardianship;

(c) Costs associated with a home study; and

(d) Other costs directly related to establishing the guardianship of the child or youth.

(3) The department will not reimburse nonrecurring guardianship expenses that are reimbursable from other sources including, but not limited to, the guardian's employer.

NEW SECTION

WAC 110-85-0130 Reimbursement process. (1) Guardians requesting reimbursement must submit to the department a copy of the bills or receipts itemizing the expenses specified in the agreement for which they are seeking reimbursement.

(2) The department must reimburse documented actual costs up to the maximum amount specified in the agreement, which must not exceed $2,000 per child or youth.

GAP AGREEMENT MODIFICATION, SUSPENSION, AND TERMINATION

NEW SECTION

WAC 110-85-0140 Modification of GAP agreement. (1) The terms of a GAP agreement may be modified only if both the guardian and the department agree to the modification. The department will consider a modification when:

(a) Requested by the guardian;

(b) Specific circumstances warrant renegotiation and adjustment of the GAP cash payment as determined by the department; or

(c) The child or youth is placed outside of the guardian's home and the guardian is not providing financial or other support for the care of the child or youth.

(2) Guardians may request a modification to the GAP agreement at any time.

(3) When guardians request to modify their GAP agreement's cash payment:

(a) Guardians must:

(i) Submit their request in writing to the regional GAP gatekeeper explaining how the child's or youth's needs or circumstances of the family have changed.

(ii) Provide supporting documentation upon the department's request.

(b) The regional GAP gatekeeper must initiate a review of the GAP agreement no later than 30 calendar days after receipt of the guardian's request for modification.

(c) Guardians and the department will renegotiate the GAP cash payment.

(4) If the guardians and the department agree to modify the GAP agreement:

(a) The regional GAP gatekeeper will use the date the department received the guardian's written request for the modification as the effective date on the modified GAP agreement.

(b) Guardians and the department must sign an amendment to the GAP agreement.

(5) If the guardians and department cannot reach an agreement on the modification, the department will deny the guardian's request for modification and provide them with written notice of the denial and their right to appeal the denial, per chapter 110-03 WAC.

NEW SECTION

WAC 110-85-0150 Suspension of GAP agreement subsidy. (1) The department may suspend a guardian's GAP agreement subsidy if:

(a) They cannot establish that the:

(i) Guardian is legally responsible for the support of the child or youth; or

(ii) Child or youth is receiving any support from the guardians.

(b) They have provided notice to the guardian of the department's determination under (a)(i) or (ii) of this subsection and of their intent to suspend the GAP subsidy payment in 30 calendar days and the guardian does not provide documentation within that time frame to refute the department's determination; and

(c) The guardian fails to provide satisfactory documentation that the guardian is legally responsible for the support of the child or youth or that they are providing support to the child or youth.

(2) If the guardian:

(a) Provides the department with satisfactory documentation of continued legal responsibility or financial support for the child or youth, the subsidy will not be suspended.

(b) Fails to provide the department satisfactory documentation, the department must send a notice stating the date the subsidy will be suspended. When this occurs, the guardian has a right to request an administrative hearing to challenge the suspension and the department must provide notice of that right, per chapter 110-03 WAC.

NEW SECTION

WAC 110-85-0160 Circumstances to terminate the GAP agreement. The GAP agreement will be terminated if the terms of the GAP agreement are not met or any one of the following events occur:

(1) The youth reaches 18 years of age and the GAP agreement is not eligible to be extended under WAC 110-85-0210;

(2) The youth turns 21 years of age;

(3) The child or youth dies;

(4) The guardian of the child or youth dies or becomes incapacitated, unless a successor guardian has been named in:

(a) The GAP agreement and named successor guardian becomes the guardian; or

(b) An amended GAP agreement and the named successor guardian becomes the guardian;

(5) The child or youth is under 18 years old and the department determines the child or youth is no longer receiving any support from

the guardian or the guardian is no longer legally responsible for the child or youth; or

(6) Upon the request of the guardian.

NEW SECTION

WAC 110-85-0170 Guardian's right to an administrative hearing. (1) Guardians have the right to an administrative hearing per chapter 110-03 WAC to contest the following department actions:

(a) Failure to respond with reasonable promptness to a written application for modification or request for services;

(b) Denial of a written request to modify the GAP cash payment or preauthorized services in the guardianship assistance agreement;

(c) Delay of more than 30 calendar days when responding to a written request for modification of the GAP agreement;

(d) Denial of a request for nonrecurring guardianship expenses;

(e) Suspension of GAP subsidy; and

(f) Termination of GAP subsidy.

(2) To request an administrative hearing, guardians must submit a request to the office of administrative hearings within 90 calendar days of receipt of any of the department's decisions listed in subsection (1) of this section.

(3) The office of administrative hearings must apply the rules in this chapter.

SUBSIDY RELATED QUESTIONS

NEW SECTION

WAC 110-85-0180 GAP subsidies and other financial programs to meet the children's and youth's basic needs. (1) Guardians may not receive foster care payments for a child or youth while receiving GAP cash payments for the same child or youth.

(2) If the guardian is receiving a GAP cash payment for a child or youth, they are not eligible for a nonneedy relative grant, in loco parentis, or legal guardian grant through the department of social and health services community services office.

(3) Guardians may not request GAP subsidies after finalizing the guardianship, unless an extenuating circumstance described in WAC 110-85-0250 exists.

NEW SECTION

WAC 110-85-0190 Duty to inform the department of a family's change in circumstance. (1) Guardians must inform the department's

regional GAP gatekeeper within 30 days of the change in circumstance that might affect the child's or youth's eligibility for GAP subsidy. Failure to report a change in circumstance may result in:

(a) An overpayment;

(b) Missed payment;

(c) Lead to modification of their agreement; or

(d) A suspension of their GAP subsidy.

(2) Changes in circumstance that must be reported include, but are not limited to:

(a) Significant changes in the child's or youth's physical, mental, or behavioral condition;

(b) The guardian's marital status;

(c) The legal or physical custody of the child or youth;

(d) The family's mailing address;

(e) The child's or youth's enrollment in school; or

(f) Changes to the youth's eligibility criteria for EGAP subsidy.

NEW SECTION

WAC 110-85-0200 Guardianship family resides in or moves to another state. If the guardianship family resides in or moves to another state, the GAP subsidy is affected as follows:

(1) The Washington state department remains responsible for any GAP cash payments; and

(2) Medical services:

(a) If the child or youth is eligible for Title IV-E medical services through the medicaid program, the state in which the guardian family resides is responsible for providing their medical benefits; and

(b) If the resident's state plan does not include the needed service that Washington state's medicaid plan includes, then it remains Washington state's responsibility to provide the needed service subject to Washington state's medicaid plan's limits and requirements.

NEW SECTION

WAC 110-85-0210 EGAP agreement and subsidy program. (1) The GAP agreement subsidy may be extended when the youth reaches 18 years of age and the following criteria is met:

(a) The guardian contacts the regional GAP gatekeeper prior to the youth's 18th birthday:

(i) To request services continue; and

(ii) Provides documentation of their continued eligibility, per WAC 110-85-0050.

(b) They are enrolled in high school or in a high school equivalency program.

(c) They meet the eligibility criteria for the extended foster care program in RCW 74.13.031, except that the youth must not be dependent on their 18th birthday.

(2) If subsection (1)(a), (b), and (c) of this section occurs:

(a) The department may enter into an EGAP agreement so long as the youth continues to meet at least one eligibility criteria and the guardian continues to provide ongoing support or the youth turns 21.

(b) Under no circumstances may the department continue the EGAP agreement beyond the youth's 21st birthday.

(c) The guardian will continue to receive the GAP cash payments.

(3) To transfer EGAP to a successor guardian, they must have been named as the successor guardian on the GAP agreement.

NEW SECTION

WAC 110-85-0220 Transferring GAP subsidy to a subsequent successor guardian. (1) In the event of the death or incapacity of the guardian, the GAP subsidy will transfer to the successor guardian named in the GAP agreement.

(2) The GAP agreement must be amended when the named successor guardian becomes the guardian.

(3) Before the GAP cash payment is transferred to the successor guardian:

(a) The successor guardian and all individuals aged 16 and older living in the successor guardian's home must pass the department's background check requirements.

(b) The successor guardian must establish guardianship of the child or youth.

(4) The successor guardian does not need to be a relative or have a foster care license to receive the GAP subsidy.

NEW SECTION

WAC 110-85-0230 GAP subsidies and residential treatment placement services. If a child or youth needs residential treatment, no additional GAP subsidies will be provided to pay for residential treatment placements.

NEW SECTION

WAC 110-85-0240 GAP subsidy and out-of-home placement. If children or youth are receiving GAP subsidy and are placed in out-of-home care, the department may:

(1) Continue the GAP subsidy during their out-of-home placement as long as the permanency plan is to return home.

(2) Terminate the GAP agreement, per WAC 110-85-0160, if the guardian is no longer legally responsible for the child or youth.

EXTENUATING CIRCUMSTANCES

NEW SECTION

WAC 110-85-0250 Extenuating circumstances. (1) If both the child or youth and guardian met eligibility requirements in WAC 110-85-0050 before the guardianship was established, but the guardian did not have a GAP agreement, the guardian may still obtain the subsidy if an administrative law judge makes a finding of extenuating circumstances through an administrative hearing, per chapter 110-03 WAC.

(2) If the guardians believe extenuating circumstances exist, the:

(a) Guardians must apply for GAP subsidy.

(b) Department will deny the application.

(c) Guardians may then request a review by an administrative law judge to determine if extenuating circumstances exist that authorized the guardian and the department to enter into a GAP agreement after the guardianship has been established.

(3) An administrative law judge may make a finding of extenuating circumstances if one or more of the following situations exist:

(a) The agency that placed the child or youth for guardianship was aware of relevant facts regarding the child or youth, the biological family, or child's or youth's background that were not presented to the guardian prior to the guardianship;

(b) The department gave erroneous advice or made an erroneous determination that a child or youth is ineligible for GAP; or

(c) The department failed to advise the guardian regarding the availability of GAP.

(4) If an administrative hearing results in the finding of extenuating circumstances, the effective date of a GAP agreement is the date the guardianship was established, unless the guardianship was established two or more years prior to the date of the order finding extenuating circumstances.

(5) Under no circumstances may the department back date a GAP agreement more than two years from the date of the order finding extenuating circumstances, which authorizes the department to enter a GAP agreement.

WSR 24-06-066
PROPOSED RULES
DEPARTMENT OF HEALTH
[Filed March 4, 2024, 5:25 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-15-019.

Title of Rule and Other Identifying Information: Home care aide workforce, reducing barriers. The department of health (department) is considering rule making to implement legislation to increase the home care aide workforce by amending WAC 246-980-010, 246-980-025, 246-980-040, 246-980-100, 246-980-110, 246-980-115, and 246-980-140; and creating WAC 246-980-045. The department is considering amending chapter 246-980 WAC to align with statutory changes and implement E2SHB 1694 (chapter 424, Laws of 2023), and E2SSB 5278 (chapter 323, Laws of 2023). These bills address date of hire, the home care aide workforce, certification examinations, and other aspects of the profession.

Hearing Location(s): On April 16, 2024, at 11:00 a.m., at the Department of Health, 111 Israel Road S.E., TC2 Room 166 and 167, Tumwater, WA 98501; or virtually via Zoom. Register in advance for this webinar. After registering you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: April 23, 2024.

Submit Written Comments to: Jennifer Osbun, P.O. Box 47850, Olympia, WA 98504-7850, email https://fortress.wa.gov/doh/policyreview/, by April 16, 2024.

Assistance for Persons with Disabilities: Contact Jennifer Osbun, phone 360-236-2737, TTY 711, email homecareaide@doh.wa.gov, by April 4, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: E2SSB 5278 requires the department to develop systems to reduce delays between training and testing, including establishing rules regarding the number of times and under what circumstances individuals may take the exam. These proposed rules update the process for applying for a home care aide credential to allow applicants to schedule their own examination directly with the examination vendor at the time of application, rather than waiting for the department to authorize them to sit for the exam. These proposed rules also allow caregivers three retakes of the exam, rather than two, and allow home care aides that are expired more than five years to either retake training or retake the exam, rather than requiring them to do both. The proposed changes meet the intent of the legislation to reduce barriers for home care aide certification.

E2SHB 1694 updated the definition of "date of hire." This requires the department to also update that definition within the rule. E2SHB 1694 also updated continuing education (CE) requirements for credentials expired five years or less. The department must update the current CE requirements to align with this legislative update. E2SHB 1694 also updated the list of family members that a caregiver can provide care to without requiring a credential. In turn, the department is amending the exemption section of the rule to align with that legislative change.

Reasons Supporting Proposal: E2SHB 1694 amended RCW 18.88B.010 to define date of hire and RCW 18.88B.021 to define multiple dates of hire. E2SHB 1694 also created a new section in chapter 18.88B RCW on renewing and reinstating an expired credential, created a new section

in chapter 18.88B RCW to allow an auto-renewal process for those with a credential expired more than six months and less than two years effective from September 1, 2023, and expiring July 1, 2025, and made additional changes to department of social and health services statutes.

E2SSB 5278 amended RCW 18.88B.031 to remove the requirement that training be completed prior to taking the certification examination, allowing students to take the certification examination during or after completing the training.

The department, in alignment with the intent of E2SHB 1694 and E2SSB 5278, is proposing rules that reduce barriers to entering and remaining in the home care aide workforce, including streamlining the certification examination and the credentialing process.

Statutory Authority for Adoption: RCW 18.88B.021, 18.88B.031, 18.88B.041, and 18.88B.060.

Statute Being Implemented: E2SHB 1694, E2SSB 5278.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Jennifer Osbun, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2737.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Jennifer Osbun, P.O. Box 47850, Olympia, WA 98504-7850, phone 360-236-2737, TTY 711, email jennifer.osbun@doh.wa.gov, homecareaide@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: The proposed amendments affect home care aides, not small businesses.

Scope of exemption for rule proposal:

Is fully exempt.

March 4, 2024
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-5130.2

AMENDATORY SECTION (Amending WSR 18-20-072, filed 9/28/18, effective 10/29/18)

WAC 246-980-010 Definitions. The definitions in this section and in RCW 74.39A.009 apply throughout this chapter unless the context clearly requires otherwise.

(1) "Activities of daily living" means self-care abilities related to personal care such as bathing, body care, bed mobility, eating,

locomotion, medication assistance, use of the toilet, personal hygiene, dressing, and transfer.

(2) "Date of hire" means((~~:~~

~~(a) The date of service authorization for individual providers hired by the department of social and health services; or~~

~~(b)~~)) the first day the long-term care worker is employed by any employer as a long-term care worker or the date the long-term care worker provides direct care for pay from any employer((~~, other than the department of social and health services;~~

~~(c) The date of hire is specific to each long-term care worker, not to the employer, and does not change if a long-term care worker changes employers. If a long-term care worker is or has been employed by more than one employer, the earliest date of hire will be the date of hire for that worker~~)).

(3) "Department" means the department of health.

(4) "Direct care worker" means a paid caregiver who provides hands-on personal care services to individuals with disabilities or the elderly requiring long-term care.

(5) "Instrumental activities of daily living" means routine activities performed in the home or the community such as meal preparation, shopping, house cleaning, laundry, maintaining employment, travel to medical services, use of the telephone, and management of personal finances.

(6) "Medication assistance" has the same meaning as ((~~chapter 246-888 WAC~~)) RCW 69.41.010.

(7) "Secretary" means the secretary of the department of health.

AMENDATORY SECTION (Amending WSR 18-20-072, filed 9/28/18, effective 10/29/18)

WAC 246-980-025 Individuals exempt from obtaining a home care aide certification. (1) The following individuals are not required to obtain certification as a home care aide. If they choose to voluntarily become certified, they ((~~must~~)) shall successfully pass the entry level training required by RCW 74.39A.074 and meet the requirements of WAC 246-980-040 ((~~(1)(b) and (c)~~)).

(a) An individual provider caring only for a biological, step, or adoptive child or parent.

(b) An individual provider caring only for a sibling, aunt, uncle, cousin, niece, nephew, grandparent, or grandchild (including by marriage or domestic partnership).

(c) A long-term care worker providing approved services only for a spouse or registered domestic partner and funded through the United States Department of Veterans Affairs home and community-based programs.

(d) An individual provider who provides ((~~twenty~~)) 20 hours or less of care for one person in any calendar month.

((~~(c)~~)) (e) An individual employed by a community residential service business.

((~~(d)~~)) (f) An individual employed by a residential habilitation center licensed under chapter 71A.20 RCW or a facility certified under 42 C.F.R. Part 483.

((~~(e)~~)) (g) A direct care worker who is not paid by the state or by a private agency or facility licensed by the state to provide personal care services.

((~~(f)~~)) (h) A person working as an individual provider who only provides respite services and works less than ((~~three hundred~~)) 300 hours in any calendar year.

((~~(g)~~)) (i) Any direct care worker exempt under RCW 18.88B.041(1).

(2) The following long-term care workers are not required to obtain certification as a home care aide. If they choose to voluntarily become certified, they must meet the requirements of WAC 246-980-040 ((~~(1)(b) and (c)~~)). The training requirements under RCW 74.39A.074(1) are not required.

(a) An individual who holds an active credential by the department as a:

(i) Registered nurse, a licensed practical nurse, or advanced registered nurse practitioner under chapter 18.79 RCW; or

(ii) Nursing assistant-certified under chapter 18.88A RCW.

(b) A home health aide who was employed by a medicare certified home health agency within the year before being hired as a long-term care worker and has met the requirements of 42 C.F.R. Part 484.36.

(c) A person who is in an approved training program for certified nursing assistant under chapter 18.88A RCW, provided that the training program is completed within ((~~one hundred twenty~~)) 120 calendar days of the date of hire and that the nursing assistant-certified credential has been issued within ((~~two hundred~~)) 200 calendar days of the date of hire.

(d) An individual with special education training and an endorsement granted by the superintendent of public instruction under RCW 28A.300.010 and is approved by the secretary.

(e) An individual employed as a long-term care worker on January 6, 2012, or who was employed as a long-term care worker between January 1, 2011, and January 6, 2012, and who completed all of the training requirements in effect as of the date of hire. This exemption expires if the long-term care worker has not provided care for three consecutive years.

(i) The department may require the exempt long-term care worker who was employed as a long-term care worker between January 1, 2011, and January 6, 2012, to provide proof of that employment. Proof may include a letter or similar documentation from the employer that hired the long-term care worker between January 1, 2011, and January 6, 2012, indicating the first and last day of employment, the job title, a job description, and proof of completing training requirements. Proof of training will also be accepted directly from the approved instructor or training program, if applicable.

(ii) For an individual provider reimbursed by the department of social and health services, the department will accept verification from the department of social and health services or the training partnership.

AMENDATORY SECTION (Amending WSR 21-02-002, filed 12/23/20, effective 1/23/21)

WAC 246-980-040 Certification requirements. ((~~(1)~~)) To qualify for certification as a home care aide, the applicant ((~~must~~)) shall:

((~~(a)~~)) (1) Successfully complete all training required by RCW 74.39A.074(1) within ((~~one hundred twenty~~)) 120 calendar days of the date of hire as a long-term care worker;

((~~(b)~~)) (2) Successfully pass the home care aide certification examination, after completing training; and

((~~(c)~~)) (3) Become certified within ((~~two hundred~~)) 200 days of date of hire, or ((~~two hundred sixty~~)) 260 days if granted a provisional certificate under RCW 18.88B.041.

((~~(2) An applicant for certification as a home care aide must submit to the department:~~

~~(a) A completed application for both certification and the examination on forms provided by the department;~~

~~(b) The exam fee set by the examination vendor and required fees under WAC 246-980-990; and~~

~~(c) A certificate of completion from an approved training program indicating that the applicant has successfully completed the entry level training required by RCW 74.39A.074. The certificate of completion or other official verification may also be submitted directly from the approved instructor or training program.~~

~~(3) An applicant must submit to a state and federal background check as required by RCW 74.39A.056.~~

~~(4) An applicant exempt from certification under WAC 246-980-025(2) who voluntarily chooses to be certified must provide documentation of qualification for the exemption. The applicant is not required to take the training required in subsection (1)(a) of this section or provide proof of training completion to the department.~~))

NEW SECTION

WAC 246-980-045 Application requirements. (1) An applicant for certification as a home care aide shall submit to the department:

(a) A completed application on forms provided by the department;

(b) The required fees under WAC 246-980-990; and

(c) A certificate of completion from an approved training program indicating that the applicant has successfully completed the entry level training required by RCW 74.39A.074. The certificate of completion or other official verification may be submitted directly from the approved instructor or training program.

(2) An applicant must submit to a state and federal background check as required by RCW 74.39A.056 and 18.130.064.

AMENDATORY SECTION (Amending WSR 18-20-072, filed 9/28/18, effective 10/29/18)

WAC 246-980-100 Examination and reexamination for home care aide certification. (1) The certification examination will consist of both a written knowledge test and a skills demonstration.

(2) The certification examination will test the core competencies((~~,~~)) including, but not limited to:

(a) Communication skills;

(b) Worker self-care;

(c) Problem solving;

(d) Maintaining dignity;

(e) Consumer directed care;

(f) Cultural sensitivity;

(g) Body mechanics;

(h) Fall prevention;
(i) Skin and body care;
(j) Home care aide roles and boundaries;
(k) Supporting activities of daily living; and
(l) Food preparation and handling.

(3) ((~~An applicant must apply to take the examination by completing the application for both certification and the examination and returning it to the department.~~)) The department will notify the examination contractor once an applicant meets ((~~all~~)) requirements to take the certification examination.

(4) The applicant shall contact the examination contractor ((~~will notify an applicant of the date, time, and place of~~)) to schedule the examination and submit payment, if required. The examination fees are set by the vendor.

(5) The examination contractor will notify both the department and an applicant of the examination results.

((~~(a)~~)) (6) An applicant who does not successfully pass any portion of the examination ((~~can~~)) may follow the examination contractor's procedures for review and appeal.

((~~(b)~~)) (7) An applicant who does not successfully pass any portion of the examination may retake that portion of the examination ((~~two~~)) three times.

((~~(i)~~)) (a) To retake the examination, an applicant ((~~must submit an application for reexamination, along with the required reexamination fee directly to the examination contractor.~~

~~(ii) An application for reexamination may be submitted~~)) shall contact the examination contractor to:

(i) Schedule a new exam; and

(ii) Pay the reexamination fee.

(b) An applicant may schedule a reexamination any time after ((~~an applicant receives~~)) notice of not successfully completing any portion of the certification examination.

(c) An applicant who does not successfully pass both portions of the certification examination ((~~within two years of successfully completing the required training or who does not successfully pass both portions of the certification examination after completing the certification examination three~~)) after four consecutive times:

(i) ((~~Must~~)) Shall retake and successfully complete the core competencies portion of the entry-level training as required by RCW 74.39A.074 before retaking both portions of the certification examination; and

(ii) Cannot continue to provide care as a long-term care worker until the certification has been issued.

AMENDATORY SECTION (Amending WSR 13-19-087, filed 9/18/13, effective 10/19/13)

WAC 246-980-110 Continuing education. (1) A home care aide ((~~must~~)) shall demonstrate completion of ((~~twelve~~)) 12 hours of continuing education per year as required by RCW 74.39A.341. The required continuing education must be obtained during the period between renewals. Continuing education is subject to the provisions of ((~~chapter 246-12 WAC, Part 7~~)) WAC 246-12-170 through 246-12-240.

(2) Verification of completion of the continuing education requirement is due upon renewal of an active credential. If the first

renewal period is less than a full year from the date of certification, no continuing education will be due for the first renewal period.

(3) No continuing education is required for renewal of a credential that has been expired five years or less.

AMENDATORY SECTION (Amending WSR 18-20-072, filed 9/28/18, effective 10/29/18)

WAC 246-980-115 Renew or reinstate an expired certification. (1) To renew a home care aide certification the practitioner ((~~must~~)) shall:

(a) Renew the certification every year by the home care aide's birthday as provided in ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-020 through 246-12-051;

(b) Submit a completed application as provided by the department; and

(c) Provide verification of ((~~twelve~~)) 12 hours of continuing education as required by RCW 74.39A.341 and WAC 246-980-110 with the renewal application.

(2) To reinstate an expired certification:

(a) If the certification has been expired for ((~~less than three years~~)) five years or less, the practitioner ((~~must submit proof of twelve continuing education hours as required by RCW 74.39A.341 and WAC 246-980-110 for each year it has been expired, and~~)) shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

(b) If the certification has been expired for ((~~three years or~~)) more than five years, the practitioner ((~~must~~)) shall successfully repeat the training ((~~and~~)) requirements or the examination requirements in WAC 246-980-040 and meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-020 through 246-12-051.

((~~(c) A practitioner previously exempt from certification by WAC 246-980-025(2) who voluntarily chooses to be certified is not required to complete training to reinstate a certification expired over three years so long as they continue to be exempt under WAC 246-980-025(2) at the time of reapplying.~~))

AMENDATORY SECTION (Amending WSR 18-20-072, filed 9/28/18, effective 10/29/18)

WAC 246-980-140 Scope of practice for long-term care workers. (1) A long-term care worker performs activities of daily living or activities of daily living and instrumental activities of daily living. A person performing only instrumental activities of daily living is not acting under the long-term care worker scope of practice.

(a) "Activities of daily living" means self-care abilities related to personal care such as bathing, eating, medication assistance, using the toilet, dressing, and transfer. This may include fall prevention, skin and body care.

(b) "Instrumental activities of daily living" means activities in the home and community including cooking, shopping, house cleaning, doing laundry, working, and managing personal finances.

(2) A long-term care worker documents observations and tasks completed, as well as communicates observations.

(3) A long-term care worker may perform medication assistance as described in ((~~chapter 246-888 WAC~~)) RCW 69.41.010.

(4) A long-term care worker may perform nurse delegated tasks, to include medication administration, if he or she meets and follows the requirements in WAC 246-980-130.

(5) A long-term care worker may provide skills acquisition training on instrumental activities of daily living and the following activities of daily living tasks: Dressing, application of deodorant, washing hands and face, hair washing, hair combing and styling, application of makeup, menses care, shaving with an electric razor, tooth brushing or denture care, and bathing tasks excluding any transfers in or out of the bathing area.

(6) This section applies to all long-term care workers, whether required to be certified or exempt.

WSR 24-06-067
PROPOSED RULES
DEPARTMENT OF HEALTH
(Board of Physical Therapy)
[Filed March 4, 2024, 5:42 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-16-028.

Title of Rule and Other Identifying Information: Physical therapists intramuscular needling requirements. The board of physical therapy (board) and department of health (department) are proposing amendments to chapter 246-915 WAC to add new WAC 246-915-390 Intramuscular needling endorsement, and to amend WAC 246-915-990 Physical therapist fees and renewal cycle, to implement 2SHB 1039 (chapter 198, Laws of 2023).

Hearing Location(s): On April 15, 2024, at 11:00 a.m., at the Washington State Department of Labor and Industries Headquarters, 7273 Linderson Way S.W., Room S119, Tumwater, WA 98501; or virtually via Microsoft Teams. Please follow this link at the date and time of the hearing to join the meeting on a device or to call in to the meeting on the phone https://teams.microsoft.com/l/meetup-join/19%3ameeting_ZjkzNzVlMjMtZjc0Yy00YTlhLWE3MjItODU2MjZhMWY4Yzg2%40thread.v2/0?context=%7b%22Tid%22%3a%2211d0e217-264e-400a-8ba0-57dcc127d72d%22%2c%22Oid%22%3a%22b0a413cc-861e-438f-ad33-52df6d9a4283%22%7d, Meeting ID 257 244 104 388, Passcode 3vfHpP; or call in (audio only) +1 564-999-2000,,288754786# United States, Olympia, 833-322-1218,,288754786# United States (toll-free), Phone Conference ID 288 754 786#.

Date of Intended Adoption: April 15, 2024.

Submit Written Comments to: Allyson McIver, P.O. Box 47852, Olympia, WA 98504-7852, email https://fortress.wa.gov/doh/policyreview/, fax 360-236-2901, physical.therapy@doh.wa.gov, by April 8, 2024.

Assistance for Persons with Disabilities: Contact Allyson McIver, phone 360-236-2878, fax 360-236-2901, TTY 711, email physical.therapy@doh.wa.gov, by April 8, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The board and the department are proposing amendments to chapter 246-915 WAC, Physical therapists and physical therapist assistants, to clarify statutory requirements included in 2SHB 1039 for attaining an intramuscular needling endorsement. 2SHB 1039 expands the scope of practice of physical therapists to perform intramuscular needling, also known as dry needling, pending the issuance of an intramuscular needling endorsement.

The board and the department are proposing to add a new section in chapter 246-915 WAC to provide an overview of the requirements and process for applying for an intramuscular needling endorsement. New WAC 246-915-390 expands upon and clarifies the education and training requirements included in 2SHB 1039, creates a process for physical therapists to apply for the endorsement, and updates definitions related to the endorsement. The board and the department are also proposing to amend WAC 246-915-990 to establish a fee to cover the cost of the endorsement.

Reasons Supporting Proposal: The proposed rules are needed to clarify education, training, fee, and application requirements for a physical therapist seeking the endorsement. Rule making provides guidance for physical therapists seeking the endorsement and creates a

clear and consistent application process. The proposed rules also set standards, ensuring that physical therapists who are seeking the endorsement are prepared with the skills and education needed to provide safe intramuscular services to the public.

Statutory Authority for Adoption: RCW 18.74.023, 43.70.110, 43.70.250, and 43.70.280.

Statute Being Implemented: RCW 18.74.200.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health and board of physical therapy, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Allyson McIver, Program Manager, 111 Israel Road S.W., Tumwater, WA 98501, 360-236-2878.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Allyson McIver, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-2878, fax 360-236-2901, TTY 711, email physical.therapy@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: The proposed rules pertain to attaining an intramuscular needling endorsement by a licensed physical therapist.

Scope of exemption for rule proposal:

Is fully exempt.

March 4, 2024
Kathryn Dale, PT, DSc
Chair, Physical Therapy Board
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-5123.2

NEW SECTION

WAC 246-915-390 Intramuscular needling—Endorsement. (1) "Intramuscular needling" also known as "dry needling" is defined under RCW 18.74.010.

(2) As established in RCW 18.74.200 a physical therapist may perform intramuscular needling, also known as dry needling after being issued an intramuscular needling endorsement by the secretary.

(3) The secretary, upon approval by the board, shall issue an endorsement to a physical therapist who has at least one year of postgraduate practice experience that averages at least 36 hours a week and consists of direct patient care and who provides evidence in a manner acceptable to the board of a total of 325 hours of instruction and clinical experience that meet or exceed the following criteria:

(a) A total of 100 hours of didactic instruction in the following areas:

(i) Anatomy and physiology of the musculoskeletal and neuromuscular systems;

(ii) Anatomical basis of pain mechanisms, chronic pain, and referred pain;

(iii) Trigger point evaluation and management;

(iv) Universal precautions in avoiding contact with a patient's bodily fluids; and

(v) Preparedness and response to unexpected events including, but not limited to, injury to blood vessels, nerves, and organs, and psychological effects or complications.

(b) A total of 75 hours of in-person intramuscular needling instruction in the following areas:

(i) Intramuscular needling technique;

(ii) Intramuscular needling indications and contraindications;

(iii) Documentation and informed consent for intramuscular needling;

(iv) Management of adverse effects;

(v) Practical psychomotor competency; and

(vi) Occupational safety and health administration's bloodborne pathogens protocol.

(c) A successful clinical review of a minimum of 150 hours of at least 150 individual intramuscular needling treatment sessions by a qualified provider. After receiving 100 hours of didactic instruction and 75 hours of in-person intramuscular needling instruction, a physical therapist seeking endorsement has up to 18 months to complete a minimum of 150 treatment sessions for review.

(4) A physical therapist may not delegate intramuscular needling and must remain in constant attendance of the patient for the entirety of the procedure.

(5) A physical therapist can apply for endorsement before they have one year of clinical practice experience if they can meet the requirement of 100 hours of didactic instruction and 75 hours of in-person intramuscular needling instruction through their prelicensure coursework and have completed all other applicable requirements.

(6) For the purpose of subsection (3)(c) of this section, "clinical review" may include:

(a) The direct or indirect supervision of intramuscular needling treatment sessions by a qualified provider.

(b) Review of chart notes from intramuscular needling treatment sessions by a qualified provider.

(c) Oversight by a qualified provider of intramuscular needling treatment sessions completed through an internship or apprenticeship.

(7) For the purpose of subsections (3)(c) and (6) of this section, a qualified provider is one of the following:

(a) A physician licensed under chapter 18.71 RCW; an osteopathic physician licensed under chapter 18.57 RCW; a licensed naturopath under chapter 18.36A RCW; a licensed acupuncture and Eastern medicine practitioner under chapter 18.06 RCW; or a licensed advanced registered nurse practitioner under chapter 18.79 RCW;

(b) A physical therapist credentialed to perform intramuscular needling in any branch of the United States armed forces;

(c) A licensed physical therapist who currently holds an intramuscular needling endorsement in Washington state; or

(d) A physical therapist licensed under the laws of another jurisdiction who meets the requirements for obtaining an intramuscular

needling endorsement but does not currently hold an endorsement in Washington state.

(8) To apply for the endorsement:

(a) A licensed physical therapist shall submit to the department:

(i) A completed endorsement application as provided by the department;

(ii) Endorsement fees required under WAC 246-915-990;

(iii) Evidence of completion of the education and training requirements listed in RCW 18.74.200; and

(iv) A completed affidavit demonstrating successful completion of the clinical review requirement listed in RCW 18.74.200.

(b) A licensed physical therapist who is credentialed to perform intramuscular needling through any branch of the military meets the requirements of the intramuscular needling endorsement and shall submit to the department:

(i) A completed endorsement application verifying their military credential to perform intramuscular needling; and

(ii) Endorsement fees required under WAC 246-915-990.

(9) A physical therapist shall have patients receiving intramuscular needling sign an informed consent form that includes:

(a) The definition of intramuscular needling as set forth in RCW 18.74.010;

(b) A description of the risks of intramuscular needling;

(c) A description of the benefits of intramuscular needling;

(d) A description of the potential side effects of intramuscular needling; and

(e) A statement clearly differentiating the procedure from the practice of acupuncture. Acupuncture shall be defined in accordance with the definition of "acupuncture and Eastern medicine" under RCW 18.06.010.

(10) Intramuscular needling may not be administered as a standalone treatment within a physical therapy care plan.

(11) If a physical therapist is intending to perform intramuscular needling on a patient who the physical therapist knows is being treated by an acupuncturist or acupuncture and Eastern medicine practitioner for the same diagnosis, the physical therapist shall make reasonable efforts to coordinate patient care with the acupuncturist or acupuncture and Eastern medicine practitioner to prevent conflict or duplication of services.

AMENDATORY SECTION (Amending WSR 23-07-057, filed 3/9/23, effective 6/1/23)

WAC 246-915-990 Physical therapist fees and renewal cycle. (1) Licenses must be renewed every year on the practitioner's birthday as provided in chapter 246-12 WAC.

(2) The following nonrefundable fees will be charged:

Title of Fee	Fee
Original application	
Application	$80.00
Active license renewal	
License renewal	100.00
Late renewal penalty	50.00

Title of Fee	Fee
Expired license reissuance	50.00
Inactive license renewal	
License renewal	35.00
Expired license reissuance	50.00
Duplicate license	10.00
Endorsement	
Intramuscular needling endorsement	100.00
Verification of license	25.00

WSR 24-06-069
PROPOSED RULES
DEPARTMENT OF
LABOR AND INDUSTRIES
[Filed March 5, 2024, 8:52 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-07-139.

Title of Rule and Other Identifying Information: Voluntary use of personal protective equipment (PPE). Chapter 296-155 WAC, Safety standards for construction work, WAC 296-155-249; chapter 296-307 WAC, Safety standards for agriculture, WAC 296-307-10030; and chapter 296-800 WAC, Safety and health core rules, WAC 296-800-16080.

Hearing Location(s): On April 23, 2024, at 1:30 p.m., at Enduris Training Center, 1610 South Technology Boulevard, Suite 100, Spokane, WA 99224. A prehearing overview will begin at 1:00 p.m. The hearing will start at 1:30 p.m. and will continue until all oral comments are received;

On April 30, 2024, at 10:30 a.m., at the Department of Labor and Industries (L&I), 12806 Gateway Drive South, Tukwila, WA 98168. A prehearing overview will begin at 10:00 a.m. The hearing will start at 10:30 a.m. and will continue until all oral comments are received; and

On May 2, 2024, at 10:30 a.m., electronically https://lni-wa-gov.zoom.us/j/81062827834?pwd=cmh1d3pZNXFtaDRySGxIS0RUUm9kUT09, Passcode (if prompted) VPpe@10a; or join by phone (audio only) 253-215-8782, Meeting ID 810 6282 7834, Passcode 00284359. A prehearing overview will begin at 10:00 a.m. The hearing will start at 10:30 a.m. and will continue until all oral comments are received.

Date of Intended Adoption: June 4, 2024.

Submit Written Comments to: Carmyn Shute, Administrative Regulations Analyst, L&I, Division of Occupational Safety and Health, P.O. Box 44620, Olympia, WA 98504-4620, email Carmyn.Shute@Lni.wa.gov, fax 360-902-5619, by 5:00 p.m. May 17, 2024.

Assistance for Persons with Disabilities: Contact Carmyn Shute, administrative regulations analyst, phone 360-870-4525, fax 360-902-5619, email Carmyn.Shute@Lni.wa.gov, by 5:00 p.m., April 15, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: L&I is proposing permanent sections in rule to allow the voluntary use of PPE when workers feel the need to protect themselves from noise, dust, or possible infectious or contagious diseases. The voluntary use of PPE must not introduce hazards to the work environment and any PPE, including facial coverings, must not interfere with an employer's security requirements.

The proposed sections in rule model RCW 49.17.485 Personal protective devices and equipment—Public health emergency, but is not limited to declared public health emergencies. In the event a public health emergency is declared, the proposed sections in rule would already be effective and no material change would be needed to comply with RCW 49.17.485.

Reasons Supporting Proposal: Allowing workers to voluntarily use appropriate and safe PPE when it is not otherwise required for the job is essential for the preservation of worker health and safety. During the COVID-19 pandemic, when a mask mandate was not in place, workers in multiple industries continued to wear masks as a means of protection and to reduce transmission of infectious or contagious disease.

Statutory Authority for Adoption: RCW 49.17.010, 49.17.040, 49.17.050, and 49.17.060.

Statute Being Implemented: Chapter 49.17 RCW.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: L&I, governmental.

Name of Agency Personnel Responsible for Drafting: Tracy West, Tumwater, Washington, 509-237-2372; Implementation and Enforcement: Craig Blackwood, Tumwater, Washington, 360-902-5828.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Carmyn Shute, Administrative Regulations Analyst, L&I, Division of Occupational Safety and Health, P.O. Box 44620, Olympia, WA 98504-4620, phone 360-870-4525, fax 360-902-5619, email Carmyn.Shute@Lni.wa.gov.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. The proposed sections in rule only require an employer to allow their employees to use PPE. There is no cost to the employer, as they do not need to supply or maintain the PPE.

March 5, 2024
Joel Sacks
Director

OTS-4065.6

NEW SECTION

WAC 296-155-249 Voluntary use of personal protective equipment (PPE). (1) Every employer that does not require employees or contractors to wear a specific type of personal protective equipment as determined under the PPE hazard assessment, employer policy, or where otherwise required to comply with safety and health standard rules, must allow its employee's or contractor's voluntary use of PPE (PPE is an item or items used to protect the eyes, face, head, body, arms, hands, legs, and feet such as goggles, helmets, head covers, gloves, rubber slickers, disposable coveralls, safety shoes, protective shields, and barriers). This only applies when:

(a) The voluntary use of personal protective devices and equipment does not introduce hazards to the work environment and is consistent with applicable rules established by the department;

(b) The voluntary use of personal protective devices and equipment does not interfere with an employer's security requirements; and

(c) The voluntary use of these personal protective devices and equipment does not conflict with standards for that specific type of equipment established by the department of health or DOSH.

(2) WAC 296-842-11005 does not apply to the voluntary use of filtering-facepiece respirators, as defined under WAC 296-842-10200, un-

der this section. Voluntary use of respirators not considered filtering-facepieces, such as elastomeric respirators, must comply with WAC 296-842-11005 and 296-842-11010.

(3) An employer may verify that voluntary use of personal protective equipment meets all regulatory requirements for workplace health and safety.

(4) Employers do not have to purchase, store, maintain, or otherwise provide protective devices or equipment for voluntary use by employees under this section.

(5) RCW 49.17.485 precludes DOSH from issuing variances under RCW 49.17.080 related to voluntary personal protective devices and equipment during a public health emergency as defined in RCW 49.17.485.

OTS-4066.6

NEW SECTION

WAC 296-307-10030 Voluntary use of personal protective equipment (PPE). (1) Every employer that does not require employees or contractors to wear a specific type of personal protective equipment as determined under the PPE hazard assessment, employer policy, or where otherwise required to comply with safety and health standards rules, must allow its employee's or contractor's voluntary use of PPE (PPE is an item or items used to protect the eyes, face, head, body, arms, hands, legs, and feet such as goggles, helmets, head covers, gloves, rubber slickers, disposable coveralls, safety shoes, protective shields, and barriers). This only applies when:

(a) The voluntary use of personal protective devices and equipment does not introduce hazards to the work environment and is consistent with applicable rules established by the department;

(b) The voluntary use of personal protective devices and equipment does not interfere with an employer's security requirements; and

(c) The voluntary use of these personal protective devices and equipment does not conflict with standards for that specific type of equipment established by the department of health or DOSH.

(2) WAC 296-842-11005 does not apply to the voluntary use of filtering-facepiece respirators, as defined under WAC 296-842-10200, under this section. Voluntary use of respirators not considered filtering-facepieces, such as elastomeric respirators, must comply with WAC 296-842-11005 and 296-842-11010.

(3) An employer may verify that voluntary use of personal protective equipment meets all regulatory requirements for workplace health and safety.

(4) Employers do not have to purchase, store, maintain, or otherwise provide protective devices or equipment for voluntary use by employees under this section.

(5) RCW 49.17.485 precludes DOSH from issuing variances under RCW 49.17.080 related to voluntary personal protective devices and equipment during a public health emergency as defined in RCW 49.17.485.

OTS-4067.6

NEW SECTION

WAC 296-800-16080 Voluntary use of personal protective equipment (PPE). (1) Every employer that does not require employees or contractors to wear a specific type of personal protective equipment as determined under the PPE hazard assessment, employer policy, or where otherwise required to comply with safety and health standards rules, must allow its employee's or contractor's voluntary use of PPE (PPE is an item or items used to protect the eyes, face, head, body, arms, hands, legs, and feet such as goggles, helmets, head covers, gloves, rubber slickers, disposable coveralls, safety shoes, protective shields, and barriers). This only applies when:

(a) The voluntary use of personal protective devices and equipment does not introduce hazards to the work environment and is consistent with applicable rules established by the department;

(b) The voluntary use of personal protective devices and equipment does not interfere with an employer's security requirements; and

(c) The voluntary use of these personal protective devices and equipment does not conflict with standards for that specific type of equipment established by the department of health or DOSH.

(2) WAC 296-842-11005 does not apply to the voluntary use of filtering-facepiece respirators, as defined under WAC 296-842-10200, under this section. Voluntary use of respirators not considered filtering-facepieces, such as elastomeric respirators, must comply with WAC 296-842-11005 and 296-842-11010.

(3) An employer may verify that voluntary use of personal protective equipment meets all regulatory requirements for workplace health and safety.

(4) Employers do not have to purchase, store, maintain, or otherwise provide protective devices or equipment for voluntary use by employees under this section.

(5) RCW 49.17.485 precludes DOSH from issuing variances under RCW 49.17.080 related to voluntary personal protective devices and equipment during a public health emergency as defined in RCW 49.17.485.

WSR 24-06-071
PROPOSED RULES
DEPARTMENT OF REVENUE
[Filed March 5, 2024, 9:28 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-03-078.

Title of Rule and Other Identifying Information: WAC 458-20-252 Hazardous substance tax.

Hearing Location(s): On April 10, 2024, at 10:00 a.m. This meeting will be conducted over the internet/telephone. Please contact Barbara Imperio at barbarai@dor.wa.gov for login/dial-in information.

Date of Intended Adoption: May 7, 2024.

Submit Written Comments to: Darius Massoudi, P.O. Box 47453, Olympia, WA 98504-7453, email DariusM@dor.wa.gov, fax 360-534-1606, 360-534-1572.

Assistance for Persons with Disabilities: Contact Julie King, phone 360-704-5733, TTY 800-833-6384, by April 8, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: This proposal is to update WAC 458-20-252 to account for volumetric changes to petroleum products caused by differences in temperature and pressure.

Reasons Supporting Proposal: SSB [ESSB] 5993 (2019) added a new volumetric per barrel rate for petroleum products subject to the hazardous substance tax. This rule-making effort will add a definition for the term "barrel" in RCW 82.21.030(1) to address changes in volume due to differences in temperature and pressure, and other updates to enhance readability of the rule.

Statutory Authority for Adoption: RCW 82.01.060(2), 82.32.300, and 82.21.030.

Statute Being Implemented: RCW 82.21.030(1); and SSB [ESSB] 5993 (2019).

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Governmental.

Name of Agency Personnel Responsible for Drafting: Darius Massoudi, 6400 Linderson Way S.W., Tumwater, WA 98501, 360-534-1572; Implementation and Enforcement: Heidi Geathers, 6400 Linderson Way S.W., Tumwater, WA 98501, 360-534-1615.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. This rule is not a significant legislative rule as defined by RCW 34.05.328.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. The proposed rule does not impose more-than-minor costs on businesses, as it standardizes definitions for "billed gallons," "gross gallons," and "net gallons" with the existing fuel tax definitions in WAC 308-77-005, separately administered by the Washington state department of licensing; and does not propose any new tax rate, tax measure, reporting, or recordkeeping requirements not already established by statute.

March 5, 2024

Brenton Madison
Rules Coordinator

OTS-4891.2

AMENDATORY SECTION (Amending WSR 20-02-055, filed 12/24/19, effective 1/24/20)

WAC 458-20-252 Hazardous substance tax. (1) Introduction. Under chapter 82.21 RCW (referred to in this rule as the "law"), a hazardous substance tax is imposed upon the wholesale value of certain substances and products, with specific credits and exemptions provided. The tax is an excise tax upon the privilege of possessing hazardous substances in this state.

Before July 1, 2019, the tax was imposed upon the wholesale value of the hazardous substance. Starting July 1, 2019, the tax is imposed in one of two ways:

Upon the wholesale value of certain hazardous substances ("value-based tax"); or

Upon the volume of certain hazardous substances ("volumetric tax").

The volumetric tax applies to petroleum products that are easily measured on a per barrel basis. The value-based tax applies to all other hazardous substances, including petroleum products that are not easily measured on a per barrel basis.

(a) Chapter 82.21 RCW defines certain specific substances as being hazardous and includes other substances by reference to federal legislation governing such things. It also provides authority to the director of the state department of ecology to designate by rule any other substance or product as hazardous that could present a threat to human health or the environment. (Chapter 173-342 WAC.)

(b) Chapter 82.21 RCW is administered exclusively under this rule. The law relates exclusively to the possession of hazardous substances and products. The law does not relate to waste, releases or spills of any materials, cleanup, compensation, or liability for such things, nor does tax liability under the law depend upon such factors. The incidence or privilege that incurs tax liability is simply the possession of the hazardous substance or product, whether or not such possession actually causes any hazardous or dangerous circumstance.

(c) The hazardous substance tax is imposed upon any possession of a hazardous substance or product in this state by any person who is not expressly exempt of the tax. However, it is the intent of the law that the economic burden of the tax should fall upon the first such possession in this state. Therefore, the law provides that if the tax has not been paid upon any hazardous substance or product the department of revenue may collect the tax from any person who has had possession. The amount of tax paid then constitutes a debt owed by the first person having had taxable possession to the person who pays the tax.

(2) Definitions. For purposes of this rule the following definitions apply.

(a) ((~~"Tax" means the hazardous substance tax imposed under chapter 82.21 RCW.~~

~~(b)~~)) "Barrel" means a container that holds 42 billed gallons of a petroleum product, as defined in this rule. Starting July 1, 2019, it is the tax measure or base for petroleum products that are easily measured on a per barrel basis.

(b) "Billed gallon" means a U.S. gallon of petroleum product, whether net or gross as billed to the purchaser.

(c) "Gross gallon" means a U.S. gallon of petroleum product of 231 cubic inches as measured at the terminal rack.

(d) "Hazardous substance" means:

(i) Any substance that, on March 1, 2002, is a hazardous substance under section 101(14) of the Federal Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), 42 U.S.C. Sec. 9601(14), as amended by Public Law 99-499 on October 17, 1986, except that hazardous substance does not include the following noncompound metals when in solid form in a particle larger than ((~~one hundred~~)) 100 micrometers (0.004 inches) in diameter: Antimony, arsenic, beryllium, cadmium, chromium, copper, lead, nickel, selenium, silver, thallium, or zinc. These substances consist of chemicals and elements in their purest form. A CERCLA substance that contains water is still considered pure. Combinations of CERCLA substances as ingredients together with nonhazardous substances will not be taxable unless the end product is specifically designated as a hazardous substance by the department of ecology;

(ii) Petroleum products (further defined below);

(iii) Pesticide products required to be registered under section 136a of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. Sec. 136 et seq., as amended by Public Law 104-170 on August 3, 1996; and

(iv) Anything else enumerated as a hazardous substance in chapter 173-342 WAC by the department of ecology.

((~~(c) "Product(s)" means any item(s) containing a combination of ingredients, some of which are hazardous substances and some of which are not hazardous substances.~~

~~(d)~~)) (e) "Net gallon" means a U.S. gallon of petroleum product of 231 cubic inches at 60 degrees Fahrenheit and a pressure of 14.7 pounds per square inch (1 atmosphere).

(f) "Person" means any natural or artificial person, including a business organization of any kind, and has the further meaning defined in RCW 82.04.030.

The term "natural person," for purposes of the tax exemption in subsection (4)(b) of this rule regarding substances used for personal or domestic purposes, means human beings in a private, as opposed to a business sense.

(g) "Petroleum product" means any plant condensate, lubricating oil, crankcase motor oil, gasoline, aviation fuel, kerosene, diesel motor fuel, benzol, fuel oil, residual fuel, asphalt base, liquefied or liquefiable gases, such as butane, ethane and propane, and every other product derived from the refining of crude oil, but the term does not include crude oil.

The term "derived from the refining of crude oil" as used herein, means produced because of and during petroleum processing. "Petroleum processing" includes all activities of a commercial or industrial nature wherein labor or skill is applied, by hand or machinery, to crude oil or any byproduct of crude oil so that as a result thereof a fuel or lubricant is produced for sale or commercial or industrial use. "Fuel" includes all combustible gases and liquids suitable for the generation of energy. The term "derived from the refining of crude

oil" does not mean petroleum products that are manufactured from refined oil derivatives, such as petroleum jellies, cleaning solvents, asphalt paving, etc. Such further manufactured products become hazardous substances only when expressly so designated by the director of the department of ecology in chapter 173-342 WAC.

((~~(e) "Possession" means control of a hazardous substance located within this state and includes both actual and constructive possession.~~

~~(i) "Control" means the power to sell or use a hazardous substance or to authorize the sale or use by another.~~

~~(ii) "Actual possession" occurs when the person with control has physical possession.~~

~~(iii) "Constructive possession" occurs when the person with control does not have physical possession.~~

~~(f) "Previously taxed hazardous substance" means a hazardous substance upon which the tax has been paid and which has not been remanufactured or reprocessed in any manner.~~

~~(i) Remanufacturing or reprocessing does not include the mere repackaging or recycling for beneficial reuse. Rather, these terms embrace activities of a commercial or industrial nature involving the application of skill or labor by hand or machinery so that as a result, a new or different substance or product is produced.~~

~~(ii) "Recycling for beneficial reuse" means the recapturing of any used substance or product, for the sole purpose of extending the useful life of the original substance or product in its previously taxed form, without adding any new, different, or additional ingredient or component.~~

~~(iii) Example: Used motor oil drained from a crankcase, filtered, and containerized for reuse is not remanufactured or reprocessed. If the tax was paid on possession of the oil before use, the used oil is a previously taxed substance.~~

~~(iv) Possessions of used hazardous substances by persons who merely operate recycling centers or collection stations and who do not reprocess or remanufacture the used substances are not taxable possessions.~~

~~(g) "Wholesale value" means the fair market value determined by the wholesale selling price.~~

~~In cases where no sale has occurred, wholesale value means the fair market wholesale value, determined as nearly as possible according to the wholesale selling price at the place of use of similar substances of like quality and character. In such cases the wholesale value shall be the "value of the products" as determined under the alternate methods set forth in WAC 458-20-112.~~

~~Before July 1, 2019, the wholesale value was the tax measure or base for all hazardous substances. Starting July 1, 2019, the wholesale value is the tax measure or base for all hazardous substances other than petroleum products that are easily measured on a per barrel basis.~~))

(h) "Possession" means control of a hazardous substance located within this state and includes both actual and constructive possession.

(i) "Control" means the power to sell or use a hazardous substance or to authorize the sale or use by another.

(ii) "Actual possession" occurs when the person with control has physical possession.

(iii) "Constructive possession" occurs when the person with control does not have physical possession.

(i) "Previously taxed hazardous substance" means a hazardous substance upon which the tax has been paid and which has not been remanufactured or reprocessed in any manner.

(i) Remanufacturing or reprocessing does not include the mere repackaging or recycling for beneficial reuse. Rather, these terms embrace activities of a commercial or industrial nature involving the application of skill or labor by hand or machinery so that as a result, a new or different substance or product is produced.

(ii) "Recycling for beneficial reuse" means the recapturing of any used substance or product, for the sole purpose of extending the useful life of the original substance or product in its previously taxed form, without adding any new, different, or additional ingredient or component.

(iii) Example: Used motor oil drained from a crankcase, filtered, and containerized for reuse is not remanufactured or reprocessed. If the tax was paid on possession of the oil before use, the used oil is a previously taxed substance.

(iv) Possessions of used hazardous substances by persons who merely operate recycling centers or collection stations and who do not reprocess or remanufacture the used substances are not taxable possessions.

(j) "Product" means any item containing a combination of ingredients, some of which are hazardous substances and some of which are not hazardous substances.

(k) "Selling price" means consideration of any kind expressed in terms of money paid or delivered by a buyer to a seller, without any deductions for any costs whatsoever. Bona fide discounts actually granted to a buyer result in reductions in the selling price rather than deductions.

((~~(i)~~)) (l) "State," for purposes of the credit provisions of the hazardous substance tax, means:

(i) The state of Washington.

(ii) States of the United States or any political subdivisions of such other states.

(iii) The District of Columbia.

(iv) Territories and possessions of the United States.

(v) Any foreign country or political subdivision thereof.

((~~(j) "Person" means any natural or artificial person, including a business organization of any kind, and has the further meaning defined in RCW 82.04.030.~~

~~The term "natural person," for purposes of the tax exemption in subsection (4)(b) of this rule regarding substances used for personal or domestic purposes, means human beings in a private, as opposed to a business sense.~~

~~(k)~~)) (m) Except as otherwise expressly defined in this rule, the definitions of terms provided in chapters 82.04, 82.08, and 82.12 RCW apply equally for this rule. Other terms not expressly defined in these chapters or this rule are to be given their common and ordinary meanings.

((~~(l) "Barrel" means a container that holds forty-two gallons of a petroleum product, as defined in this rule. Starting July 1, 2019, it is the tax measure or base for petroleum products that are easily measured on a per barrel basis.~~)) (n) "Tax" means the hazardous substance tax imposed under chapter 82.21 RCW.

(o) "Wholesale value" means the fair market value determined by the wholesale selling price.

In cases where no sale has occurred, wholesale value means the fair market wholesale value, determined as nearly as possible according to the wholesale selling price at the place of use of similar substances of like quality and character. In such cases the wholesale value shall be the "value of the products" as determined under the alternate methods set forth in WAC 458-20-112.

Before July 1, 2019, the wholesale value was the tax measure or base for all hazardous substances. Starting July 1, 2019, the wholesale value is the tax measure or base for all hazardous substances other than petroleum products that are easily measured on a per barrel basis.

(3) Tax rate and measure. The tax is imposed upon the privilege of possessing a hazardous substance in this state.

(a) For value-based tax. The value-based tax rate is seven tenths of one percent (.007). The value-based tax measure or base is the wholesale value of the substance, as defined in this rule. Before July 1, 2019, the value-based tax applied to all hazardous substances. Starting July 1, 2019, the value-based tax rate applies to all hazardous substances other than petroleum products that are easily measured on a per barrel basis.

(b) For volumetric tax. Starting July 1, 2019, the volumetric tax rate is ((~~one dollar and nine cents~~)) $1.09 per barrel and applies to petroleum products that are easily measured on a per barrel basis. Starting July 1, 2020, the volumetric tax rate on petroleum products will be adjusted to reflect the percentage change in the implicit price deflator for nonresidential structures as published by the United States Department of Commerce, Bureau of Economic Analysis for the most recent ((~~twelve~~)) 12-month period ending December 31st of the prior year.

(i) Density adjustments. For petroleum products that are easily measured on a per barrel basis, taxpayers will determine the amount of tax due based on billed gallons. Billed gallons may be calculated by using either gross gallons or net gallons. However, for contracts that adjust the formula for calculating billed gallons throughout the year to reduce the quantity of reported barrels, the department may employ the net gallons standard.

(ii) Example. Barrels are measured and reported to the department as billed gallons. However, to calculate billed gallons, Company A has negotiated a contract to employ the gross gallons standard during the winter in a location where average temperatures are 40 degrees Fahrenheit, while adjusting to the net gallons standard at the same location during the summer where average temperatures are 70 degrees Fahrenheit. Company A's seasonal formula for calculating billed gallons would ordinarily result in reducing the measured quantity of barrels throughout the year versus choosing a single formula to measure billed gallons. Therefore, the department may employ the net gallons standard for the entirety of the contract to measure the quantity of barrels.

(c) The department of revenue maintains lists of petroleum products that are easily measured, and petroleum products that are not easily measured, on a per barrel basis, on its website at dor.wa.gov. Petroleum products that remain in a liquid state at 77 degrees Fahrenheit and a pressure of 14.7 pounds per square inch (1 atmosphere) are subject to hazardous substance tax on a per barrel basis. These lists are not exclusive. If additional petroleum products are identified in the future, the department will add them to the applicable list. Products added to the lists will be subject to hazardous substance tax for

all periods that the tax applies, even if the product was not on a list at the time.

(4) Exemptions. The following are expressly exempt from the tax:

(a) Any successive possessions of any previously taxed hazardous substances are tax exempt.

(i) Any person who possesses a hazardous substance that has been acquired from any other person who is registered with the department of revenue and doing business in this state may take a written statement certifying that the tax has been previously paid. Such certifications must be taken in good faith and must be in the form provided in subsection (14) of this rule. Blanket certifications may be taken, as appropriate, which must be renewed at intervals not to exceed four years. These certifications may be used for any single hazardous substance or any broad classification of hazardous substances, e.g., "all chemicals."

(ii) In the absence of taking such certifications, the person who possesses any hazardous substance must retain proofs that it purchased or otherwise acquired the substance from a previous possessor in this state. It is not necessary for subsequent possessors to obtain certificates of previously taxed hazardous substances in order to perfect their tax exemption. Documentation that establishes any evidence of previous tax payment by another person will suffice. This includes invoices or billings from in-state suppliers that reflect their payment of the tax or simple bills of lading or delivery documents revealing an in-state source of the hazardous substances.

(iii) This exemption for taxes previously paid is available for any person in successive possession of a taxed hazardous substance even though the previous payment may have been satisfied by the use of credits or offsets available to the previous person in possession.

(iv) Example. Company A brings a substance into this state upon which it has paid a similar hazardous substance tax in another state. Company A takes a credit against its Washington tax liability in the amount of the other state's tax paid. It then sells the substance to Company B, and provides Company B with a certificate of previously taxed substance. Company B's possession is tax exempt even though Company A has not directly paid Washington's tax but has used a credit against its Washington liability.

(b) Any possession of a hazardous substance by a natural person for use of a personal or domestic nature, rather than a business nature, is tax exempt.

(i) This exemption extends to relatives, as well as other natural persons who reside with the person possessing the substance, and also to regular employees of that person who use the substance for the benefit of that person.

(ii) This exemption does not extend to possessions by any independent contractors hired by natural persons, which contractors themselves provide the hazardous substance.

(iii) Examples: Possessions of spray materials by an employee-gardener or soaps and cleaning solvents by an employee-domestic servant, when such substances are provided by the natural person for whose domestic benefit such things are used, are tax exempt. Also, possessions of fuel by private persons for use in privately owned vehicles are tax exempt.

(c) Any possession of any hazardous substance, other than pesticides or petroleum products, possessed by a retailer for making sales to consumers, in an amount that is determined to be "minimal" by the department of ecology. That department has determined that the term

"minimal" means less than $1,000.00 worth of such hazardous substances measured by their wholesale value, possessed during any calendar month.

(d) Possessions of alumina or natural gas are tax exempt.

(e) Persons or activities that the state is prohibited from taxing under the United States Constitution are tax exempt.

(i) This exemption extends to the U.S. government, its agencies and instrumentalities, and to any possession the taxation of which has been expressly reserved or preempted under the laws of the United States.

(ii) The tax will not apply with respect to any possession of any hazardous substance purchased, extracted, produced or manufactured outside this state that is shipped or delivered into this state until the interstate transportation of such substance has finally ended in this state. Thus, out-of-state sellers or producers need not pay the tax on substances shipped directly to customers in this state. The customers must pay the tax upon their first possession unless otherwise expressly exempt.

(iii) Out-of-state sellers or producers will be subject to tax upon substances shipped or delivered to warehouses or other in-state facilities owned, leased, or otherwise controlled by them.

(iv) However, the tax will not apply with respect to possessions of substances that are only temporarily stored or possessed in this state in connection with through, interstate movement of the substances from points of origin to points of destination both of which are outside of this state.

(f) The former exemption for petroleum products for export sale or use outside this state as fuel was effectively repealed by I-97 (1988). There are no exemptions under the law for any possessions of hazardous substances in this state simply because such substances may later be sold or used outside this state.

(g) Any possession of an agricultural crop protection product that is solely for use by a farmer or certified applicator as an agricultural crop protection product and is warehoused in this state or transported to or from this state is tax exempt, provided that the person possessing the product does not use, manufacture, package for sale, or sell the product in this state. The following definitions apply throughout this subsection unless the context clearly requires otherwise.

(i) "Agricultural crop protection product" means a chemical regulated under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. Sec. 136 as amended as of September 1, 2015, when used to prevent, destroy, repel, mitigate, or control predators, diseases, weeds, or other pests.

(ii) "Certified applicator" has the same meaning as provided in RCW 17.21.020.

(iii) "Farmer" has the same meaning as in RCW 82.04.213.

(iv) "Manufacturing" includes mixing or combining agricultural crop protection products with other chemicals or other agricultural crop protection products.

(v) "Package for sale" includes transferring agricultural crop protection products from one container to another, including the transfer of fumigants and other liquid or gaseous chemicals from one tank to another.

(vi) "Use" has the same meaning as in RCW 82.12.010.

(5) Credits. There are three distinct kinds of tax credits against liability that are available under the law.

(a) A credit may be taken by any manufacturer or processor of a hazardous substance produced from ingredients or components that are themselves hazardous substances, and upon which the hazardous substance tax has been paid by the same person or is due for payment by the same person.

(i) Example. A manufacturer possesses hazardous chemicals that it combines to produce an acid, which is also designated as a hazardous substance or product. When it reports the tax upon the wholesale value of the acid it may use a credit to offset the tax by the amount of tax it has already paid or reported upon the hazardous chemical ingredients or components. In this manner the intent of the law to tax hazardous substances only once is fulfilled.

(ii) Under circumstances where the hazardous ingredient and the hazardous end product are both possessed by the same person during the same tax reporting period, the tax on the respective substances must be computed and the former must be offset against the latter so that the tax return reflects the tax liability after the credit adjustment.

(iii) This credit may be taken only by manufacturers who have the first possession in this state of both the hazardous ingredients and the hazardous end product.

(b) A credit may be taken in the amount of the hazardous substance tax upon the value of fuel that is carried from this state in the fuel tank of any airplane, ship, truck, or other vehicle.

(i) The credit may be claimed only for the amount of tax reported or actually due to be paid on the fuel, not the amount representing the value of the fuel.

(ii) The purpose of this credit is to exclude from taxation any possessions of fuel that remains in the fuel tanks of any carrier vehicles powered by such fuel when they leave this state, regardless of where or from whom such fuel-in-tanks was acquired.

(iii) The nature of this credit is such that it generally has application only for interstate and foreign private or common carriers that carry fuel into this state ((~~and/~~))or purchase fuel in this state. The intent is that the tax will apply only to so much of such fuel as is actually consumed by such carriers within this state.

(iv) In order to equitably and efficiently administer this tax credit, any fuel that is brought into this state in carrier vehicle fuel tanks must be accounted for separately from fuel that is purchased in this state for use in such fuel tanks. Formulas approved by the department of revenue for reporting the amount of fuel consumed in this state for purposes of this tax or other excise tax purposes will satisfy the separate accounting required under this subsection.

(v) Fuel-in-tanks brought into this state must be fully reported for tax and then the credit must be taken in the amount of such fuel that is taken back out of this state. This is to be done on the same periodic excise tax return so that the net effect is that the tax is actually paid only upon the portion of fuel consumed here.

(vi) The credit for fuel-in-tanks purchased in this state must be accounted for by using a fuel-in-tanks credit certificate in substantially the following form:

Certificate of Credit for Fuel Carried from this State in Fuel Tanks

I hereby certify that the petroleum products specified herein, purchased by or transferred to the undersigned, from (name of seller or transferor), are entitled to the credit for fuel that is carried from this state in the fuel tank of any airplane, ship, truck, or oth-

er vehicle operated by a private or common carrier in interstate or foreign commerce. I will become liable for and pay the taxes due upon all or any part of such fuel that is not so carried from this state. This certification is given with full knowledge of, and subject to the legally prescribed penalties for fraud and tax evasion.

Registration No.	..... (if applicable)
Type of Business	.....
Firm Name	.....
Business Address	.....
Registered Name	..... (if different)
Tax Reporting Agent	..... (if applicable)
Authorized Signature	.....
Title	.....
Identity of Fuel	..... (kind and amount by volume)

Date: .....

(vii) This certificate may be executed and provided to any possessor of fuel in this state, throughout the chain of distribution, with respect to fuel that ultimately will be sold and delivered into any carrier's fuel tanks in this state. Thus, refiners or manufacturers will take such certificates directly from carriers or from their wholesale purchasers who will sell to such carriers. Similarly, fuel dealers and distributors will take such certificates from carriers to whom they sell such fuel. These certificates must be retained as a permanent part of such seller's business records.

(viii) Persons who execute and provide these credit certificates to their fuel suppliers must retain suitable purchase and sales records as may be necessary to determine the amount of tax for which such persons may be liable.

(ix) Blanket certificates may be used to cover recurrent purchases of fuel by the same purchaser. Such blanket certificates must be renewed every two years.

(c) A credit may be taken against the tax owed in this state in the amount of any other state's hazardous substance tax that has been paid by the same person measured by the wholesale value of the same hazardous substance.

(i) In order for this credit to apply, the other state's tax must be significantly similar to Washington's tax in all its various respects. The taxable incident must be possessing the substance; the tax purpose must be that the substance is hazardous; and the tax measure must be stated in terms of the wholesale value<u>, or volume,</u> of the substance, without deductions for costs of doing business, such that the other state's tax does not constitute an income tax or added value tax.

(ii) This credit may be taken for the amount of any other state's qualifying tax that has actually been paid before Washington state's tax is incurred because the substance was previously possessed by the same person in another taxing jurisdiction.

(iii) The amount of credit is limited to the amount of tax paid in this state upon possession of the same hazardous substance in this state. Also, the credit may not be applied against any tax paid or owed in this state other than the hazardous substance tax imposed under chapter 82.21 RCW.

(iv) Exchange agreements under which hazardous substances or products possessed in this state are exchanged through any accounts crediting system with like substances possessed in other states do not qualify for this credit. The substance taxed in another state, and for which this credit is sought, must be actually, physically possessed in this state.

(v) Persons claiming this credit must maintain records necessary to verify that the credit taking qualifications have been met. Additional information regarding recordkeeping requirements is provided in WAC 458-20-19301. ((~~The department of revenue will publish an excise tax bulletin listing other states' taxes that qualify for this credit.~~))

(6) Newly defined hazardous substances. Under chapter 82.21 RCW the director of the department of ecology may identify and designate other substances or products as being hazardous substances for purposes of the tax. The director of the department of ecology may also delete substances or products previously designated as hazardous substances. Such actions are done by amending chapter 173-342 WAC.

(a) The law allows the addition or deletion of substances or products as hazardous substances by rule amendments, no more often than twice in any calendar year.

(b) When such additions or deletions are made, they do not take effect for tax purposes until the first day of the following month that is at least ((~~thirty~~)) 30 days after the effective date of rule amendment by the department of ecology.

(i) Example. The department of ecology amends chapter 173-342 WAC by adding a new substance and the effective date of the amendment is June 15th. Possession of the substance does not become taxable until August 1st.

(ii) The tax is owed by any person who has possession of the newly designated hazardous substance upon the tax effective date as explained herein. It is immaterial that the person in possession on that date was not the first person in possession of the substance in this state before it was designated as hazardous.

(7) Recurrent tax liability. It is the intent of the law that all hazardous substances possessed in this state should incur this tax liability only once unless they are expressly exempt. This is true of hazardous ingredients of products as well as the manufactured end product itself, if designated as a hazardous substance. The *exemption* for previously taxed hazardous substances does not apply to "products" that have been manufactured or remanufactured simply because an ingredient or ingredients of that product may have already been taxed when possessed by the manufacturer. Instead of an exemption, manufacturers in possession of both the hazardous ingredient((~~(s)~~)) and end product((~~(s)~~)) should use the *credit* provision explained at subsection (5)(a) of this rule.

(a) However, the term "product" is defined to mean only an item or items that contain a combination of both hazardous ((~~substance(s)~~)) substances and nonhazardous ((~~substance(s)~~)) substances. The term does not include combinations of only hazardous substances. Thus, possessions of substances produced by combining other hazardous substances upon all of which the tax has previously been paid will not again be taxable.

(b) When any hazardous substance((~~(s)~~)) is first produced during and because of any physical combination or chemical reaction that occurs in a manufacturing or processing activity, the intermediate possession of such substance((~~(s)~~)) within the manufacturing or process-

ing plant is not considered a taxable possession if the substance((~~(s)~~)) becomes a component or ingredient of the product being manufactured or processed or is otherwise consumed during the manufacturing or processing activity.

However, when any intermediate hazardous substance is first produced during a manufacturing or processing activity and is withdrawn for sale or transfer outside of the manufacturing or processing plant, a taxable first possession occurs.

(c) Concentrations or dilutions for shipment or storage. The mere addition or withdrawal of water or other nonhazardous substances to or from hazardous substances designated under CERCLA or FIFRA for the sole purpose of transportation, storage, or the later manufacturing use of such substances does not result in any new hazardous product.

(8) How and when to pay tax. The tax must be reported on a special line of the combined excise tax return designated "hazardous substances." It is due for payment together with the timely filing of the return upon which it is reported, covering the tax reporting period during which the hazardous substance((~~(s)~~)) is first possessed within this state. Any person who is not expressly exempt of the tax and who possesses any hazardous substance in this state, without having proof that the tax has previously been paid on that substance, must report and pay the tax.

(a) It may be that the person who purchases a hazardous substance will not have billing information from which to determine the wholesale value of the substance when the tax return for the period of possession is due. In such cases the tax is due for payment no later than the next regular reporting due date following the reporting period in which the substance((~~(s)~~)) is first possessed.

(b) The taxable incident or event is the possession of the substance. Tax is due for payment by the purchaser of any hazardous substance whether or not the purchase price has been paid in part or in full.

(c) Special provision for manufacturers, refiners, and processors. Manufacturers, refiners, and processors who possess hazardous substances are required to report the tax and take any available exemptions and credits only at the time that such hazardous substances are withdrawn from storage for purposes of their sale, transfer, remanufacture, or consumption.

(9) How and when to claim credits. Credits should be claimed and offset against tax liability reported on the same excise tax return when possible. The tax return form provides a line for reporting tax on hazardous substances and a line for taking credits as an offset against the tax reported. It is not required that any documents or other evidence((~~s~~)) of entitlement to credits be submitted with the report. Such proofs must be retained in permanent records for the purpose of verification of credits taken.

(10) Special provision for ((~~consumer/first~~)) consumer as first possessor((~~s~~)). Under circumstances where the consumer is the first person in possession of any nonexempt hazardous substance (e.g., substances imported by the consumer), or where the consumer is the person who must pay the tax upon substances previously possessed in this state (fuel purchased for export in fuel tanks) the consumer's tax measure will be the wholesale value determined as nearly as possible according to the wholesale selling price at the place of use of similar substances of like quality and character.

(11) Hazardous substances or products on consignment. Consignees who possess hazardous substances or products in this state with the

power to sell such things, in their own name or on behalf of a disclosed or undisclosed consignor are liable for payment of the tax. The exemption for previously taxed substances is available for such consignees only if the consignors have paid the tax and the consignee has retained the certification or other proof of previous tax payment referred to in subsection (4)(a)(i) and (ii) of this rule. Possession of consigned hazardous substances by a consignee does not constitute constructive possession by the consignor.

(12) Hazardous substances untraceable to source. Various circumstances may arise whereby a person will possess hazardous substances in this state, some of which have been previously taxed in this or other states and some of which may not. In such cases formulary tax reporting may be used((~~, only~~)) upon a special ruling by the department of revenue.

Example. Fungible petroleum products from sources both within and outside this state are commingled in common storage facilities. Formulary reporting is appropriate based upon volume percentages reflecting the ratio of in-state production to out-of-state production or other form of acquisition.

(13) Administrative provisions. The provisions of chapter 82.32 RCW regarding due dates, reporting periods, tax return requirements, interest and penalties, tax audits and limitations, disputes and appeals, and all such general administrative provisions apply equally to the hazardous substance tax. ((~~Special requested rulings covering unique circumstances generally will be issued within sixty days from the date upon which complete information is provided to the department of revenue.~~)) Taxpayers may request, from the department, tax rulings covering unique circumstances not addressed in this rule.

(14) Certification of previously taxed hazardous substance. Certification that the hazardous substance tax has already been paid by a person previously in possession of the substance((~~(s)~~)) may be taken in substantially the following form:

I hereby certify that this purchase - all purchases of (omit one) ....
(identify ((~~substance(s)~~)) substances purchased) by ..... , (name of purchaser)
who possesses registration no. ..... ,
(buyer's number, if registered)

consists of the purchase of a hazardous substance((~~(s)~~)) or product((~~(s)~~)) upon which the hazardous substance tax has been paid in full by a person previously in possession of the substance((~~(s)~~)) or product((~~(s)~~)) in this state. This certificate is given with full knowledge of, and subject to the legally prescribed penalties for fraud and tax evasion, and with the full knowledge and agreement that the undersigned hereby assumes any liability for hazardous substance tax which has not been previously paid because of possession of the hazardous substance((~~(s)~~)) or product((~~(s)~~)) identified herein.

..... The registered seller named below personally paid the tax upon possession of the hazardous substances.

..... A person in possession of the hazardous substances prior to the possession of the registered seller named below paid the tax.

(Check the appropriate line.)

Name of registered seller ..... Registration No. .....

Firm name ..... Address .....

Type of business . . . . . .
Authorized signature . . . . . Title . . . . . .
Date . . . . . .

WSR 24-06-080
PROPOSED RULES
DEPARTMENT OF
LABOR AND INDUSTRIES
[Filed March 5, 2024, 3:31 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-21-058.

Title of Rule and Other Identifying Information: Chapter 296-136 WAC, Labor standards for quotas at warehouse distribution centers. New chapter under Title 296 WAC, Department of labor and industries (L&I).

Hearing Location(s): On April 9, 2024, at 9:30 a.m., at the Spokane Enduris Training Center, 1610 South Technology Boulevard, Spokane, WA 99224. A prehearing overview will begin at 9:00 a.m. The hearing will start at 9:30 a.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's division of occupational safety and health (DOSH);

On April 11, 2024, at 6:00 p.m., virtual/telephonic hearing. Join electronically https://lni-wa-gov.zoom.us/j/89225681620?pwd=bkh6emF3bGUraHlxbFk5dTJ2TjJMQT09, Passcode Ware@530; or join by phone (audio only) US 253-215-8782, Meeting ID 892 2568 1620, Passcode 12275394. A prehearing overview will begin at 5:30 p.m. The hearing will start at 6:00 p.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's DOSH; and

On April 15, 2024, at 1:30 p.m., at L&I, 12806 Gateway Drive South, Tukwila, WA 98168. A prehearing overview will begin at 1:00 p.m. The hearing will start at 1:30 p.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's DOSH.

Date of Intended Adoption: May 31, 2024.

Submit Written Comments to: Reed Simock, L&I, Fraud Prevention and Labor Standards (FPLS), Employment Standards, P.O. Box 44510, Olympia, WA 98504-4510, email WarehouseRules@Lni.wa.gov, fax 360-902-5300, by April 22, 2024, by 5:00 p.m.

Assistance for Persons with Disabilities: Contact Reed Simock, phone 360-480-3237, fax 360-902-5300. email WarehouseRules@Lni.wa.gov, by April 1, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The Washington state legislature passed 2SHB 1762, chapter 306, Laws of 2023, during the 2023 legislative session. 2SHB 1762, codified under chapter 49.84 RCW, establishes protections for employees at certain warehouse distribution centers who are subject to quotas. L&I's FPLS division enforces the following labor standards under chapter 49.84 RCW:

- Provide quota descriptions to employees.
- Ensure quotas account for:
  - Rest breaks.
  - Time to travel to break locations.
  - Time to perform an activity required by the employer to complete the work subject to a quota.
- Prohibit retaliation.

FPLS is adopting rules to clarify and implement the requirements of 2SHB 1762. The proposed rules also describe FPLS's enforcement mechanisms, including the complaint, investigation, citation, and ap-

peals processes. The proposed rules also provide for remedies and penalties for violations of the rules.

Other requirements related to quotas for workers at certain warehouse distribution centers under chapter 49.84 RCW are enforced by L&I's DOSH. DOSH is conducting simultaneous rule making for the provisions of chapter 49.84 RCW enforced by the division in chapter 296-35 WAC.

Reasons Supporting Proposal: Rules are needed to clarify and enforce the new requirements of 2SHB 1762, codified in chapter 49.84 RCW.

Statutory Authority for Adoption: RCW 49.84.060.

Statute Being Implemented: RCW 49.84.020, 49.84.030, 49.84.035, 49.84.037, 49.84.040, 49.84.045, 49.84.050.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: L&I, governmental.

Name of Agency Personnel Responsible for Drafting: Reed Simock, Tumwater, Washington, 360-480-3237; Implementation and Enforcement: Bryan Templeton, Tumwater, Washington, 360-902-5310.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Reed Simock, L&I, FPLS, Employment Standards, P.O. Box 44510, Olympia, WA 98504-4510, phone 360-480-3237, fax 360-902-5300, email Warehouse-Rules@Lni.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: Under RCW 49.84.010 (9)(a), the proposed rule only applies to employers with 100 [or] more employees at a single warehouse distribution center in the state or 1,000 or more employees at one or more warehouse distribution centers in the state.

Scope of exemption for rule proposal:

Is fully exempt.

March 5, 2024
Joel Sacks
Director

OTS-5225.3

Chapter 296-136 WAC
LABOR STANDARDS FOR QUOTAS AT WAREHOUSE DISTRIBUTION CENTERS

NEW SECTION

WAC 296-136-010 Definitions. (1) "Adverse action" means any action taken or threatened by an employer against an employee for their

exercise of chapter 49.84 RCW rights, which may include, but is not limited to:

(a) Terminating, suspending, demoting, or denying a promotion;

(b) Changing the number of work hours for which the employee is scheduled;

(c) Altering the employee's preexisting work schedule;

(d) Reducing the employee's rate of pay;

(e) Threatening to take, or taking action, based upon the immigration status of an employee, former employee, or an employee or former employee's family member; and

(f) Preventing future job opportunities whether for the employer or elsewhere.

(2) "Affiliate" means a person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with another person. For purposes of this subsection, "control" means the possession, directly or indirectly, of more than 50 percent of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting shares, by contract, or otherwise.

(3) "Aggregated data" has the same meaning as "aggregated work speed data" and means information that an employer has combined or collected in summary or other form such that the data cannot be identified with any individual.

(4) "Defined time period" means any unit of time measurement equal to or less than the duration of an employee's shift, and includes hours, minutes, and seconds and any fraction thereof.

(5) "Department" means the department of labor and industries.

(6) "Designated employee representative" means any employee representative including, but not limited to, an authorized employee representative that has a collective bargaining relationship with the employer.

(7) "Director" means the director of the department of labor and industries or the director's designee.

(8) "Employee" means an employee who is not exempt under RCW 49.46.010 (3)(c) and works at a warehouse distribution center.

(9) "Employee work speed data" has the same meaning as "work speed data" and means information an employer collects, stores, analyzes, or interprets relating to an individual employee's performance of a quota including, but not limited to, quantities of tasks performed, quantities of items or materials handled or produced, rates or speeds of tasks performed, measurements or metrics of employee performance in relation to a quota, and time categorized as performing tasks or not performing tasks. Work speed data does not include qualitative performance assessments, personnel records, or itemized wage statements pursuant to department rules, except for any content of those records that includes work speed data as defined in this subsection.

(10) "Employer" means a person who directly or indirectly, or through an agent or any other person, including through the services of a third-party employer, temporary services, or staffing agency, independent contractor, or any similar entity, at any time, employs or exercises control over the wages, hours, or working conditions of 100 or more employees at a single warehouse distribution center in the state or 1,000 or more employees at one or more warehouse distribution centers in the state.

(a) For the purposes of determining the number of employees employed at a single warehouse distribution center or at one or more

warehouse distribution centers, all employees employed directly or indirectly, or through an agency or any other person, and all employees employed by an employer and its affiliates, must be counted.

(b) For the purposes of determining responsible employers, all agents or other persons, and affiliates must be deemed employers and are jointly and severally responsible for compliance with this chapter.

(11) "Establishment" means a single physical location where business is conducted or where services or industrial operations are performed. Normally, one business location has only one establishment. When distinct and separate economic activities are performed at a single physical location each would be considered separate establishments provided:

(a) No one industry description in the North American Industrial Classification System applies to the joint activities of the establishments;

(b) Separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information; and

(c) Employment and output are significant for both activities.

(12) "Person" means an individual, corporation, partnership, limited partnership, limited liability partnership, limited liability company, business trust, estate, trust, association, joint venture, agency, instrumentality, or any other legal or commercial entity, whether domestic or foreign.

(13) "Plain language" means language that is clear, concise, and visually easy to read. It must use common words, rather than jargon, acronyms, or unnecessary legal language.

(14) "Preferred language" means the employee's language of choice.

(15) "Quota" means a work performance standard, whether required or recommended, where:

(a) An employee is assigned or required to perform at a specified productivity speed, or perform a quantified number of tasks, or to handle or produce a quantified amount of material, within a defined time period and under which the employee may suffer an adverse employment action if they fail to complete the performance standard; or

(b) An employee's actions are categorized between time performing tasks and not performing tasks, if the employee may suffer an adverse employment action if they fail to meet the performance standard.

(16) "Reasonable travel time" means that the employee must have enough time to access break locations considering the architecture and geography of the facility and location within the facility that the employee is located at the time a break is required.

(17) "Similar employee" means a covered employee performing similar tasks at the same warehouse distribution center.

(18) "Warehouse distribution center" means an establishment engaged in activities as defined by any of the following North American Industry Classification System codes; however, such establishment is denominated:

(a) 493 for warehousing and storage, but does not include 493130 for farm product warehousing and storage;

(b) 423 for merchant wholesalers, durable goods;

(c) 424 for merchant wholesalers, nondurable goods; or

(d) 454110 for electronic shopping and mail-order houses.

NEW SECTION

WAC 296-136-020 Determining employer size for quota requirement coverage. Employer size for the purposes of this chapter is determined based on the number of employees on the day of the alleged violation or the average number of employees over the previous 12 months, whichever is greater. For businesses operating less than one year, the size is based on the maximum number of employees since the company has been in business.

NEW SECTION

WAC 296-136-030 Warehouse quota written descriptions and notices. (1) An employer must provide to each employee, upon hire, or within 30 calendar days of July 1, 2024, a written description as required by RCW 49.84.020 which includes:

(a) Each quota to which the employee is subject, including the quantified number of tasks to be performed or materials to be produced or handled within a defined time period;

(b) Any potential adverse employment action that could result from failure to meet each quota; and

(c) Any incentives or bonus programs associated with meeting or exceeding each quota.

(2) The format of the written description may be provided in an electronic or hard copy.

(3) The written description must be in plain language.

(4) The initial written description must be provided immediately in English or English and the employee's choice of the top six other languages spoken in the state, according to the current languages identified by the Washington office of financial management. If an employee makes the employer aware of a preferred language outside of English and the top six other languages spoken in the state, the employee must receive the initial written description within 15 calendar days and any future written descriptions in their preferred language and English.

(5) The written description must inform the employee of their protections under RCW 49.84.020 and associated rules.

(6) When providing a written description with an incentive or bonus program associated, such description must:

(a) Describe any rate(s) in which the incentive or bonus is paid; and

(b) How any rate(s) apply to the quantified number of tasks to be performed or materials to be produced or handled within a defined time period.

(7) Whenever there is a change to the quota that results in a different quota than the most recent written description provided to the employee, the employer must:

(a) Notify the employee verbally or in writing as soon as possible and before the employee is subject to the new quota; and

(b) Provide the employee with an updated written description of each quota to which the employee is subject within two business days of the quota change in English and the employee's choice of the top six other languages spoken in the state, according to the current languages identified by the Washington office of financial management, or

any preferred language outside of English and the top six other languages spoken in the state, if previously identified by the employee.

(8) Whenever an employer takes an adverse action against an employee in whole or in part for failure to meet a quota, the employer must provide that employee with the applicable quota for the employee and the personal work speed data for the employee that was the basis for the adverse action.

NEW SECTION

WAC 296-136-040 Quota time periods and reasonable travel time. (1) The time period considered in a quota, including time designated as productive time or time on task must include:

(a) Time for rest breaks and reasonable time to travel to designated locations for rest breaks;

(b) Reasonable travel time to on-site designated meal break locations. Meal breaks are not considered time on task or productive time unless the employee is required by the employer to remain on duty on the premises or at a prescribed worksite in the interest of the employer;

(c) Time to perform any activity required by the employer in order to do the work subject to any quota;

(d) Time to use the bathroom, including reasonable travel time; and

(e) Time to take any actions necessary for the employee to exercise the employee's right to a safe and healthful workplace pursuant to chapter 49.17 RCW including, but not limited to, time to access tools or safety equipment necessary to perform the employee's duties.

(2) "Reasonable travel time" allows any employee enough time to access break locations and must consider the architecture and geography of the facility and location within the facility that the employee is located at the time a break is required.

(3) Employees must be allowed time to take meal and rest periods as required by WAC 296-126-092.

(4) Employees paid on a commission or piece work basis, wholly or partially, must be paid in accordance with WAC 296-126-021.

NEW SECTION

WAC 296-136-050 Labor standard quota violations except under chapter 49.17 RCW. (1) A quota violates a labor standard under chapter 49.84 RCW and applicable labor standard rules if the quota:

(a) Does not provide sufficient time as required under RCW 49.84.025 (1)(a), (b), and (c); or

(b) Prevents the performance of any activity required by the employer for the employee to do the work subject to any quota. "Any activity" includes travel to food safety stations, clock in stations, or supervisor check-ins.

(2) An employee is not required to meet a quota that violates chapter 49.84 RCW or any applicable labor standard rule.

(3) An employer may not take adverse action against an employee for failing to meet a quota that violates RCW 49.84.030, this section,

or that was not disclosed to the employee as required under RCW 49.84.020 and any applicable rule.

NEW SECTION

WAC 296-136-060 Employer recordkeeping requirements. (1) An employer must establish, maintain, and preserve contemporaneous, true, and accurate records of the following:

(a) Each employee's own personal work speed data;

(b) The aggregated work speed data for similar employees at the same warehouse distribution center; and

(c) The written descriptions of each quota the employee was provided pursuant to RCW 49.84.020 and any applicable rule.

(2) The required records must be maintained and preserved throughout the duration of each employee's period of employment and for the period required by this subsection.

(a) Except as required under (b) of this subsection, subsequent to an employee's separation from the employer, records relating to the six-month period prior to the date of the employee's separation from the employer must be preserved for at least three years from the date of the employee's separation.

(b) Where an employer has taken adverse action against an employee in whole or in part for failure to meet a quota, the employer must preserve the records relating to the basis for the adverse action for at least three years from the date of the adverse action.

(c) The employer must make records available to the director upon request.

(3) Records on how the time periods required under RCW 49.84.025 or WAC 296-136-040 were considered in determining any quota must be preserved for three years.

(4) Nothing in this section requires an employer to collect or keep such records if the employer does not use quotas or monitor work speed data.

(5) An employer who fails to allow adequate inspection of records in an inspection by the department within a reasonable time period may not use such records in any appeal to challenge the correctness of any citation and notice issued by the department.

NEW SECTION

WAC 296-136-070 Employee right to request written description and records. (1) An employee has the right to request, at any time, a written description of each quota to which the employee is subject, a copy of the employee's own personal work speed data for the prior six months, and a copy of the prior six months of aggregated work speed data for similar employees at the same warehouse distribution center.

(2) A former employee has the right to request, within three years subsequent to the date of their separation from the employer, a written description of the quota to which they were subject as of the date of their separation, a copy of the employee's own personal work speed data for the six months prior to their date of separation, and a copy of aggregated work speed data for similar employees at the same

warehouse distribution center for the six months prior to their date of separation.

(3) An employer must provide records requested under this section at no cost to the employee or former employee.

(4) An employer must provide records requested under this section as soon as practicable and subject to the following:

(a) Requested records of written descriptions of a quota must be provided no later than two business days following the date of the receipt of the request;

(b) Requested personal work speed data and aggregated work speed data must be provided no later than seven business days following the date of the receipt of the request; and

(c) Requested written descriptions must be available in the employee's preferred language.

(5) Nothing in this section requires an employer to use quotas or monitor work speed data. An employer that does not use quotas or monitor work speed data has no obligation to provide records under this section.

NEW SECTION

WAC 296-136-080 Protection from adverse action for failure to meet a quota in violation of labor standards. (1) An employer may not take adverse action against an employee in whole or in part for failing to meet a quota that violates RCW 49.84.030 or this chapter. A quota that violates the law may not be any factor leading to an adverse action by the employer.

(2) A person who has adverse action taken against them in whole or in part for failure to meet a quota that violates RCW 49.84.030 or this chapter may file a complaint with the department in accordance with WAC 296-136-140.

NEW SECTION

WAC 296-136-090 Retaliation protections. (1) A person including, but not limited to, an employer, his or her agent, or person acting as or on behalf of a hiring entity, or the officer or agent of any entity, business, corporation, partnership, or limited liability company, may not discharge or in any way retaliate, discriminate, or take adverse action against an employee or former employee for exercising any rights established in this chapter, or for being perceived as exercising rights established in this chapter including, but not limited to:

(a) Initiating a request for information about a quota or personal work speed data pursuant to RCW 49.84.037 or associated rules; and

(b) Making a complaint to the employer, the director, or any local, state, or federal governmental agency or official, related to a quota that is allegedly in violation of this chapter.

(2) An employee or former employee need not explicitly refer to this section or the rights established in this chapter to be protected from an adverse action. The protection provided in this section applies to former employees and to employees who mistakenly but in good faith allege violations of this chapter.

(3)(a) If a person takes adverse action against an employee or former employee within 90 days of the employee engaging or attempting to engage in activities protected by this chapter, there is a rebuttable presumption that the adverse action is a retaliatory action in violation of this section.

(b) The presumption may be rebutted by a preponderance of the evidence that:

(i) The action was taken for other permissible reasons; and

(ii) The engaging or attempting to engage in activities protected by this chapter was not a motivating factor in the adverse action.

(4) An employee or former employee who believes that they were subject to retaliation under this section may file a complaint with the department in accordance with WAC 296-136-140.

NEW SECTION

WAC 296-136-100 Department investigations. (1)(a) An employee may file a complaint with the department alleging a violation under this chapter or applicable rules under this section, except for violations and enforcement of RCW 49.84.032 and 49.84.040 and associated rules. The department must investigate the complaint.

(b) The department may not investigate any such alleged violation of rights that occurred more than three years before the date that the employee filed the complaint.

(c) If an employee files a timely complaint with the department, the department must investigate the complaint and issue either a citation and notice of assessment or a determination of compliance within 90 days after the date on which the department received the complaint, unless the complaint is otherwise resolved. The department may extend the period by providing advance written notice to the employee and the employer setting forth good cause for an extension of the period and specifying the duration of the extension.

(d) The department must send the citation and notice of assessment or the determination of compliance to both the employer and the employee by service of process or using a method by which the mailing can be tracked or the delivery can be confirmed to their last known addresses.

(2) If the department's investigation finds that the employee's allegation cannot be substantiated, the department must issue a determination of compliance to the employee and the employer detailing such finding.

(3) The director or their designated representatives may investigate and gather data regarding the wages, hours, and other conditions and practices of employment in any industry subject to this chapter, and may enter and inspect such places and such records (and make such transcriptions thereof), question such employees, and investigate such facts, conditions, practices, or matters as they may deem necessary or appropriate to determine whether any person has violated any provision of this chapter, or which may aid in the enforcement of the provisions of this chapter.

(4) The director may initiate an investigation without an employee's complaint to ensure compliance with this chapter. The department may also initiate an investigation on behalf of one or more employees when the director otherwise has reason to believe that a violation has occurred or will occur.

(5) The department may conduct a consolidated investigation for any alleged violation identified under chapter 49.84 RCW, or associated rules, when there are common questions of law or fact. If the department consolidates such matters into a single investigation, it will provide notice to the employer.

(6) The department may request an employer perform a self-audit of any records relating to chapter 49.84 RCW which must be provided within a reasonable time. Reasonable timelines will be specified in the self-audit request. The department must determine reasonable time based on the number of affected employees and the period of time covered by the self-audit. The records examined by the employer in order to perform the self-audit must be made available to the department upon request.

(7) Upon the department's request, an employer must notify affected employees in writing that the department is conducting an investigation. The department may require the employer to include a general description of each investigation as part of the notification, including the allegations and whether the notified employee may be affected. The employer may consult with the department to provide the information for the description of the notification of investigation.

(8) Upon receiving a complaint, the department may request or subpoena the records of the warehouse distribution center.

(9) In addition to any enforcement authority provided in this chapter or applicable rules, the department may enforce any violation under this chapter or applicable rules, except for violations and enforcement of RCW 49.84.032, by filing an action in the superior court for the county in which the violation is alleged to have occurred. If the department prevails, it is entitled to reasonable attorneys' fees and costs, in the amount to be determined by the court.

NEW SECTION

WAC 296-136-110 Investigation—Civil penalties. (1) If the department determines that the employer has violated a requirement of WAC 296-136-100, the department may order the employer to pay the department a civil penalty of not less than $1,000 for a first violation. Repeat violations may escalate as follows: The second violation may not exceed $5,000. The third violation and each violation thereafter may not exceed $10,000.

(2) For enforcement actions under this section, if any person fails to pay an assessment under this chapter, or under any rule under this chapter, after it has become a final and unappealable order, or after the court has entered final judgment in favor of the agency, the director may initiate collection procedures in accordance with the collection procedures under RCW 49.48.086.

(3) If the department finds that a quota violates chapter 49.84 RCW, the department may order the employer to review and provide a corrected written quota to the affected employee or employees within 15 calendar days and place a letter in the employee's personnel file to acknowledge the correction. If the employer fails to do so, the employer may be subject to the penalties under subsection (1) of this section and associated rules.

(4) Civil penalties must be deposited into the supplemental pension fund established under RCW 51.44.033.

NEW SECTION

WAC 296-136-120 Enforcement of meal and rest break violations resulting from quota violations. (1) If an employee files a complaint with the department alleging that employer has violated a requirement of this chapter or any rule adopted under this chapter resulting in a rest or meal period violation, the department will investigate the complaint pursuant to the procedures outlined in RCW 49.84.045, WAC 296-136-100, and 296-136-130.

(2) During an investigation, if the department discovers information suggesting additional violations of chapter 49.84 RCW or associated rules, the department may investigate and take appropriate enforcement action without any additional complaint in accordance with WAC 296-136-100. The department may also conduct a consolidated investigation for any alleged violation identified under chapter 49.84 RCW in accordance with WAC 296-136-100.

(3) If the department determines that the employer has violated a requirement of this chapter or any rule adopted under this chapter resulting in a rest or meal period violation, the employer must pay the employee one additional hour of pay at the employee's regular rate of pay for each day there is a violation. The employer must pay the employee at the employee's regular rate of pay for rest and meal periods where the employee is required to remain on duty or on the employer's premises at the employer's direction subject to call. The regular rate of pay is the hourly rate at which the employee is paid, but may not be less than the established minimum wage rate. The regular rate of pay is determined by dividing the amount of compensation received per week by the total number of hours worked during that week.

(4) If the department determines that an employer has violated a requirement of this chapter or any rule adopted under this chapter resulting in a rest or meal period violation, the department may order the employer to pay to the employee interest of one percent per month on all amounts owed. The interest owed must be calculated from the first date amounts were owed to the employee, except that the department may not order the employer to pay any interest that were owed more than three years before the date the complaint was filed with the department.

NEW SECTION

WAC 296-136-130 Appeals. (1) For enforcement actions under RCW 49.84.045, WAC 296-136-100, and 296-136-120, a person, firm, or corporation aggrieved by a citation and notice of assessment or determination of compliance by the department or any rules adopted under this chapter may appeal the citation and notice of assessment or determination of compliance to the director by filing a notice of appeal with the director within 15 calendar days of the department's issuance of the citation and notice of assessment or determination of compliance. A citation and notice of assessment or determination of compliance not appealed within 15 calendar days is final and binding, and not subject to further appeal.

(2) A notice of appeal filed with the director under this section stays the effectiveness of the citation and notice of assessment or determination of compliance pending final review of the appeal by the director as provided in chapter 34.05 RCW.

(3) Upon receipt of a notice of appeal, the director must assign the hearing to an administrative law judge of the office of administrative hearings to conduct the hearing and issue an initial order. The hearing and review procedures must be conducted in accordance with chapter 34.05 RCW, and the standard of review by the administrative law judge of an appealed citation and notice of assessment must be de novo. Any party who seeks to challenge an initial order must file a petition for administrative review with the director within 30 days after service of the initial order. The director must conduct an administrative review in accordance with chapter 34.05 RCW.

(4) The director must issue all final orders after appeal of the initial order. The final order of the director is subject to judicial review in accordance with chapter 34.05 RCW.

(5) Orders that are not appealed within the time period specified in this section and chapter 34.05 RCW are final and binding, and not subject to further appeal.

(6) An employer who fails to allow adequate inspection of records in an investigation by the department under this chapter within a reasonable time period may not use such records in any appeal under this section to challenge the correctness of any determination by the department of the penalty assessed.

NEW SECTION

WAC 296-136-140 Retaliation—Enforcement. (1) An employee or former employee who believes that they were subject to retaliation by their employer, as defined in chapter 49.84 RCW and associated rules, for the exercise of any employee right under chapter 49.84 RCW, may file a complaint with the department within 180 days of the alleged retaliatory action. The department may, at its discretion, extend the 180-day period on recognized equitable principles or because extenuating circumstances exist. For example, the department may extend the 180-day period when there is evidence that the employer has concealed or misled the employee regarding the alleged retaliatory action.

(2) If an employee files a timely complaint with the department alleging retaliation, the department will investigate the complaint and issue either a citation and notice of assessment or a determination of compliance within 90 days after the date on which the department received the complaint, unless the complaint is otherwise resolved. The department may extend the time period by providing advance written notice to the employee and the employer setting forth good cause for an extension of the time period, and specifying the duration of the extension.

(3) The department may consider a complaint to be otherwise resolved when the employee and the employer reach a mutual agreement to remedy any retaliatory action, or the employee voluntarily and on the employee's own initiative withdraws the complaint. Mutual agreements include, but are not limited to, rehiring, reinstatement, back pay, and reestablishment of benefits.

(4) If the department's investigation finds that the employee's allegation of retaliation was rebutted by the employer and cannot be substantiated, the department will issue a determination of compliance to the employee and the employer detailing such finding.

(5) If the department's investigation finds that the employer retaliated against the employee, and the complaint is not otherwise resolved, the department may, at its discretion, notify the employer that the department intends to issue a citation and notice of assessment, and may provide up to 30 days after the date of such notification for the employer to take corrective action to remedy the retaliatory action. If the complaint is not otherwise resolved, then the department shall issue a citation and notice of assessment. The department's citation and notice of assessment may:

(a) Order the employer to make payable to the employee earnings that the employee did not receive due to the employer's retaliatory action, including interest of one percent per month on all earnings owed. The earnings and interest owed will be calculated from the first date earnings were owed to the employee;

(b) Order the employer to restore the employee to the position of employment held by the employee when the retaliation occurred, or restore the employee to an equivalent position with equivalent employment hours, work schedule, benefits, pay, and other terms and conditions of employment;

(c) Order the employer to pay the department a civil penalty as specified in WAC 296-136-150.

(6) The department will send the citation and notice of assessment or determination of compliance to both the employer and employee by service of process or using a method by which the mailing can be tracked or the delivery can be confirmed to their last known addresses.

(7) During an investigation of the employee's retaliation complaint, if the department discovers information suggesting alleged violations by the employer of the employee's other wage and labor standard protections in statutes and applicable rules, the department may investigate and take appropriate enforcement action without requiring the employee to file a new or separate complaint. If the department determines that the employer violated additional wage and labor standard protections in statutes and applicable rules, the employer may be subject to additional enforcement actions for the violation of such rights. If the department discovers information alleging the employer retaliated against or otherwise violated wage and labor standard protections in statutes and applicable rules, the department may launch further investigation under chapters 49.46 and 49.84 RCW, and all applicable rules, without requiring additional complaints to be filed.

(8) The department may prioritize retaliation investigations as needed to allow for timely resolution of complaints.

(9) Nothing in chapter 49.84 RCW or associated rules impedes the department's ability to investigate under the authority prescribed in RCW 49.84.040.

NEW SECTION

WAC 296-136-150 Retaliation—Civil penalties. (1) If the department's investigation finds that an employer retaliated against an employee, pursuant to the procedures outlined in WAC 296-136-140, the department may order the employer to pay the department a civil penalty. A civil penalty for an employer's retaliatory action will not be less than $1,000 or an amount equal to 10 percent of the total amount

of unpaid earnings attributable to the retaliatory action, whichever is greater. The maximum civil penalty for an employer's retaliatory action shall be $20,000 for the first violation, and $40,000 for each repeat violation.

(2) The department may, at any time, waive or reduce any civil penalty assessed against an employer under this section if the department determines that the employer has taken corrective action to remedy the retaliatory action.

(3) The department will deposit civil penalties paid under this section in the supplemental pension fund established under RCW 51.44.033.

(4) Collections of amounts owed for unpaid citations and notices of assessment, as detailed in WAC 296-136-140(5), will be handled pursuant to the procedures outlined in RCW 49.48.086.

NEW SECTION

WAC 296-136-160 Retaliation appeals. (1) For enforcement actions under RCW 49.84.040 and associated rules, a person, firm, or corporation aggrieved by a citation and notice of assessment or a determination of compliance may, within 30 days after the date of such decision, submit a request for reconsideration to the department setting forth the grounds for seeking such reconsideration, or submit an appeal to the director pursuant to the procedures outlined in subsection (4) of this section. If the department receives a timely request for reconsideration, the department will either accept the request or treat the request as a notice of appeal.

(2) If a request for reconsideration is accepted, the department will send notice of the request for reconsideration to the employer and the employee. The department will determine if there are any valid reasons to reverse or modify the department's original decision to issue a citation and notice of assessment or determination of compliance within 30 days of receipt of such request. The department may extend this period by providing advance written notice to the employee and employer setting forth good cause for an extension of the period, and specifying the duration of the extension. After reviewing the reconsideration, the department will either:

(a) Notify the employee and the employer that the citation and notice of assessment or determination of compliance is affirmed; or

(b) Notify the employee and the employer that the citation and notice of assessment or determination of compliance has been reversed or modified.

(3) A request for reconsideration submitted to the department shall stay the effectiveness of the citation and notice of assessment or the determination of compliance pending the reconsideration decision by the department.

(4) Within 30 days after the date the department issues a citation and notice of assessment or a determination of compliance, or within 30 days after the date the department issues its decision on the request for reconsideration, a person, firm, or corporation aggrieved by a citation and notice of assessment or a determination of compliance may file with the director a notice of appeal.

(5) A notice of appeal filed with the director under this section shall stay the effectiveness of the citation and notice of assessment

or the determination of compliance pending final review of the appeal by the director as provided for in chapter 34.05 RCW.

(6) Upon receipt of a notice of appeal, the director shall assign the hearing to an administrative law judge of the office of administrative hearings to conduct the hearing and issue an initial order. The hearing and review procedures shall be conducted in accordance with chapter 34.05 RCW, and the standard of review by the administrative law judge of an appealed citation and notice of assessment or determination of compliance shall be de novo. Any party who seeks to challenge an initial order shall file a petition for administrative review with the director within 30 days after service of the initial order. The director shall conduct administrative review in accordance with chapter 34.05 RCW.

(7) If a request for reconsideration is not submitted to the department within 30 days after the date of the original citation and notice of assessment or determination of compliance, and a person, firm, or corporation aggrieved by a citation and notice of assessment or determination of compliance did not submit an appeal to the director, then the citation and notice of assessment or determination of compliance is final and binding, and not subject to further appeal.

(8) The director shall issue all final orders after appeal of the initial order. The final order of the director is subject to judicial review in accordance with chapter 34.05 RCW.

(9) Director's orders that are not appealed within the time period specified in this section and chapter 34.05 RCW are final and binding, and not subject to further appeal.

(10) An employer who fails to allow adequate inspection of records required under chapter 49.84 RCW and this chapter within a reasonable time period when requested by the department during an investigation may not use such records in any appeal to challenge the correctness of any determination by the department.

NEW SECTION

WAC 296-136-170 Discretionary enforcement provisions. (1) The department may enforce this section by engaging in coordinated and strategic enforcement efforts with the divisions within the department including, but not limited to, the division of fraud prevention and labor standards, the division of occupational safety and health, and insurance services. The department may access data from various divisions including employer-reported injury data and enforcement actions in warehouses, and the identity of uninsured employers, and employers who are committing workers' compensation fraud, wage theft, or other information relevant to the department's authority.

(2) The department may strategically collaborate with stakeholders to educate workers and employers about their rights and obligations under this part, respectively, in order to increase compliance.

NEW SECTION

WAC 296-136-180 Severability clause. If any provision of the rules in this chapter, or their application to any person or circumstance is held invalid, the remainder of these rules or their applica-

tion of the provision to other persons or circumstances is not affected.

WSR 24-06-081
PROPOSED RULES
DEPARTMENT OF
LABOR AND INDUSTRIES
[Filed March 5, 2024, 3:33 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-21-059.

Title of Rule and Other Identifying Information: Safety standards for quotas at warehouse distribution centers. Chapter 296-35 WAC, new chapter under Title 296 WAC, Department of labor and industries (L&I); and chapter 296-360 WAC, Discrimination, pursuant to RCW 49.17.160.

Hearing Location(s): On April 9, 2024, at 9:30 a.m., at the Enduris Training Center, 1610 Technology Boulevard, Suite 100, Spokane, WA 99224. A prehearing overview will begin at 9:00 a.m. The hearing will start at 9:30 a.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's division of fraud prevention and labor standards (FPLS);

On April 11, 2024, at 6:00 p.m., virtual and telephonic hearing. Join electronically https://lni-wa-gov.zoom.us/j/89225681620?pwd=bkh6emF3bGUraHlxbFk5dTJ2TjJMQT09, Passcode (if prompted) Ware@530; or join by phone (audio only) 253-215-8782, Meeting ID 892 2568 1620, Passcode 12275394. A prehearing overview will begin at 5:30 p.m. The hearing will start at 6:00 p.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's FPLS; and

On April 15, 2024, at 1:30 p.m., at L&I, 12806 Gateway Drive South, Tukwila, WA 98168. A prehearing overview will begin at 1:00 p.m. The hearing will start at 1:30 p.m. and will continue until all oral comments are received. This public hearing will be held jointly with L&I's FPLS.

Date of Intended Adoption: May 31, 2024.

Submit Written Comments to: Carmyn Shute, Administrative Regulations Analyst, L&I, Division of Occupational Safety and Health (DOSH), P.O. Box 44620, Olympia, WA 98504-4620, email WarehouseRules@Lni.wa.gov, fax 360-902-5619, by 5:00 p.m., April 22, 2024.

Assistance for Persons with Disabilities: Contact Carmyn Shute, administrative regulations analyst, phone 360-870-4525, fax 360-902-5619, email WarehouseRules@Lni.wa.gov, by April 1, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: L&I's DOSH and FPLS are required to implement and enforce 2SHB 1762, codified as chapter 49.84 RCW, an act related to protecting the health and safety of employees in warehouses. L&I must adopt WAC rules to fully and adequately enforce the law. This act becomes effective July 1, 2024.

WAC 296-360-200 Retaliation protections and enforcement—Warehouse distribution centers, establishes protected activities covered by this chapter and RCW 49.84.062 and 49.84.040.

WAC 296-35-010 Scope, sets scope of the rule.

WAC 296-35-100 Definitions, establishes definitions that apply to this chapter. Definitions are numerated for ease in cross referencing.

WAC 296-35-200 Quota time periods and reasonable travel time, establishes that time periods applied to quotas must include reasonable travel time and time to use the bathroom.

WAC 296-35-250 Employer size determination, establishes how L&I will determine the employer size for purposes of establishing penalties under chapter 49.17 RCW.

WAC 296-35-300 Quota—Violations of WISHA, establishes violations for quotas that expose an employee to occupational health and safety hazards. A nonexhaustive table of examples is provided.

WAC 296-35-350 Employer recordkeeping requirements, establishes the requirement for employers to maintain and preserve all records related to how a quota is determined for three years.

WAC 296-35-400 Protection from adverse action for failure to meet a quota in violation of WISHA, establishes that an employer may not take adverse action against and employee for failing to meet a quota that violates RCW 49.84.032 or this chapter.

WAC 296-35-500 Retaliation protections and enforcement, establishes that employers or their designee may not take adverse action against an employee or former employee for exercising any rights established by this chapter or RCW 49.84.032.

WAC 296-35-600 Severability clause, declares that if any provision of this rule is held invalid, the remainder of the rule is not affected.

Reasons Supporting Proposal: L&I's DOSH must adopt rules under WAC to implement and enforce the requirements related to warehouse worker quotas under chapter 49.84 RCW.

Statutory Authority for Adoption: RCW 49.84.060, 49.17.010, 49.17.040, 49.17.050, and 49.17.060.

Statute Being Implemented: Chapters 49.17 and 49.84 RCW.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: L&I, governmental.

Name of Agency Personnel Responsible for Drafting: Tracy West, Tumwater, Washington, 509-237-2372; Implementation and Enforcement: Craig Blackwood, Tumwater, Washington, 360-902-5828.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Carmyn Shute, Administrative Regulations Analyst, L&I, DOSH, P.O. Box 44620, Olympia, WA 98504-4620, phone 360-870-4525, fax 360-902-5619, email WarehouseRules@Lni.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: Under RCW 49.84.010 (9)(a), the proposed rule only applies to employers with 100 [or] more employees at a single warehouse distribution center in the state or 1,000 or more employees at one or more warehouse distribution centers in the state.

Scope of exemption for rule proposal:

Is fully exempt.

March 5, 2024
Joel Sacks
Director

OTS-5213.4

Chapter 296-35 WAC
SAFETY STANDARDS FOR QUOTAS FOR WAREHOUSE DISTRIBUTION CENTERS

NEW SECTION

WAC 296-35-010 Scope. This chapter applies to employers as defined in this chapter at warehouse distribution centers.

NEW SECTION

WAC 296-35-100 Definitions. (1) **Adverse action.** Any action taken or threatened by an employer against an employee for their exercise of chapter 49.84 RCW rights, which may include, but is not limited to:

(a) Terminating, suspending, demoting, or denying a promotion;

(b) Changing the number of work hours for which the employee is scheduled;

(c) Altering the employee's preexisting work schedule;

(d) Reducing the employee's rate of pay;

(e) Threatening to take, or taking action, based upon the immigration status of an employee, former employee, or an employee or former employee's family member; and

(f) Preventing future job opportunities whether for the employer or elsewhere.

(2) **Affiliate.** A person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with another person. For purposes of this subsection, "control" means the possession, directly or indirectly, of more than 50 percent of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting shares, by contract, or otherwise.

(3) **Defined time period.** Any unit of time measurement equal to or less than the duration of an employee's shift, and includes hours, minutes, and seconds and any fraction thereof.

(4) **Department.** The department of labor and industries.

(5) **Director.** The director of the department of labor and industries or the director's designee.

(6) **Employee.** An employee who is not exempt under RCW 49.46.010 (3)(c) and works at a warehouse distribution center.

(7) **Employer.** A person who directly or indirectly, or through an agent or any other person, including through the services of a third-party employer, temporary services, or staffing agency, independent contractor, or any similar entity, at any time, employs or exercises control over the wages, hours, or working conditions of 100 or more employees at one or more warehouse distribution centers in the state.

(a) For the purposes of determining the number of employees employed at a single warehouse distribution center or at one or more warehouse distribution centers, all employees employed directly or indirectly, or through an agency or any other person, and all employees employed by an employer and its affiliates, must be counted.

(b) For the purposes of determining responsible employers, all agents or other persons, and affiliates must be deemed employers and

are jointly and severally responsible for compliance with this chapter.

(8) **Establishment.** A single physical location where business is conducted or where services or industrial operations are performed. Normally, one business location has only one establishment.

When distinct and separate economic activities are performed at a single physical location each would be considered separate establishments provided:

(a) No one industry description in the North American Industrial Classification System applies to the joint activities of the establishments;

(b) Separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information; and

(c) Employment and output are significant for both activities.

(9) **Occupational safety and health standards.** For purposes of this chapter, means potential sources of harm or adverse health effects for workers including, but not limited to, physical safety hazards, chemical hazards, biological hazards, physical safety hazards, and ergonomic risk factors. See table of examples in WAC 296-35-300.

(10) **Person.** An individual, corporation, partnership, limited partnership, limited liability partnership, limited liability company, business trust, estate, trust, association, joint venture, agency, instrumentality, or any other legal or commercial entity, whether domestic or foreign.

(11) **Quota.** A work performance standard, whether required or recommended, where:

(a) An employee is assigned or required to perform at a specified productivity speed, or perform a quantified number of tasks, or to handle or produce a quantified number of tasks, or to handle or produce a quantified amount of material, within a defined time period and under which the employee may suffer an adverse employment action if they fail to complete the performance standard; or

(b) An employee's actions are categorized between time performing tasks and not performing tasks, if the employee may suffer an adverse employment action if they fail to meet the performance standard.

(12) **Reasonable travel time.** The employee must have enough time to access bathroom locations considering the architecture and geography of the facility and the location within the facility that the employee is located at the time a bathroom is required.

(13) **Warehouse distribution center.** An establishment engaged in activities as defined by any of the following North American Industry Classification System codes, however such establishment is denominated:

(a) 493 for warehousing and storage, but does not include 493130 for farm product warehousing and storage;

(b) 423 for merchant wholesalers, durable goods;

(c) 424 for merchant wholesalers, nondurable goods; or

(d) 454110 for electronic shopping and mail-order houses.

NEW SECTION

WAC 296-35-200 Quota time periods and reasonable travel time.

(1) The time period considered in a quota, including designated as

productive time or time on task must include time to use the bathroom, including reasonable travel time; and

(2) The time period considered in a quota, including designated as productive time or time on task must include time to take any actions necessary for the employee to exercise the employee's right to a safe and healthful workplace pursuant to chapter 49.17 RCW including, but not limited to, time to access tools or safety equipment necessary to perform the employee's duties.

NEW SECTION

WAC 296-35-250 Employer size determination. Employer size, for the purposes of this chapter, is determined based on the number of employees on the day of the alleged violation or the average number of employees over the previous 12 months, whichever is greater, except for the purposes of establishing penalties under chapter 49.17 RCW and associated rules. For the purposes of setting penalties under chapter 49.17 RCW and associated rules, the size of business will be measured on the maximum number of employees at all workplaces nationwide, in the previous 12 months. For businesses operating for less than one year, the size will be based on the maximum number of employees since the company has been in business.

NEW SECTION

WAC 296-35-300 Quota—Violations of WISHA. (1) A quota violates chapter 49.17 RCW if the quota:

(a) Does not provide sufficient time as required under WAC 296-35-200;

(b) Prevents the performance of any activity related to occupational safety and health required by the employer for the employee to do the work subject to any quota; or

(c) Exposes an employee to occupational safety and health hazards in violation of chapter 49.17 RCW and the applicable rules or regulations. A quota that substantially contributes to a hazard or the exposure to a hazard is a violation of this subsection.

(2) An employee is not required to meet a quota that violates this section.

(3) The following table is a nonexhaustive list of examples of activities or equipment for use in understanding this section and how to determine what may contribute to a quota being found in violation of chapter 49.84 RCW or this chapter.

Examples	WAC Reference (Where applicable)
Examples of tools and equipment necessary to perform the employee's duties in WAC 296-35-200 including, but not limited to:	
Carts and hand trucks.	WAC 296-800-11030 Prohibit employees from using tools and equipment that are not safe.
Step stools and ladders.	Chapter 296-876 WAC, Ladders, portable and fixed.
Dock plates.	WAC 296-24-75006 Dockboards (bridge plates).
Safety shoes.	WAC 296-800-160600 Make sure your employees use appropriate foot protection.

Examples	WAC Reference (Where applicable)
High visibility vests.	WAC 296-800-16015 Select appropriate PPE for your employees.
Examples of safety or health related activities mentioned in WAC 296-35-300 (1)(b).	
Cleaning up spills or moving obstructions from aisles.	WAC 296-24-73505, walking working surfaces general requirements.
Inspecting powered industrial vehicle before use.	Chapter 296-863 WAC, Forklifts and other powered industrial trucks.
Setting up ladders properly.	Chapter 296-876 WAC, Ladders, portable and fixed.
Waiting for help with team lifting.	WAC 296-800-11035 Establish, supervise, and enforce rules that lead to a safe and healthy work environment that are effective in practice.
Examples of where the quota exposes employees to an occupational safety and health hazards under WAC 296-35-300 (1)(c).	
Heat stress.	WAC 296-800-11005 Provide a workplace free from recognized hazards. WAC 296-62-09013 Temperature, radiant heat, or temperature-humidity combinations.
Unsafe floor conditions, rushing (slip/trip/fall).	WAC 296-24-73505, walking working surfaces general requirements.
Manual material handling.	WAC 296-800-11005 Provide a workplace free from recognized hazards.
Powered industrial vehicle operations.	Chapter 296-863 WAC, Forklifts and other powered industrial trucks.
Safe material storage.	WAC 296-800-22035 Store things safely.
Machine safety.	Chapter 296-806 WAC, Safety standards for machine safety.
Lockout/tagout.	Chapter 296-803 WAC, Lockout/tagout (control of hazardous energy).
Recognized ergonomic hazards.	WAC 296-800-11005 Provide a workplace free from recognized hazards.

NEW SECTION

WAC 296-35-350 Employer recordkeeping requirements. (1) An employer must maintain and preserve all records required under WAC 296-136-060.

(2) Records on how the time periods required under RCW 49.84.025 or WAC 296-35-200 were considered in determining any quota must be preserved for three years.

(3) Nothing in this section requires an employer to collect or keep such records if the employer does not use quotas or monitor work speed data.

(4) The records must be made available to the department or director upon request. An employer who fails to allow adequate inspection of records in an inspection by the department within a reasonable time period may not use such records in any appeal to challenge the correctness of any citation and notice issued by the department.

NEW SECTION

WAC 296-35-400 Protection from adverse action for failure to meet a quota in violation of WISHA. (1) An employer may not take ad-

verse action against an employee in whole or in part for failing to meet a quota that violates RCW 49.84.032 or this chapter. A quota that violates the law may not be a factor leading to an adverse action by the employer.

(2) A person who has adverse action taken against them in whole or in part for failure to meet a quota that violates RCW 49.84.032 or this chapter may file a complaint within 90 days of the adverse action with the department in accordance with WAC 296-360-030.

(3) Complaints under this section will be investigated according to chapter 296-360 WAC, including appropriate relief, payment of damages, penalties, and appeal of citations of notices of assessment.

NEW SECTION

WAC 296-35-500 Retaliation protections and enforcement. (1) A person including, but not limited to, an employer, their agent, a person acting as or on behalf of a hiring entity, or the officer or agent of any entity, business, corporation, partnership, or limited liability company, may not discharge or in any way retaliate, discriminate, or take adverse action against an employee or former employee for exercising any rights established in this chapter including, but not limited to:

(a) The right to make a complaint to the employer, the director, or any local, state, or federal governmental agency or official, related to a quota that is allegedly in violation of chapter 49.17 RCW, RCW 49.84.032, or this chapter;

(b) The right to participate in any proceeding related to a quota that is allegedly in violation of chapter 49.17 RCW, RCW 49.84.032, or this chapter; and

(c) The right to testify in any proceeding related to a quota that is allegedly in violation of chapter 49.17 RCW, RCW 49.84.032, or this chapter, including any statements given in the course of judicial, quasi-judicial, and administrative proceedings, including inspections, investigations, administrative adjudications, and rules hearings.

(2)(a) If a person takes adverse action against an employee or former employee within 90 days of the employee engaging or attempting to engage in activities protected by this chapter, there is a rebuttable presumption that the adverse action is a retaliatory action in violation of this chapter.

(b) The presumption may be rebutted by a preponderance of the evidence that:

(i) The action was taken for other permissible reasons; and

(ii) Engagement or attempted engagement in activities protected by this chapter was not a motivating factor in the adverse action.

(3) An employee or former employee who believes that they were subject to retaliation under this section may file a complaint with the department in accordance with WAC 296-360-030.

(4) Complaints under this section will be investigated according to chapter 296-360 WAC, including appropriate relief, payment of damages, penalties, and appeal of citations of notices of assessment, except the presumption in subsection (3) of this section applies.

NEW SECTION

WAC 296-35-600 Severability clause. If any provision of the rules in this chapter, or their application to any person or circumstances is held invalid, the remainder of these rules or their application of the provision to other persons or circumstances is not affected.

OTS-5214.1

NEW SECTION

WAC 296-360-200 Retaliation protections and enforcement—Warehouse distribution centers. This chapter applies to protected activities established in RCW 49.84.032, 49.84.040, and associated rules under chapter 296-35 WAC. WAC 296-35-400 establishes protected activities covered by this chapter, and includes a rebuttable presumption on when an adverse action has taken place.

WSR 24-06-084
PROPOSED RULES
DEPARTMENT OF HEALTH
[Filed March 5, 2024, 4:20 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 20-17-011.

Title of Rule and Other Identifying Information: Reporting emergency medical services (EMS) data to the Washington EMS information system (WEMSIS). The department of health (department) is proposing amendments to existing sections and the addition of two new sections to chapter 246-976 WAC relating to EMS data systems to meet the requirements of section 19 of SSB 5380 (chapter 314, Laws of 2019).

Hearing Location(s): On April 16, 2024, at 9:00 a.m., at the Washington State Department of Health, 111 Israel Road S.E., Town Center 2, Room 166, Tumwater, WA 98501; or via Zoom. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_AQyxzyEIT22tT8umvSFHAQ. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: April 23, 2024.

Submit Written Comments to: Jim Jansen, P.O. Box 47853, Olympia, WA 98504-7853, email https://fortress.wa.gov/doh/policyreview, fax 360-236-2830, jim.jansen@doh.wa.gov, by April 16, 2024.

Assistance for Persons with Disabilities: Contact Jim Jansen, phone 360-236-2821, fax 360-236-2830, TTY 711, email jim.jansen@doh.wa.gov, by April 2, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is proposing amendments to WAC 246-976-001, 246-976-430, and 246-976-910 and the addition of new WAC 246-976-445 and 246-976-455 to comply with SSB 5380. The proposed rules establish requirements for submitting patient data using WEMSIS. The department is also proposing other housekeeping changes to implement these amendments.

Reasons Supporting Proposal: Amending the identified existing sections and establishing two new sections in chapter 246-976 WAC is needed to align existing ambulance and aid service requirements with RCW 70.168.090, as amended by SSB 5380. RCW 70.168.090 directs the department to require licensed ambulance and aid services to report patient data electronically to the department and allow for certain data sharing for the purpose of substance abuse treatment.

Statutory Authority for Adoption: RCW 43.70.040 and 70.168.090.

Statute Being Implemented: RCW 70.168.090.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of health, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Jim Jansen, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2821.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Jim Jansen, P.O. Box 47853, Olympia, WA 98504-7853, phone 360-236-2821, fax 360-236-2830, TTY 711, email jim.jansen@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules relate only to internal governmental operations that are not subject to violation by a nongovernment party; and rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: The following sections of rule are exempt under RCW 34.05.310 (4)(d): WAC 246-976-430 and 246-976-910. The following section is exempt under RCW 34.05.310 (4)(b): WAC 246-976-445.

Scope of exemption for rule proposal:

Is partially exempt:

Explanation of partial exemptions: The following sections of rule are exempt under RCW 34.05.310 (4)(d): WAC 246-976-430 and 246-976-910. The following section is exempt under RCW 34.05.310 (4)(b): WAC 246-976-445.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated.

A brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

As revised under SSB 5380 (chapter 314, Laws of 2019), and codified in RCW 70.168.090, the bill establishes requirements for licensed ambulance and aid services to report patient data electronically to the department and to allow for certain data sharing privileges for the purpose of substance use disorder treatment. Amendments to existing EMS data rules and the addition of new sections to chapter 246-976 WAC are needed to establish clear and concise data submission standards to WEMSIS and to produce quality, usable data for improving standards of care and best practice for the benefit and safety of the public.

Compliance requirements for EMS services will include use of an electronic record collection system for EMS service reporting, which may be either a state-provided electronic system at no cost to the EMS service or an external solution that is compliant with national data standards. EMS services will be required to assign at least one staff member the role of WEMSIS administrator. The WEMSIS administrator is responsible for completing the EMS data system training course provided by the department and acting as the point of contact for WEMSIS related communications and functionality issues at their EMS service. At minimum, EMS services will need access to a computer and internet connection to submit EMS records to the department.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS):

Small Business Economic Impact Statement (SBEIS) Table 1. Summary of Businesses Required to Comply to the Proposed Rule

NAICS Code (4, 5, or 6 Digit)	NAICS Business Description	Number of Businesses in Washington State	Minor Cost Threshold
621910	Ambulance services. This industry comprises establishments primarily engaged in providing transportation of patients by ground or air; along with medical care. These services are often provided during a medical emergency but are not restricted to emergencies. The vehicles are equipped with lifesaving equipment operated by medically trained personnel.	467	.3 percent of average annual gross business income: $17,473.00[1]

[1] 2020 Dataset pulled from DOR https://apps.dor.wa.gov/ResearchStats/Content/GrossBusinessIncome/Report.aspx.

Analysis of probable costs of businesses in the industry to comply to the proposed rule, including the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue:

WAC 246-976-001 Purpose.

Description: The rule identifies the purpose of the chapter of rules. The proposed rule change adds the language "Development and operation of a statewide electronic EMS data system" to the purpose statement.

Cost(s): There are no probable costs to businesses.

New WAC 246-976-455 EMS Data system—Provider responsibilities.

Description: The following describes what is being established in the proposed new WAC section:

The following are exempt [from] the analysis:

- Subsections (1) and (2) are moved here from existing WAC 246-976-330 without change. This is exempt from analysis under RCW 34.05.328 (5)(b)(iv). The proposed change to existing language clarifies language in the rule without changing its effect.
- Subsection (3)(h) requires patient care records to be available for inspection by county medical program directors or the department.

The following are new requirements and are not exempt from the analysis:

- Subsection (3), a licensed EMS service must send a complete electronic patient care report to the department within 48 hours. The EMS service must submit any updates or modifications within 48 hours of the update/modification.
- Subsection (3)(d) and (e), EMS service must identify WEMSIS administrator(s) who must complete department training course within 18 months.
- Subsection (3)(f) requires procedures to be in place for internal monitoring of data validity, which may include methods to reabstract data for accuracy.
- Subsection (3)(g) requires records to be correct/resubmit if they fail department validity test within 30 days.
- Subsection (3)(i), by January 31 each year, submit or update demographic info about EMS service for the previous calendar year.
- Subsection (4) clarifies what ambulance and aid services are included; all activations, including 911 and interfacility transports where treatment or transport occurred, patient refusal of

treatment or transport, canceled transport, and activations that cross Washington borders that result in dispatch to a location in Washington or transported to a facility in Washington.

- Subsection (5) requires submission of data elements in adherence with National Emergency Medical Services Information System EMS data standards, except where they differ from subsection (6).
- Subsection (6) lists the data elements that must be included.

Cost(s): The costs to comply with the proposed rules are indeterminate, but less than $17,000 as the volume of work for each EMS service varies depending on call volume. The department anticipates the following probable costs:

Areas of cost to EMS services may be experienced to support the following needs:

(1) **Data entry to the EMS data collection system:** The department currently provides a free data entry system available to all EMS services. To utilize the system, EMS staff will need to enter record information into the system; this may require several minutes per call and minor associated costs for staff time to conduct this task may be incurred.

Many EMS services choose to seek an alternative data collection system compliant with national data standards and can submit data to the state data system. These private data collection and management systems are acquired at a cost to the EMS service but are not required for participation in the state EMS data system. Those EMS services that choose to use the state solution may do so at no cost.

(2) **Administrative management of an EMS service's data system account:** Each EMS service will be required to assign an EMS data system administrator to act as the point of contact for department staff on issues related to account access, data errors, training opportunities, and various data quality and EMS performance reports generated by the state. Time required to fulfill this role is estimated at ~1 hour per month in addition to one-time training and any future time required to obtain technical assistance from department staff.

The department estimates a one-time cost of $250.00, based on 5-10 hours of training and system set up for an administrative or provider staff at an average rate of $25.00 per hour[2].

[2] This cost estimate is based on the office of financial management job classification data for an Administrative Assistant 4 salary step F). Office of Financial Management: Job Classifications, Administrative Assistant 4, Range 46. (accessed 2024, February 6) State of Washington Class Salary Range | Office of Financial Management.

(3) **Collection of information related to patient care:** The department does not anticipate significant additional administrative and personnel costs for EMS services to support data submission to the department, as EMS services are already required to keep patient care records for patients to whom care is provided.

An indeterminant burden is expected in staff time to submit records to the department for EMS "aid services" that do not transport patients to the hospital and may need to adopt new processes for recording and submitting EMS records. Some recording of medical services provided to patients by aid services is already expected due to providers' normal course of duty.

In May 2022, according to the Bureau of Labor Statistics[3], the median pay for EMTs was $36,680 per year ($17.63 per hour)[4]. With the estimated time required for data entry at 15 minutes per call, we estimate that each call will have a cost for data entry of $4.40. Total annual cost to the EMS service will depend on the number of EMTs em-

ployed and the number of calls received, which vary drastically by EMS service.

[3] *EMTs and Paramedics: Occupational Outlook Handbook: U.S. Bureau of Labor Statistics.* (accessed 2023, May 30). https://www.bls.gov/ooh/healthcare/emts-and-paramedics.htm.

[4] The department calculated the per hourly salary by dividing the annual salary by 52 weeks by 40 hours per week.

For those "aid" services not currently collecting data on patients, the call volume is expected to be low, limiting the total time burden anticipated for this activity.

Some volunteer "aid" EMS services rely on their partner ambulance services to submit a record that represents all care received. These aid services will need to report their data under this legislation and have expressed concerns around the cost and time to report the data. To this we have provided information about the free direct data entry system offered through the department. Resistance to this new requirement by a minority of EMS services is expected regardless of the cost mitigation options available.

(4) **Training available to EMS providers and staff:** The department will make available training related to data reporting, navigation of the electronic EMS data system, and the value of EMS data to public health and patient care. This training will be offered as a module through the existing department-managed EMS training program. Time expectations to complete this training are expected to fall within existing training and continued education expectations for EMS providers, adding no additional cost expectation for EMS services.

Summary of all Cost(s):

SBEIS Table 2. Summary of Section 3 Probable Cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-976-001 Purpose	$0
WAC 246-976-455 EMS data system—Provider responsibilities	$250.00 + $4.40/call for those services that do not already report their own patient data.

Analysis on if the proposed rule may impose more-than-minor costs for businesses in the industry. Includes a summary of how the costs were calculated: No, the costs of the proposed rule are *less than* the minor cost threshold of $17,473.00.

Summary of how the costs were calculated: The minor cost threshold for ambulance services is calculated to be $17,473 which is .3 percent of gross annual income. The costs to comply with the proposed rule are an estimated $250.00, based on 5-10 hours of training and system set up for administrative or provider staff at an average rate of $25.00 per hour. For those services that do not already report their own patient data (i.e. they rely on their partner ambulance services to submit a record) an additional cost of $4.40 is estimated per call.

A copy of the detailed cost calculations may be obtained by contacting Jim Jansen, P.O. Box 47853, Olympia, WA 98504-7853, phone 360-236-2821, fax 360-236-2830, email jim.jansen@doh.wa.gov.

March 5, 2024
Kristin Peterson, JD
Chief of Policy
for Umair A. Shah, MD, MPH
Secretary

OTS-4616.1

AMENDATORY SECTION (Amending WSR 11-07-078, filed 3/22/11, effective 5/15/11)

WAC 246-976-001 Purpose. The purpose of these rules is to implement RCW 18.71.200 through 18.71.215, and chapters 18.73 and 70.168 RCW; and those sections of chapter 70.24 RCW relating to EMS personnel and services.

(1) This chapter establishes criteria for:

(a) Training and certification of EMS providers;

(b) Licensure and inspection of ambulance services and aid services;

(c) Verification of prehospital trauma services;

(d) Development and operation of a statewide trauma registry;

(e) The designation process and operating requirements for designated trauma care services;

(f) A statewide emergency medical communication system;

(g) Administration of the statewide EMS/TC system;

(h) Development and operation of a statewide electronic EMS data system.

(2) This chapter does not contain detailed procedures to implement the state EMS/TC system. Requests for procedures, guidelines, or any publications referred to in this chapter must be obtained from the Office of Community Health Systems, Department of Health, Olympia, WA 98504-7853 or on the internet at www.doh.wa.gov.

AMENDATORY SECTION (Amending WSR 19-07-040, filed 3/14/19, effective 4/14/19)

WAC 246-976-430 Trauma registry—Provider responsibilities. (1) A trauma care provider shall protect the confidentiality of data in their possession and as it is transferred to the department.

(2) A verified prehospital agency that transports trauma patients must:

(a) Provide an initial report of patient care to the receiving facility at the time the trauma patient is delivered as described in WAC ((~~246-976-330~~)) 246-976-455.

(b) Within ((~~twenty-four~~)) 24 hours after the trauma patient is delivered, send a complete patient care report to the receiving facility to include the data shown in Table A.

Table A:
Prehospital Patient Care Report Elements for the Washington Trauma Registry

Data Element	Prehospital-Transport:	Inter-Facility:
Incident Information		
Transporting emergency medical services (EMS) agency number	X	X
Unit en route date/time	X	
Patient care report number	X	X
First EMS agency on scene identification number	X	

Data Element	Prehospital-Transport:	Inter-Facility:
Crew member level	X	X
Method of transport	X	X
Incident county	X	
Incident zip code	X	
Incident location type	X	
Patient Information		
Name	X	X
Date of birth, **or** age	X	X
Sex	X	X
Cause of injury	X	
Use of safety equipment	X	
Extrication required	X	
Transportation		
Facility transported from (code)		X
Times		
Unit notified by dispatch date/time	X	X
Unit arrived on scene date/time	X	X
Unit left scene date/time	X	X
Vital Signs		
Date/time of first vital signs taken	X	
First systolic blood pressure	X	
First respiratory rate	X	
First pulse	X	
First oxygen saturation	X	
First Glasgow coma score (GCS) with individual component values (eye, verbal, motor, total, and qualifier)	X	
Treatment		
Procedure performed	X	

(3) A designated trauma service must:

(a) Have a person identified as responsible for trauma registry activities, and who has completed the department trauma registry training course within ((~~eighteen~~)) 18 months of hire. For level I-III trauma services the person identified must also complete the abbreviated injury scale (AIS) course within ((~~eighteen~~)) 18 months of hire;

(b) Report data elements for all patients defined in WAC 246-976-420;

(c) Report patients with a discharge date for each calendar quarter in a department-approved format by the end of the following quarter;

(d) Have procedures in place for internal monitoring of data validity, which may include methods to reabstract data for accuracy; and

(e) Correct and resubmit records that fail the department's validity tests as described in WAC 246-976-420(7) within three months of notification of errors.

(4) A designated trauma rehabilitation service must provide data, as identified in subsection (7) of this section, to the trauma registry in a format determined by the department upon request.

(5) A designated trauma service must submit the following data elements for trauma patients:

(a) Record identification data elements must include:
(i) Identification (ID) of reporting facility;
(ii) Date and time of arrival at reporting facility;
(iii) Unique patient identification number assigned to the patient by the reporting facility.
(b) Patient identification data elements must include:
(i) Name;
(ii) Date of birth;
(iii) Sex;
(iv) Race;
(v) Ethnicity;
(vi) Last four digits of the patient's Social Security number;
(vii) Home zip code.
(c) Prehospital data elements must include:
(i) Date and time of incident;
(ii) Incident zip code;
(iii) Mechanism/type of injury;
(iv) External cause codes;
(v) Injury location codes;
(vi) First EMS agency on-scene identification (ID) number;
(vii) Transporting agency ID and unit number;
(viii) Transporting agency patient care report number;
(ix) Cause of injury;
(x) Incident county code;
(xi) Work related;
(xii) Use of safety equipment;
(xiii) Procedures performed.
(d) Prehospital vital signs data elements (from first EMS agency on scene) must include:
(i) Time;
(ii) First systolic blood pressure;
(iii) First respiratory rate;
(iv) First pulse rate;
(v) First oxygen saturation;
(vi) First GCS with individual component values (eye, verbal, motor, total, and qualifiers);
(vii) Intubated at time of first vital sign assessment;
(viii) Pharmacologically paralyzed at time of first vital sign assessment;
(ix) Extrication.
(e) Transportation data elements must include:
(i) Date and time unit dispatched;
(ii) Time unit arrived at scene;
(iii) Time unit left scene;
(iv) Transportation mode;
(v) Transferred in from another facility;
(vi) Transferring facility ID number.
(f) Emergency department (ED) data elements must include:
(i) Readmission;
(ii) Direct admit;
(iii) Time ED physician was called;
(iv) Time ED physician was available for patient care;
(v) Trauma team activated;
(vi) Level of trauma team activation;
(vii) Time of trauma team activation;
(viii) Time trauma surgeon was called;
(ix) Time trauma surgeon was available for patient care;

(x) Vital signs in ED, which must also include:
(A) First systolic blood pressure;
(B) First temperature;
(C) First pulse rate;
(D) First spontaneous respiration rate;
(E) Controlled rate of respiration;
(F) First oxygen saturation measurement;
(G) Lowest systolic blood pressure (SBP);
(H) GCS score with individual component values (eye, verbal, motor, total, and qualifiers);
(I) Whether intubated at time of ED GCS;
(J) Whether pharmacologically paralyzed at time of ED GCS;
(K) Height;
(L) Weight;
(M) Whether mass casualty incident disaster plan implemented.
(xi) Injury scores must include:
(A) Injury severity score;
(B) Revised trauma score on admission;
(C) Pediatric trauma score on admission;
(D) Trauma and injury severity score.
(xii) ED procedures performed;
(xiii) Blood and blood components administered;
(xiv) Date and time of ED discharge;
(xv) ED discharge disposition, including:
(A) If transferred, ID number of receiving hospital;
(B) Was patient admitted to hospital?
(C) If admitted, the admitting service;
(D) Reason for transfer (sending facility).
(g) Diagnostic and consultative data elements must include:
(i) Whether the patient received aspirin in the four days prior to the injury;
(ii) Whether the patient received any oral antiplatelet medication in the four days prior to the injury, such as clopidogrel (Plavix), or other antiplatelet medication, and, if so, include:
(A) Whether the patient received any oral anticoagulation medication in the four days prior to the injury, such as warfarin (Coumadin), dabigatran (Pradaxa), rivaroxaban (Xarelto), or other anticoagulation medication, and, if so, include:
(B) The name of the anticoagulation medication.
(iii) Date and time of head computed tomography scan;
(iv) Date and time of first international normalized ratio (INR) performed at the reporting trauma service;
(v) Results of first INR ((~~preformed [performed]~~)) <u>performed</u> at the reporting trauma service;
(vi) Date and time of first partial thromboplastin time (PTT) performed at the reporting trauma service;
(vii) Results of first PTT performed at the reporting trauma service;
(viii) Whether any attempt was made to reverse anticoagulation at the reporting trauma service;
(ix) Whether any medication (other than Vitamin K) was first used to reverse anticoagulation at the reporting trauma service;
(x) Date and time of the first dose of anticoagulation reversal medication at the reporting trauma service;
(xi) Elapsed time from ED arrival;
(xii) Date of rehabilitation consult;
(xiii) Blood alcohol content;

(xiv) Toxicology results;

(xv) Whether a brief substance abuse assessment, intervention, and referral for treatment done at the reporting trauma service;

(xvi) Comorbid factors/preexisting conditions;

(xvii) Hospital events.

(h) Procedural data elements:

(i) First operation information must include:

(A) Date and time operation started;

(B) Operating room (OR) procedure codes;

(C) OR disposition.

(ii) For later operations information must include:

(A) Date and time of operation;

(B) OR procedure codes;

(C) OR disposition.

(i) Admission data elements must include:

(i) Date and time of admission order;

(ii) Date and time of admission or readmission;

(iii) Date and time of admission for primary stay in critical care unit;

(iv) Date and time of discharge from primary stay in critical care unit;

(v) Length of readmission stay(s) in critical care unit;

(vi) Other in-house procedures performed (not in OR).

(j) Disposition data elements must include:

(i) Date and time of facility discharge;

(ii) Most recent ICD diagnosis codes/discharge codes, including nontrauma diagnosis codes;

(iii) Disability at discharge (feeding/locomotion/expression);

(iv) Total ventilator days;

(v) Discharge disposition location;

(vi) If transferred out, ID of facility the patient was transferred to;

(vii) If transferred to rehabilitation, facility ID;

(viii) Death in facility.

(A) Date and time of death;

(B) Location of death;

(C) Autopsy performed;

(D) Organ donation requested;

(E) Organs donated.

(ix) End-of-life care and documentation;

(A) Whether the patient had an end-of-life care document before injury;

(B) Whether there was any new end-of-life care decision documented during the inpatient stay at the reporting trauma service;

(C) Whether the patient receive a consult for comfort care, hospice care, or palliative care during the inpatient stay at the reporting trauma service;

(D) Whether the patient received any comfort care, in-house hospice care, or palliative care during the inpatient stay (i.e., was acute care withdrawn) at the reporting trauma service;

(k) Financial information must include:

(i) Total billed charges;

(ii) Payer sources (by category);

(iii) Reimbursement received (by payer category).

(6) Designated trauma rehabilitation services must provide the following data upon request by the department for patients identified in WAC 246-976-420(3).

(a) Data submission elements will be based on the current inpatient rehabilitation facility patient assessment instrument (IRF-PAI). All individual data elements included in the IRF-PAI categories below and defined in the data dictionary must be submitted upon request:

(i) Identification information;

(ii) Payer information;

(iii) Medical information;

(iv) Function modifiers (admission and discharge);

(v) Functional measures (admission and discharge);

(vi) Discharge information;

(vii) Therapy information.

(b) In addition to IRF-PAI data elements each rehabilitation service must submit the following information to the department:

(i) Admit from (facility ID);

(ii) Payer source (primary and secondary);

(iii) Total charges;

(iv) Total remitted reimbursement.

AMENDATORY SECTION (Amending WSR 00-08-102, filed 4/5/00, effective 5/6/00)

WAC 246-976-910 Regional quality assurance and improvement program. (1) The department will:

(a) Develop guidelines for a regional EMS/TC system quality assurance and improvement program including:

(i) Purpose and principles of the program;

(ii) Establishing and maintaining the program;

(iii) Process;

(iv) Membership of the quality assurance and improvement program committee;

(v) Authority and responsibilities of the quality assurance and improvement program committee;

(b) Review and approve written regional quality assurance and improvement plans;

(c) Provide trauma registry and EMS data to regional quality assurance and improvement programs in the following formats:

(i) Quarterly standard reports;

(ii) Ad hoc reports as requested according to department guidelines.

(2) Levels I, II, and III, and Level I, II and III pediatric trauma care services must:

(a) Establish, coordinate and participate in regional EMS/TC systems quality assurance and improvement programs;

(b) Ensure participation in the regional quality assurance and improvement program of:

(i) Their trauma service director or codirector; and

(ii) The RN who coordinates the trauma service;

(c) Ensure maintenance and continuation of the regional quality assurance and improvement program.

(3) The regional quality assurance and improvement program committee must include:

(a) At least one member of each designated facility's medical staff;

(b) The RN coordinator of each designated trauma service;

(c) An EMS provider.

(4) The regional quality assurance program must invite the MPD and all other health care providers and facilities providing trauma care in the region, to participate in the regional trauma quality assurance program.

(5) The regional quality assurance and improvement program may invite:

(a) One or more regional EMS/TC council members;

(b) A trauma care provider who does not work or reside in the region.

(6) The regional quality assurance and improvement program must include a written plan for implementation including:

(a) Operational policies and procedures that detail committee actions and processes;

(b) Audit filters for adult and pediatric patients;

(c) Monitoring compliance with the requirements of chapter 70.168 RCW and this chapter;

(d) Policies and procedures for notifying the department and the regional EMS/TC council of identified regional or statewide trauma system issues, and any recommendations;

(e) Policies regarding confidentiality of:

(i) Information related to provider's and facility's clinical care, and patient outcomes, in accordance with chapter 70.168 RCW;

(ii) Quality assurance and improvement committee minutes, records, and reports in accordance with RCW 70.168.090(4), including a requirement that each attendee of a regional quality assurance and improvement committee meeting is informed in writing of the confidentiality requirement. Information identifying individual patients may not be publicly disclosed without the patient's consent.

OTS-4614.2

NEW SECTION

WAC 246-976-445 EMS data system—Department responsibilities. (1) Purpose: The department maintains a statewide electronic emergency medical services data system, as required by RCW 70.168.090. The purpose of this data system is to:

(a) Provide data for EMS activity surveillance, analysis, and quality assurance programs;

(b) Monitor and evaluate the outcome of care provided by EMS services personnel, in support of statewide and regional quality assurance and system evaluation activities;

(c) Assess compliance with state standards for EMS care (chapters 18.71, 18.73, 70.168 RCW and this chapter);

(d) Provide information for resource planning, system design and management; and

(e) Provide a resource for research and education.

(2) Confidentiality: RCW 70.168.090 and chapter 42.56 RCW apply to EMS data, records, and reports developed pursuant to RCW 70.168.090. Data elements related to the identification of individual patient's, provider's, and facility's care outcomes shall be confidential, shall be exempt from chapter 42.56 RCW, and shall not be subject

to discovery by subpoena or admissible as evidence. Patient care quality assurance proceedings, records, and reports developed pursuant to RCW 70.168.090 are confidential, exempt from chapter 42.56 RCW, and are not subject to discovery by subpoena or admissible as evidence.

(a) The department may release confidential information from the electronic EMS data system in compliance with applicable laws and regulations. No other person may release confidential information from the data system without express written permission from the department.

(b) The department may approve requests for EMS data system data and reports consistent with applicable statutes and rules.

(c) The department has established criteria defining situations in which EMS data system information is confidential and situations in which data may be shared, in order to protect confidentiality for patients, providers, and facilities.

(d) Subsection (2)(a) through (c) of this section does not limit access to confidential data by approved regional quality assurance and improvement programs and medical program directors established under chapter 70.168 RCW and described in WAC 246-976-910 and 246-976-920.

(3) Data submission: The department establishes and maintains procedures and format for ambulance and aid services to submit data electronically. Reporting mechanisms will meet state requirements for data security, data interoperability, and national reporting standards. These will include a mechanism for the reporting agency to check data for validity and completeness before data is sent to WEMSIS.

(4) Data quality: The department establishes mechanisms to evaluate the quality of EMS data. These mechanisms will include:

(a) Detailed protocols for quality control, consistent with the department's most current data quality guidelines.

(b) Validity studies to assess the timeliness, completeness, and accuracy of case identification and data collection.

(5) Data reports and data sharing: The department may create, release, and provide access to data files and reports in accordance with RCW 70.168.090. The type of information contained in the file, including direct and indirect patient, provider and facility identifiers, determines the permitted release of, or access to, the data file or report.

(a) Annually, the department reports:

(i) Summary statistics and trends for demographic and related EMS care and activity information for the state and for each emergency medical service/trauma care (EMS/TC) region;

(ii) Benchmarking and performance measures, for system-wide evaluation and regional quality improvement programs;

(iii) Trends, patient care outcomes, and other data, for the state and each EMS/TC region, for the purpose of regional evaluation; and

(iv) Aggregate regional data upon request, excluding any confidential or identifying data.

(b) The department will provide reports to EMS services, approved regional quality assurance and improvement programs and medical program directors upon request, according to the confidentiality provisions in subsection (2) of this section and all applicable laws and regulations.

(c) In order to comply with WAC 246-976-920, the department may provide aggregate reports and directly identifiable patient record access to medical program directors for EMS services within their jurisdiction.

(d) In order to comply with RCW 70.168.090, the department will provide reports, patient data and record access related to suspected drug overdoses to government agencies, including local public health agencies, tribal authorities, and other organizations at the discretion of the department, for the purposes of including, but not limited to, identifying individuals to engage substance use disorder peer professionals, patient navigators, outreach workers, and other professionals as appropriate to prevent further overdoses and to induct into treatment and provide other needed supports as may be available. Data for this purpose will be provided upon request and according to the confidentiality provisions in subsection (2) of this section and all applicable laws and regulations.

(e) The department may share confidential data files containing one or more direct patient identifiers with researchers with approval from the Washington state institutional review board (IRB) and a signed confidentiality agreement. The department may also require researchers to enter into a data sharing agreement.

(f) The department may provide a hospital with access to the complete electronic patient care report for activations in which the patient was delivered to their facility.

(g) The department may provide data and reports to other parties not listed in (c) through (f) of this subsection upon request, according to the confidentiality provisions in subsection (2) of this section and all applicable laws and regulations.

(h) When fulfilling a request for data, the department may provide the fewest data elements and patient records necessary for the stated purpose of a requestor's project.

NEW SECTION

WAC 246-976-455 EMS data system—EMS service and provider responsibilities. (1) Licensed EMS services and certified EMS providers shall protect the confidentiality of data in their possession and as it is transferred to the receiving facility or the department.

(2) The certified EMS provider in charge of patient care shall provide the following information to the receiving facility staff:

(a) At the time of arrival at the receiving facility, a minimum of a brief written or electronic patient report including agency name, EMS personnel, and:

(i) Date and time of the medical emergency;

(ii) Time of onset of symptoms;

(iii) Patient vital signs including serial vital signs where applicable;

(iv) Patient assessment findings;

(v) Procedures and therapies provided by EMS personnel;

(vi) Any changes in patient condition while in the care of the EMS personnel;

(vii) Mechanism of injury or type of illness.

(b) Within 24 hours of arrival, a complete written or electronic patient care report that includes at a minimum:

(i) Names and certification levels of all personnel providing patient care;

(ii) Date and time of medical emergency;

(iii) Age of patient;

(iv) Applicable components of system response time;

(v) Patient vital signs, including serial vital signs if applicable;

(vi) Patient assessment findings;

(vii) Procedures performed and therapies provided to the patient; this includes the times each procedure or therapy was provided;

(viii) Patient response to procedures and therapies while in the care of the EMS provider;

(ix) Mechanism of injury or type of illness;

(x) Patient destination.

(c) For trauma patients, all other data points identified in WAC 246-976-430 for inclusion in the trauma registry must be submitted to the receiving facility within 10 days of transporting the patient to the trauma center.

(3) A licensed EMS service must:

(a) Within 48 hours after the initial dispatch, send a complete electronic patient care report to the department for all activations that meet inclusion criteria in subsection (4) of this section.

The electronic patient care reports must:

(i) Be sent in a secure format determined by the department; and

(ii) Include all data elements specified in subsection (5) of this section.

(b) Submit any and all updates or modifications to previously submitted electronic patient care reports to the department within 48 hours of the update.

(c) EMS services who are unable to submit or update electronic patient care reports within 48 hours should notify the department within 30 days from when the delay began. The service must work with the department to submit a modified submission plan in a format determined by the department.

(d) Identify one or more EMS service WEMSIS administrator(s) responsible for EMS data activities. An EMS service WEMSIS administrator must:

(i) Complete the department EMS data system training course within 18 months of being assigned to this role;

(ii) Adhere to WEMSIS data confidentiality restrictions determined by the department; and

(iii) Act as the primary contact for the department regarding WEMSIS related communications including those pertaining to data submission, data validity, data quality, account access, and reporting;

(iv) Adhere to processes and protocols for WEMSIS data use and access as determined by the department.

(e) Notify the department within 30 days of any change or addition of EMS service WEMSIS administrators or a change to an administrator's contact information. Changes submitted must be made on forms provided by the department.

(f) Have procedures in place for internal monitoring of data validity, which may include methods to reabstract data for accuracy.

(g) Correct and resubmit patient care records that fail the department's validity tests as described in WAC 246-976-445 within 30 days of notification of errors.

(h) Make all patient care records available for inspection and review upon request of the county MPD or the department. Records provided shall be in electronic format where capabilities allow and will be provided in the most secure method available.

(i) By January 31st each year, submit or update EMS service demographic information for the previous calendar year in a format determined by the department. Demographic information should include:

(i) EMS dispatch volume;
(ii) EMS patient transport volume;
(iii) EMS patient contact volume;
(iv) EMS interfacility transport volume;
(v) EMS interfacility transport volume by ALS;
(vi) EMS interfacility transport volume by ILS;
(vii) EMS interfacility transport volume by BLS;
(viii) EMS interfacility transport volume by first response;
(ix) EMS interfacility transport volume by second response;
(x) EMS ground transport volume;
(xi) EMS air transport volume;
(xii) EMS critical care transport volume.

(4) Inclusion criteria: Ambulance and aid services must submit electronic patient care reports for all activations to which they are dispatched. Criteria includes 911 and interfacility activations where treatment or transport occurred, patient refusal of treatment or transport, and canceled activations. All activations which cross Washington borders and involve a Washington licensed ambulance or aid service must be included if the service is dispatched to a location in Washington state or if a patient is transported to a facility in Washington state.

(5) A licensed ambulance or aid service must submit data elements in adherence with the National Emergency Medical Services Information System (NEMSIS) national EMS data standards and requirements except where they differ from the reporting requirements specified in subsection (6) of this section.

(6) In addition to adhering to the NEMSIS EMS data standards, all licensed ambulance or aid services must submit the following data elements for all records:

Patient last name;
Patient first name;
Middle initial or name;
Patient Social Security number;
Gender;
Race;
Age;
Age units;
Patient date of birth;
Patient driver's license;
Patient home address;
Alternate home residence;
Patient phone number;
Patient email address;
Recent exposure to infectious disease;
Recent travel;
Recent local travel;
Recent international travel;
Recent state travel;
Recent city travel;
Temperature;
Respiratory effort;
Chest/lungs assessment;
Ending travel date;
Beginning travel date;

Personal protective equipment used;
Airway device placement confirmed method;
Cardiac arrest during EMS event;
Cardiac arrest etiology;
Cardiac arrest, resuscitation attempted by EMS;
Cardiac arrest, witnessed by;
Cardiac arrest, who first initiated CPR;
Patient evaluation/care;
Crew disposition;
Transport disposition;
Reason for refusal/release;
Destination/transferred to, name;
Destination/transferred to, code;
Destination street address;
Destination zip code;
EMS transport method;
Final patient acuity;
Type of destination;
Destination team prearrival activation;
Mental status assessment;
Medication allergies;
Medical/surgical history;
Trauma triage criteria;
Cause of injury code;
Use of safety equipment;
Extrication required;
Hospital disposition;
Procedure performed date/time;
Procedure performed prior to EMS care;
Procedure performed;
Procedure number of attempts;
Procedure successful;
Symptom onset date/time;
Symptom, primary;
Symptoms, other associated;
Provider's primary impression;
Provider's secondary impression;
Last known well date/time;
PSAP call date/time;
Dispatch notified date/time;
Unit arrived on scene date/time;
Unit arrived at patient date/time;
Unit left scene date/time;
Patient arrived at destination date/time;
Destination patient transfer of care date/time.

Vital signs:

Date/time of first vital signs taken;
First systolic blood pressure;
First respiratory rate;
First pulse;
First oxygen saturation;
First Glasgow coma score (GCS) with individual component values (eye, verbal, motor, total, and qualifier);
Vital sign, taken date/time;
Vital sign, obtained prior to EMS care;
Vital sign, cardiac rhythm/ECG;
Vital sign, ECG type;

Vital sign, blood glucose level;
Vital sign, stroke scale score;
Vital sign, stroke scale type;
Vital sign, stroke scale value/severity score - LAMS;
Type of scene delay;
First EMS unit on scene;
Incident zip code;
Incident county;
Scene GPS location;
Incident location type;
Facility transported from (code);
Other EMS or public safety agencies at scene;
Type of other service at scene;
Medication administered;
Medication administered route;
Date/time medication administered;
Medication administered prior to this unit's EMS care;
Medication response;
Role/type of person administering medication;
Alcohol/drug use indicators;
Respiratory rate;
Total Glasgow coma score;
Eye assessment;
ACS risk score.

Incident information:

Emergency medical services (EMS) agency number;
Unit enroute date/time;
Patient care report number;
First EMS agency on scene identification number;
Crew member level;
Method of transport;
Incident location type;
Patient information.

Outcome (if known):

Emergency department disposition;
Hospital disposition;
External report ID/number type;
External report ID/number;
Emergency department diagnosis;
Hospital diagnosis.

WSR 24-06-087
PROPOSED RULES
DEPARTMENT OF
RETIREMENT SYSTEMS
[Filed March 6, 2024, 10:12 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 24-02-074.

Title of Rule and Other Identifying Information: Making further revisions to retiree return to work rules.

Hearing Location(s): On April 15, 2024, at 11:00 a.m., online via Microsoft Teams https://www.drs.wa.gov/sitemap/rules/#proposed-rule-hearings, Meeting ID 249 132 356 819, Passcode zbBcRf; or phone 833-322-1218, Code 669 358 536#.

Date of Intended Adoption: April 22, 2024.

Submit Written Comments to: Bianca Stoner, Department of Retirement Systems (DRS), P.O. Box 48380, Olympia, WA 98504-8380, email drs.rules@drs.wa.gov, by April 11, 2024.

Assistance for Persons with Disabilities: Contact Bianca Stoner, phone 360-664-7291, TTY 711, email drs.rules@drs.wa.gov, by April 11, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: DRS recently completed rule making to implement three retiree return to work bills, including chapter 110, Laws of 2022, and chapters 99 and 410, Laws of 2023. After completing the rule, DRS identified further revisions that are necessary to correct conflicting rules to achieve full implementation.

Statutory Authority for Adoption: RCW 41.50.050; chapter 110, Laws of 2022, and chapters 99 and 410, Laws of 2023.

Statute Being Implemented: Chapter 110, Laws of 2022, and chapters 99 and 410, Laws of 2023.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: DRS, governmental.

Name of Agency Personnel Responsible for Implementation: Candice Myrum, DRS, P.O. Box 48380, Olympia, WA 98504-8380, 360-664-7124.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. RCW 34.05.328 (5)(a)(i) does not apply to this proposed rule and DRS is not voluntarily making it applicable to DRS.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: Rules from DRS only affect members and beneficiaries of the state retirement systems and participating public employers. As a result, the rules do not affect small businesses.

Scope of exemption for rule proposal:

Is fully exempt.

March 6, 2024
Bianca Stoner
Rules Coordinator

OTS-5259.1

AMENDATORY SECTION (Amending WSR 23-24-091, filed 12/5/23, effective 12/7/23)

WAC 415-02-173 How is my benefit affected if I return to work and am impacted by more than one annual hourly limit? (1) **How is my benefit affected if I return to work in positions with two different employers that qualify for more than one annual hourly limit?**

If you return to work in more than one position, and the positions have different annual hourly limits, you will be limited to the highest annual hourly limit for all positions combined.

Examples: Don is retired from teachers' retirement system (TRS) 2 and returned to work as a teacher. Don's nonadministrative TRS position at a school district has an annual limit of 1,040 hours. While working at the school district Don also takes a position at a state agency. The state agency position is a public employees' retirement system (PERS) position and ((~~Don~~)) is subject to an annual limit of 867 hours. Don's annual hourly limit ((~~is lowered to 867~~)) remains at 1,040 hours ((~~while working in both positions~~)). Don ((~~then~~)) later separates from the ((~~state agency~~)) TRS nonadministrative school district position and Don's annual hourly limit ((~~will return to~~)) of 1,040 hours remains in effect for the remainder of the current calendar year. Don's limit will be 867 hours the following year if he continues in the PERS position.

Pat is a 2008 ERF retiree, who returned to work as a driver for the department of transportation (DOT) in a PERS position with an annual limit of 867 hours. Pat gets a second job, working as a bus driver for a school district. The nonadministrative position in the school employees' retirement system (SERS) is subject to an annual limit of 1,040 hours. Pat's benefit is governed by the ((~~lowest~~)) highest limit, in this case the ((~~PERS~~)) SERS bus driver position at ((~~DOT~~)) the school district. Pat's annual limit will be ((~~867~~)) 1,040 hours in a calendar year.

(2) **If I receive pension payments from more than one DRS administered retirement system, and each system has different annual hourly limits, how will my benefit be affected?**

If you are retired from multiple DRS systems, each of your benefits will be affected according to rules of the respective system.

Example: Alex retired from two systems, PERS and SERS, and returned to work as a bus driver in a SERS-eligible position at a school district after the mandatory 30-day break. Alex's two benefits will be impacted differently.

• PERS - To qualify for the 1,040-hour annual hourly limit in PERS, you need a 100-day break in service. Alex only has a 30-day break before returning to work, so Alex's PERS benefit will be ((~~limited~~)) subject to an 867-hour((~~s~~)) limit.

• SERS - Alex's SERS benefit does not require the 100-day break. So, Alex's annual hourly limit for the SERS benefit will be ((~~limited to~~)) 1,040 hours.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 415-02-170	How is my benefit affected if I return to work and am impacted by more than one annual hourly limit?

WSR 24-06-089
PROPOSED RULES
DEPARTMENT OF REVENUE
[Filed March 6, 2024, 11:26 a.m.]

Continuance of WSR 23-19-070.

Preproposal statement of inquiry was filed as WSR 23-12-085.

Title of Rule and Other Identifying Information: WAC 458-20-301 Capital gains excise tax—Definitions, deductions, exemptions, and allocation of gains and losses.

Hearing Location(s): On April 9, 2024, at 1:00 p.m. This meeting will be conducted over the internet/telephone. In-person option in Tumwater also available. Contact Barbara Imperio at barbarai@dor.wa.gov for dial-in/login information. To attend in person, contact barbarai@dor.wa.gov by March 26, 2024.

Date of Intended Adoption: April 19, 2024.

Submit Written Comments to: Michael Hwang, 6400 Linderson Way S.W., Tumwater, WA 98504, email MichaelHw@dor.wa.gov, 360-534-1575, by April 12, 2024.

Assistance for Persons with Disabilities: Contact Julie King, phone 360-704-5733.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: This proposed new rule seeks to clarify substantive aspects of the excise tax on capital gains by supplying additional definitions and examples related to this excise tax.

Reasons Supporting Proposal: This rule will provide useful information for taxpayers on calculating the excise tax on capital gains.

Statutory Authority for Adoption: RCW 82.01.060, 82.32.300.

Statute Being Implemented: Chapter 82.87 RCW.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Department of revenue, governmental.

Name of Agency Personnel Responsible for Drafting: Michael Hwang, 6400 Linderson Way S.W., Tumwater, WA, 360-534-1576; Implementation and Enforcement: Heidi Geathers, 6400 Linderson Way S.W., Tumwater, WA, 360-531-1615.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is not required under RCW 34.05.328. This proposed rule is not a significant legislative rule.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. The proposed rule does not create any liability for taxes or fees, reporting requirements, recordkeeping requirements, or compliance requirements not already otherwise imposed by statute.

March 6, 2024
Brent Madison
Rules Coordinator

OTS-4743.8

NEW SECTION

WAC 458-20-301 Capital gains excise tax—Definitions, deductions, exemptions, and allocation of gains and losses. (1) **Introduction.** Beginning January 1, 2022, Washington law imposes an excise tax on individuals who sell or exchange long-term capital assets. See chapter 82.87 RCW (capital gains excise tax). This rule provides interpretive guidance related to the tax, including definitions of terms and explanations regarding the treatment of specific transactions. This rule contains examples that identify a number of facts, and then it states a conclusion. The examples are provided only as a general guide. The tax results of other situations must be determined after a review of all the facts and circumstances.

(2) **Definitions and terms, and related information.**

(a) **Adjusted capital gain.** Adjusted capital gain means federal net long-term capital gain:

(i) Plus, any amount of long-term capital loss from a sale or exchange that is exempt from the capital gains excise tax, to the extent such loss was included in calculating federal net long-term capital gain;

(ii) Plus, any amount of long-term capital loss from a sale or exchange that is not allocated to Washington under RCW 82.87.100, to the extent such loss was included in calculating federal net long-term capital gain;

(iii) Plus, any amount of loss carryforward from a sale or exchange that is not allocated to Washington under RCW 82.87.100, to the extent such loss was included in calculating federal net long-term capital gain;

(iv) Less, any amount of long-term capital gain from a sale or exchange that is not allocated to Washington under RCW 82.87.100, to the extent such gain was included in calculating federal net long-term capital gain;

(v) Less, any amount of long-term capital gain from a sale or exchange that is exempt under chapter 82.87 RCW, to the extent such gain was included in calculating federal net long-term capital gain. See RCW 82.87.020; and

(vi) Plus, any amount of capital loss carryforward from a sale or exchange that occurred before January 1, 2022, to the extent such loss was included in calculating federal net long-term capital gain, and less any long-term capital gain from an installment sale that occurred before January 1, 2022, to the extent such gain was included in calculating federal net long-term capital gain. See subsection (3)(a) of this rule for additional information regarding the two adjustments described in this paragraph.

(b) **Another taxing jurisdiction.** Another taxing jurisdiction means a state of the United States other than the state of Washington, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any foreign country or political subdivision of a foreign country. See RCW 82.87.100. The United States is not "another taxing jurisdiction."

(c) **Domicile.** In general, domicile means a permanent place of abode, coupled with the intent to make the abode one's home. It is the place that you intend to return to even if you visit or temporarily reside elsewhere. Thus, actual presence in a location at any given time is not necessarily determinative of a person's domicile. An individual can have only one domicile at a time. A Washington domiciliary

who intends to move at a future date is still considered domiciled in Washington. See subsection (6)(c) of this rule for more details.

(d) **Family.** Family means the same as "member of the family" in RCW 83.100.046. See RCW 82.87.070.

(e) **Federal net long-term capital gain.** Federal net long-term capital gain means the net long-term capital gain reportable for federal income tax purposes determined as if I.R.C. §§ 55 through 59, 1400Z-1, and 1400Z-2 did not exist. See RCW 82.87.020. This information is reported on Schedule D of the U.S. Individual Income Tax Return.

(f) **Grantor trust.** A grantor trust is any trust in which the grantor or another person is treated as the owner of any portion of the trust for federal income tax purposes under I.R.C. §§ 671-679. "Grantor trust" also includes any nongrantor trust where the grantor's transfer of assets to the trust is treated as an incomplete gift under I.R.C. § 2511 and accompanying regulations, to the extent that grantor's transfer of assets to the trust is treated as an incomplete gift. The grantor of a nongrantor trust must include any long-term capital gain or loss from the sale or exchange of a capital asset attributable to the grantor's gift to the trust, to the extent such gift is incomplete, in the calculation of that individual's adjusted capital gain, if such gain or loss is allocated to this state under RCW 82.87.100.

(g) **Intangible personal property.** Intangible personal property means all personal property other than tangible personal property. For example, software is intangible personal property.

(h) **Internal Revenue Code/I.R.C.** Internal Revenue Code or I.R.C. means Title 26 U.S.C., i.e., the United States Internal Revenue Code of 1986, as amended, as of July 25, 2021, or as of such subsequent date as noted in this rule. See RCW 82.87.020.

(i) **Long-term capital asset.** Long-term capital asset means a capital asset held for more than one year. See RCW 82.87.020.

(j) **Materially participated.** Materially participated means an individual was involved in the operation of a business on a basis that is regular, continuous, and substantial. Materially participated generally has the same meaning as the term "material participation," as defined in I.R.C. § 469 and related treasury regulations, to the extent not inconsistent with the qualified family-owned small business deduction provided in RCW 82.87.070.

(k) **Nongrantor trust.** A nongrantor trust is any trust other than a grantor trust.

(l) **Permanent place of abode; place of abode.** A place of abode means a fixed dwelling or home maintained by an individual for occupancy. Permanency of a place of abode is determined by whether the place of abode serves more than a temporary purpose. Occupancy of the dwelling or home, ownership status, nature, characteristics, use, names, or labels of a dwelling are considered, but are not conclusive as to determining the permanency of a place of abode. For example, a rental apartment that an individual lives in for the tax year is indicative of a permanent place of abode, while a camp or vacation home that is suitable and in fact used only for vacations is not indicative of a permanent place of abode.

(m) **Principally directed or managed within the state of Washington.** Principally directed or managed within the state of Washington means that an organization's activities are primarily directed, controlled, and coordinated in Washington. An office location in Washington alone does not establish that the organization is principally di-

rected or managed in Washington. For example, a Washington location is insufficient for this purpose if the organization's activities are not primarily directed, controlled, and coordinated from the Washington location. Organizations may submit an affidavit to the department attesting that the organization is principally directed or managed in Washington. The affidavit is available at the department website, dor.wa.gov.

(n) **Qualified organization.** A qualified organization means an organization that is eligible to receive a charitable contribution as defined in I.R.C. § 170(c), and is principally directed or managed within the state of Washington. See RCW 82.87.080.

(o) **Qualifying interest.** Qualifying interest means an interest in a business that meets one of the following characteristics:

(i) An interest as a proprietor in a business carried on as a sole proprietorship;

(ii) An interest in a business if at least 50 percent of the business is owned, directly or indirectly, by any combination of the taxpayer or members of the taxpayer's family, or both; or

(iii) An interest in a business if at least 30 percent of the business is owned, directly or indirectly, by any combination of the taxpayer or members of the taxpayer's family, or both, and:

(A) At least 70 percent of the business is owned, directly or indirectly, by members of two families; or

(B) At least 90 percent of the business is owned, directly or indirectly, by members of three families.

(p) **Real estate.** Real estate means land and fixtures affixed to land, and also includes used mobile homes, used park model trailers, used floating homes, and improvements constructed upon leased land. See RCW 82.87.020.

(q) **Resident.**

(i) Resident generally includes any individual who is domiciled in Washington during the taxable year. However, the term does not include a Washington domiciliary if the domiciliary:

(A) Did not maintain a permanent place of abode in Washington at any time during the entire taxable year;

(B) Maintained a permanent place of abode outside of Washington during the entire taxable year; and

(C) Spent in the aggregate not more than 30 days of the taxable year in Washington. See RCW 82.87.020.

(ii) Resident also includes any individual not domiciled in Washington during the taxable year if the individual maintained a place of abode in Washington at any time during the taxable year and was physically present in Washington for more than 183 days during the taxable year. See RCW 82.87.020. A day, for purposes of this definition, means a calendar day or any portion of a calendar day.

(r) **Tangible personal property.** Tangible personal property means personal property that can be seen, weighed, measured, felt, or touched, but does not include steam, electricity, or electrical energy.

(s) **Taxpayer.** Taxpayer means an individual, i.e., a natural person, subject to the capital gains excise tax. In this rule, the taxpayer is also referred to as "you" and "your."

(t) **Washington capital gains.** Washington capital gains means an individual's adjusted capital gain, as modified in RCW 82.87.060, for each return filed under this chapter. See RCW 82.87.020 and subsection (5) of this rule for information on the deductions provided in RCW 82.87.060.

(3) **Tax imposed.**

(a) **The measure of tax; adjustments to federal net long-term capital gain.** The capital gains excise tax is imposed on the sale or exchange of long-term capital assets. The measure of the capital gains excise tax is Washington capital gains. Generally, Washington capital gains begins with the taxpayer's reportable federal net long-term capital gain, and this amount is then adjusted by certain statutory additions and subtractions to reach adjusted capital gain. For example, these adjustments remove exempt transactions or those not allocated to Washington from the taxable measure. Statutory deductions further modify adjusted capital gain to reach the taxpayer's Washington capital gains figure.

If your Washington capital gains are less than zero for a taxable year, no tax is due under this section, and you are not allowed to carryover this amount for use in the calculation of your adjusted capital gain for any other taxable year.

To the extent that a loss carryforward is included in the calculation of your federal net long-term capital gain and that loss carryforward is directly attributable to losses from sales or exchanges allocated to this state under RCW 82.87.100, the loss carryforward is included in the calculation of your adjusted capital gain. However, you may not include any losses carried back for federal income tax purposes in the calculation of your adjusted capital gain for any taxable year. See RCW 82.87.040.

(i) **The effective date of the tax.** The capital gains excise tax is imposed on the sale or exchange of capital assets on and after January 1, 2022. Sales or exchanges occurring before the January 1, 2022, effective date of the tax, are not part of the taxable measure of the capital gains excise tax. There are at least two situations affected by this timing issue:

(A) Loss carryforwards prior to 2022. Although the measure of the capital gains excise tax is federal net long-term capital gain, you must add back any loss carryforwards from sales or exchanges of long-term capital assets that occurred prior to January 1, 2022, in calculating adjusted capital gain to the extent such loss was included in calculating federal net long-term capital gain because any pre-2022 loss arose from a sale or exchange prior to the effective date of the capital gains excise tax. See subsection (2)(a) of this rule for the definition of adjusted capital gain.

(B) Installment sales. Long-term capital gain recognized from an installment sale, as defined in I.R.C. § 453, is not subject to capital gains excise tax if the sale occurred before January 1, 2022, even if some installment payments occur on or after January 1, 2022. You should remove any gain recognized from installment sales that occurred prior to January 1, 2022, in calculating adjusted capital gain to the extent such gain was included in calculating federal net long-term capital gain. See subsection (2)(a) of this rule for the definition of adjusted capital gain. If the installment sale occurred on or after January 1, 2022, you must include the long-term capital gain in the measure of the Washington capital gains excise tax in the same manner as the gain is reportable for federal tax purposes.

(ii) **Sale or exchange of long-term capital assets.** The imposition of the capital gains excise tax is conditioned on the sale or exchange of a long-term capital asset. In other words, if you sell or exchange a capital asset resulting in a long-term capital gain or loss, that gain or loss is included in calculating your adjusted capital gain. Alternatively, if you have a long-term capital gain or loss that did

not arise from a sale or exchange, then that gain or loss is not included in calculating your adjusted capital gain.

Example 1: Gifts.

Facts: In 2024, Jane received an old baseball card worth $30,000 from her brother, Jim, as a gift. Jim has no reportable federal net long-term capital gain from this transaction or from any other source.

Result: Because the transaction results in no federal long-term capital gain, Jim has no capital gains excise tax liability from the gift.

Example 2: Expatriation.

Facts: In 2024, Zander properly had federal net long-term capital gain in the amount of $500,000. A portion, $100,000, is long-term capital gain recognized under I.R.C. § 877A(a) because Zander is expatriating.

Result: Long-term capital gain is recognized under I.R.C. § 877A(a) as a result of a deemed sale. Because $100,000 of Zander's gain is not the result of a sale or exchange of a capital asset, that portion is not included in Zander's measure of Washington capital gains. He should subtract $100,000 from his federal net long-term capital gain when calculating his Washington capital gains.

Example 3: Maturity of bonds.

Facts: In 2024, Zora had federal net long-term capital gain in the amount of $500,000. A portion, $100,000, is long-term capital gain recognized under I.R.C. § 1271 upon the retirement of bonds Zora had purchased at discount.

Result: Upon the retirement of the bonds, Zora receives cash and no longer holds the capital assets (i.e., the bonds). These circumstances indicate the transaction is an exchange for purposes of the capital gains excise tax, and Zora should include the long-term capital gain recognized from the bonds in her Washington capital gains amount.

Example 4: Excess partnership distribution.

Facts: In 2024, Zane had federal net long-term capital gain in the amount of $500,000. A portion, $100,000, is long-term capital gain recognized under I.R.C. § 731 because the partnership in which Zane is a partner distributed cash to him in an amount that exceeded Zane's basis in the partnership.

Result: The long-term capital gain that Zane recognizes from the excess distribution is not due to a sale or exchange of a capital asset. Therefore, Zane should subtract $100,000 from his federal net long-term capital gain when calculating his Washington capital gains.

Example 5: Section 1256 contracts.

Facts: In 2023, Mavis, a Washington domiciliary, recognized both gains and losses from various Section 1256 contracts, as defined in I.R.C. § 1256. Mavis recognized a $300 gain from the sale of an 18-month futures contract that she held for one year and three months, a $400 loss from the sale of a three-month nonequity option contract that she held for one month, and a $100 gain from a 24-month foreign currency contract that she continues to hold, but was deemed sold at the end of the year for federal tax purposes. Under I.R.C. § 1256, 60 percent of the gain or loss from Section 1256 contracts is treated as long-term capital gain or loss, and 40 percent is treated as short-term capital gain or loss. For federal tax purposes, Mavis had $0 in net capital gain from these contracts for 2023.

Result: Although Mavis had $0 in federal net long-term capital gain from the Section 1256 contracts in 2023, only long-term capital gains and losses from Section 1256 contracts that were held for more than one year and were sold are included in calculating an individual's Washington capital gains excise tax. Here, Mavis sold or exchanged only one contract that she held for more than one year, the 18-month contract. Therefore, Mavis should calculate her Washington capital gains from her Section 1256 contracts by including only the $300 in long-term capital gain she recognized from her sale of the 18-month futures contract. The $240 long-term capital loss she recognized for federal tax purposes on the three-month contract and the $60 long-term capital gain she recognized on the 24-month contract are not part of her Washington capital gains.

(iii) **Other examples on the measure of tax.**

Example 6: Capital gain invested in qualified opportunity fund.

Facts: In 2023, Joseph, a Washington domiciliary, sold stock he had held for two years for $2,000,000. His basis in the stock was $700,000. He invests in the same year, $1,300,000 in a qualified opportunity fund, as defined in I.R.C. § 1400Z-2, and elects to defer federal taxation of the gain from the sale of his stock as permitted under I.R.C. § 1400Z-2. Joseph sells no other capital assets in 2023. As a result of the deferral, Joseph recognizes in 2023 $0 net long-term capital gain for federal tax purposes.

Result: An individual's Washington capital gains is based on their federal net long-term capital gain, which is defined as the net long-term capital gain reportable for federal income tax purposes determined as if Title 26 U.S.C. Secs. 55 through 59, 1400Z-1, and 1400Z-2 of the Internal Revenue Code did not exist. Because the definition of federal net long-term capital gain excludes Section 1400Z-2 of the Internal Revenue Code, Joseph must include the $1,300,000 in long-term capital gain from his 2023 sale of stock in calculating his 2023 Washington capital gains.

Example 7: Sale of qualified opportunity fund.

Facts: Same facts as Example 6, and Joseph sells his investment in the qualified opportunity fund in 2025 for $1,700,000. Under the basis and gain recognition rules in I.R.C. § 1400Z-2, Joseph must recognize $1,300,000 in long-term capital gain on the sale of his interest in the qualified opportunity fund for federal tax purposes.

Result: The definition of federal net long-term capital gain for purposes of the Washington capital gains excise tax excludes Section 1400Z-2 of the Internal Revenue Code. Therefore, Joseph should ignore I.R.C. § 1400Z-2 when calculating the gain from the sale of his qualified opportunity fund investment for purposes of the Washington capital gains excise tax, and, in this case, calculate his gain or loss by applying I.R.C. §§ 1001, 1011, and 1012.

Example 8: Section 1244 stock loss.

Facts: In 2023, David, who is domiciled in Washington, sold stock he had held for several years. Some of the stock sold by David was Section 1244 stock, as defined under I.R.C. § 1244(c). The sale of the Section 1244 stock resulted in a $50,000 loss, which David properly reported on his 2023 tax return as an ordinary loss. David's other stock sales in 2023 resulted in a net long-term capital gain of $1,300,000 and a net short-term capital loss of $20,000. David had no other capital gains or losses.

Result: Neither the $50,000 ordinary loss nor the $20,000 short-term capital loss David reported on his 2023 federal tax return are included in his federal net long-term capital gain. As a result, neither loss amount is included in calculating David's Washington capital gains. David's 2023 Washington capital gains amount is his federal net long-term capital gain, $1,300,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 9: Section 1061 applicable partnership interests.

Facts: Marcy owns interests in partnerships that are "applicable partnership interests" under I.R.C § 1061. Marcy is a Washington domiciliary. In 2023, she reports on her federal tax return $1,000,000 in capital gain passed through from her partnerships, all from the sale of intangible long-term capital assets. A portion of this capital gain, $200,000, is recharacterized as short-term capital gain under I.R.C. § 1061. She reports the remainder, $800,000, as long-term capital gain. Marcy has no other capital gain or losses in 2023.

Result: The $200,000 in capital gain that is recharacterized as short-term capital gain under I.R.C. § 1061 is not part of Marcy's net long-term capital gain reportable for federal income tax purposes. Therefore, Marcy's 2023 Washington capital gains amount is $800,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 10: Loss carried forward from a prior year.

Facts: In 2023, John incurs a $1,003,000 long-term capital loss from a sale of stock while John was domiciled in Washington. John does not have any capital gains against which he can apply the loss. Under I.R.C. § 1211, $3,000 of the loss is applied against ordinary income that John earned in 2023. Therefore, $1,000,000 of the loss is carried forward to 2024 under I.R.C. § 1212. In 2024, John incurs a $4,000,000 long-term capital gain from sales of stock while John continues to be domiciled in Washington. On John's federal return, John applies the $1,000,000 loss from 2023 and reports a federal net long-term capital gain of $3,000,000 for 2024.

Result: To calculate John's 2024 Washington capital gains, the starting point is John's federal net long-term capital gain of $3,000,000. None of the adjustments in RCW 82.87.020(1) apply in determining John's adjusted capital gain. Therefore, John's 2024 Washington capital gains amount is $3,000,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 11: Out-of-state loss carried forward from a prior year.

Facts: Same facts as Example 10, except John incurs a net $1,003,000 long-term capital loss from a sale of stock while John was domiciled in Oregon, and John becomes domiciled in Washington in 2024.

Result: To calculate John's 2024 Washington capital gains, the starting point is John's federal net long-term capital gain of $3,000,000. RCW 82.87.020 (1)(c) instructs that the $1,000,000 loss carryforward must be added back to the $3,000,000 federal net long-term capital gain amount because all $1,000,000 of the loss was from a sale or exchange that was not allocated to Washington. Therefore, John's 2024 Washington capital gains amount is $4,000,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 12: Short-term capital losses.

Facts: In 2023, Jason, a Washington domiciliary, realizes a $403,000 short-term capital loss from sales of securities, and a

$325,000 net long-term capital gain from a sale of investment property. That year, he also earns $125,000 in other income. For federal tax purposes, $3,000 of the short-term capital loss is applied against Jason's other income and $325,000 of the short-term capital loss is applied against Jason's long-term capital gain. The remaining $75,000 net short-term capital loss is carried forward to 2024.

Result: Jason's 2023 Washington capital gains amount is his federal net long-term capital gain, $325,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 13: Short-term loss carried forward.

Facts: Same facts as Example 12, and in 2024, Jason realizes long-term capital gain totaling $1,000,000, and short-term capital gain totaling $200,000, all from sales of securities. For federal tax purposes, the $75,000 short-term capital loss carried forward from 2023 is applied against Jason's 2024 $200,000 net short-term capital gain.

Result: Jason's 2024 Washington capital gains amount is $1,000,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

(b) **Beneficial ownership; pass-through entities.** The capital gains excise tax applies to the sale or exchange of long-term capital assets owned by individuals. Ownership includes both legal and beneficial ownership. An individual is considered to be a beneficial owner of long-term capital assets held by any pass-through or disregarded entity in which the individual holds an ownership interest, to the extent of the individual's ownership interest in the entity as reported for federal income tax purposes. See RCW 82.87.040. Accordingly, you must include both gains from the sale or exchange of capital assets of which you are the legal owner and gains passed through to you from the sale or exchange of capital assets of which you are a beneficial owner. Examples of pass-through entities for federal tax purposes include partnerships, limited liability companies, S corporations, and grantor trusts. See RCW 82.87.040. The department does not consider estates, or trusts other than grantor trusts, to be pass-through entities. However, beneficiaries of estates and nongrantor trusts may nevertheless be subject to capital gains excise tax on distributions of capital gains received from estates and nongrantor trusts.

Example 14: Mutual fund.

Facts: Jane is domiciled in Washington and an investor in a mutual fund. A mutual fund is formed as a regulated investment company, a type of pass-through entity for federal income tax purposes. In 2024, the fund earns long-term capital gain from the sale of capital assets held by the fund. Some of the capital gain is distributed to the fund's shareholders, and some of the gain is retained in the fund and reported as undistributed capital gain.

Result: Jane is liable for capital gains excise tax on her Washington capital gains arising from the sale of the fund's long-term capital assets to the extent of her ownership interest in the fund as reported for federal income tax purposes, including her share of the fund's undistributed capital gain, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 15: S corporation.

Facts: Jack is domiciled in Washington. He is a 50 percent shareholder of an S corporation. The S corporation is a long-time shareholder of a C corporation. The S corporation sells the C corporation

shares, resulting in long-term capital gain, 50 percent of which is passed through to Jack for federal income tax purposes.

Result: Jack is a beneficial owner of the S corporation's assets. Jack must include his 50 percent share of the long-term capital gain arising from the S corporation's sale of stock in calculating his Washington capital gains.

Example 16: Tiered partnership - Limited liability company.

Facts: Juan is domiciled in Washington. Juan is a 50 percent owner of a partnership. The partnership is a 50 percent owner of an LLC. The LLC sells an intangible asset that it has owned for two years, which results in long-term capital gain. As the owner of the partnership, 25 percent of the long-term capital gain from the LLC's sale of the intangible asset is passed through to Juan for federal income tax purposes.

Result: Because Juan is an owner of a pass-through entity, the partnership, and the partnership is an owner of another pass-through entity, the LLC, Juan is a beneficial owner of the LLC's assets. Therefore, Juan must include in calculating his Washington capital gains, the long-term capital gain passed through to him arising from the LLC's sale of the intangible asset.

(4) **Exemptions.** You may treat certain types of sales or exchanges as exempt from the capital gains excise tax. See RCW 82.87.050. These exemptions are subject to the following guidelines.

(a) **Real estate.** Generally, long-term capital gains from sales or exchanges of real estate are not subject to capital gains excise tax. This exemption applies to all real estate transferred by deed, real estate contract, judgment, or other lawful instruments that transfer title to real property and are filed as a public record with the counties where real property is located.

Example 17: Sale of real estate by an individual.

Facts: Pamela is a Washington domiciliary and owns investment real property in Western Washington. In 2025, a real estate developer offers to buy the real property. Pamela accepts the developer's offer and completes the sale the same year. The sale results in a $10,000,000 long-term capital gain, which Pamela reports for federal income tax purposes. Pamela's only other transaction in 2025 involving long-term capital assets is a sale of some stock that resulted in $300,000 in long-term capital gain. Her total federal net long-term capital gain in 2025 is $10,300,000.

Result: Pamela is exempt from Washington capital gains excise tax on the $10,000,000 long-term capital gain arising from the sale of the real property. In calculating adjusted capital gain for 2025, Pamela should subtract the $10,000,000 from her federal net long-term capital gain as an amount of long-term capital gain from a sale or exchange that is exempt under chapter 82.87 RCW. Pamela's 2025 Washington capital gains equals $300,000, subject to the exemptions and deductions discussed in subsections (4) and (5) of this rule.

Example 18: Sale of real estate by pass-through entity.

Facts: Paul and Pierre each own 50 percent of Invesco LLC. Invesco owns 100 percent of two other LLCs, PropertyOne LLC and PropertyTwo LLC. PropertyOne's only asset is investment real property located in Eastern Washington. In 2024, PropertyOne sells the investment property, resulting in $6,000,000 of long-term capital gain. For federal tax purposes, Paul and Pierre each recognize $3,000,000 in long-term capi-

tal gain from their distributive shares of the capital gain passed-through from PropertyOne.

Result: PropertyOne's sale of the investment property is exempt from capital gains excise tax. In calculating their Washington capital gains, Paul and Pierre should each subtract the $3,000,000 from their federal net long-term capital gain as an amount of long-term capital gain from a sale or exchange that is exempt under chapter 82.87 RCW.

(b) **Sales of entities owning real estate.** The sale of an interest in a privately held entity is exempt from the capital gains excise tax to the extent the long-term gain or loss from the sale is directly attributable to real estate owned directly by the entity.

(i) A "privately held entity" for this purpose means an entity that is not traded through public means. For example, a privately held entity does not include a corporation traded on a public exchange.

(ii) "Owned directly" means the privately held entity in which the individual has an interest legally owns (holds legal title to) the real estate.

(iii) The value of this exemption is equal to the fair market value of the real estate owned directly by the privately held entity less its basis at the time that the sale or exchange of the individual's interest occurs, multiplied by the percentage of the ownership interest in the entity that is sold or exchanged by the individual. The following are not considered in the calculation of the exemption amount:

(A) Any amount that I.R.C. § 751 treats as an amount realized from the sale or exchange of property other than a capital asset; and

(B) Real estate not owned directly by the entity in which an individual is selling or exchanging the individual's interest.

(iv) The fair market value of real estate may be established by a fair market value appraisal issued by a state-licensed real estate appraiser or an allocation of assets by the seller and the buyer made consistent with the principles required for an allocation under I.R.C. § 1060, as amended, and related treasury regulations. However, the department is not bound by the parties' agreement as to the allocation of assets, allocation of consideration, or fair market value, if such allocations or fair market value do not reflect the fair market value of the real estate. The assessed value of the real estate for property tax purposes may also be used to determine the fair market value of the real estate if the assessed value is current as of the date of the sale or exchange of the ownership interest in the entity owning the real estate and the department determines that this method is reasonable under the circumstances. In no case may the exemption value under (b) of this subsection exceed the individual's long-term capital gain from the sale or exchange of the interest in the entity for which the individual is claiming this exemption.

Example 19: Sale of private entity directly and indirectly owning real estate.

Facts: Ken, who is domiciled in Washington, owns 100 percent of Holding Company LLC. Holding Company LLC owns three assets: A 100 percent interest in First Avenue Tower LLC, a 100 percent interest in Second Avenue Tower LLC., and 100 percent of Third Avenue Tower, a commercial building. All of the entities are privately held entities. First Avenue Tower LLC owns one asset: First Avenue Tower, a commercial building with a fair market value of $4,000,000, and a basis of $1,000,000. Second Avenue Tower LLC also owns only one asset, a commercial building called Second Avenue Tower. Second Avenue Tower has a

fair market value of $8,000,000, and a basis of $5,000,000. Third Avenue Tower has a fair market value of $5,000,000, and a basis of $2,000,000.

Real estate	FMV	Basis
First Avenue Tower	$4,000,000	$1,000,000
Second Avenue Tower	$8,000,000	$5,000,000
Third Avenue Tower	$5,000,000	$2,000,000

Ken sells his entire interest in Holding Company LLC for $17,000,000. His gain from the sale is a $9,000,000 long-term capital gain.

Result: A portion of the $9,000,000 gain Ken recognizes from the sale of Holding Company LLC may qualify for exemption. Ken's long-term capital gain from the sale of his Holding Company LLC interest is ineligible for the exemption with respect to First Avenue Tower and Second Avenue Tower because Holding Company LLC does not directly own those properties. However, Holding Company LLC owns Third Avenue Tower directly. Therefore, $3,000,000 of Ken's gain from the sale of Holding Company LLC is exempt. This amount is the difference between the fair market value of Third Avenue Tower and the basis of that property.

Example 20: Sale of private entity directly and indirectly owning real estate.

Facts: Same general facts as Example 19, except Holding Company LLC liquidates First Avenue Tower LLC prior to Ken's sale of Holding Company LLC. As a result of the liquidation, at the time of Ken's sale of his Holding Company interest, Holding Company LLC directly owns the commercial building previously held by First Avenue Tower LLC, as well as Third Avenue Tower.

Result: A portion of the $9,000,000 gain Ken recognizes from the sale of Holding Company LLC may qualify for exemption. Specifically, the value of the exemption equals $6,000,000, which is the $4,000,000 fair market value of First Avenue Tower minus its $1,000,000 basis, plus the $5,000,000 fair market value of Third Avenue Tower minus its $2,000,000 basis, multiplied by Ken's 100 percent ownership interest in Holding Company LLC.

Example 21: Sale of private entity directly owning a partial interest in real estate.

Facts: Mitch is a Washington domiciliary who owns 100 percent of Mitch Holdings LLC. Mitch Holdings LLC owns one asset, a 40 percent interest in an investment property. Mitch recently decided to divest from the property and did so by selling his entire interest in Mitch Holdings LLC to another person. The assessed value of the investment property is $2,300,000.

Result: Mitch Holdings LLC is a privately held entity. Mitch's sale of Mitch Holdings LLC is exempt from the capital gains excise tax to the extent the long-term gain or loss from the sale is directly attributable to real estate owned directly by Mitch Holdings LLC, in this case, the investment property. The value of the exemption for Mitch is equal to the fair market value of Mitch Holdings LLC's interest in the investment property, less its basis. Mitch should obtain an appraisal to determine the fair market value of Mitch Holdings LLC's interest in the property. See RCW 82.87.050. While the assessed value of real estate may be used in some circumstances to determine fair market value, use of assessed value, or a percentage of the assessed

value, is not a reasonable method for determining the fair market value of a partial interest in real estate.

Example 22: Sale of private entity owning real estate; exemption limitation.

Facts: Jesse, a Washington domiciliary, owns 100 percent of Property Co., an LLC. Property Co. owns three assets: A 100 percent interest in Property One LLC, a 100 percent interest in Property Two LLC, and a piece of real estate, Property 3. Property One LLC's only asset is real estate, Property 1, which has a fair market value of $5,000,000, and a basis of $2,000,000. Property Two LLC's only asset is a piece of depressed real estate, Property 2, which has a fair market value of $2,000,000, and a basis of $10,000,000. Property 3 has a fair market value of $12,000,000, and a basis of $5,000,000.

	FMV	Basis
Property 1	$5,000,000	$2,000,000
Property 2	$2,000,000	$10,000,000
Property 3	$12,000,000	$5,000,000

Jesse sells her entire interest in Property Co. for $19,000,000. Jesse's basis in Property Co. is $17,000,000. The sale results in a $2,000,000 long-term capital gain for Jesse.

Result: The value of this exemption is equal to the fair market value of the real estate owned directly by the privately held entity, less its basis. However, the exemption value may not exceed the individual's long-term capital gain or loss from the sale or exchange of the interest in the entity. Here, Property 3 is the only real estate owned directly by Property Co. Its fair market value minus its basis is $7,000,000. However, Jesse's gain from the sale of Property Co. is only $2,000,000. Therefore, the value of the exemption from Jesse's sale of Property Co. is limited to $2,000,000.

(c) **Retirement accounts.** Sales or exchanges of assets held under retirement savings accounts or retirement savings vehicles that are exempt from federal income tax are also generally exempt from capital gains excise tax. Exempt retirement accounts include the following:

(i) Retirement savings accounts under I.R.C. § 401(k);

(ii) Tax-sheltered annuities or custodial accounts described in I.R.C. § 403(b);

(iii) Deferred compensation plans under I.R.C. § 457(b);

(iv) Individual retirement accounts or individual retirement annuities described in I.R.C. § 408;

(v) Roth individual retirement accounts described in I.R.C. § 408A;

(vi) Employee defined contribution programs, employee defined benefit plans; and

(vii) Retirement savings vehicles or accounts similar to those described above, such as exempt foreign retirement accounts.

(d) **Assets subject to condemnation.** Sales or exchange of assets pursuant to, or under imminent threat of condemnation proceedings by the United States, the state or any of its political subdivisions, or a municipal corporation, are exempt from capital gains excise tax.

(e) **Certain livestock.** Sales or exchanges of cattle, horses, or breeding livestock are exempt if, for the taxable year of the sale or exchange, more than 50 percent of the taxpayer's gross income for the taxable year, including from the sale or exchange of capital assets, is from farming or ranching.

(f) **Depreciable property.** Sales or exchanges of property that is depreciable under I.R.C. § 167(a)(1) or that qualifies for expensing under I.R.C. § 179 is exempt from capital gains excise tax. Intangibles amortizable under I.R.C. § 197 do not qualify for this exemption.

Example 23: Nondepreciable intangible property.

Facts: Bob, a Washington domiciliary, sells in 2023 all his assets in a Burger Bob franchise store that he acquired in 2018. The sale results in long-term capital gain. A portion of the long-term capital gain was attributable to Bob's sale of goodwill in the store. Bob claims an exemption from capital gains excise tax on the portion of the long-term capital gain that is attributable to goodwill.

Result: Bob's long-term capital gain from the sale of the goodwill is not exempt from capital gains excise tax because goodwill is an intangible amortizable under I.R.C. § 197 rather than property depreciable under I.R.C. § 167(a)(1) or property that qualifies for expensing under § 179.

(g) **Timber and timberland.** Sales of timber as defined in RCW 82.87.050, and timberland, as well as capital gains received as dividends and distributions from real estate investment trusts derived from gains from the sale or exchange of timber and timberland, are exempt from capital gains excise tax. Cutting or disposal of timber qualifying for capital gains treatment under I.R.C. § 631(a) or (b) is also considered a sale or exchange that is exempt from capital gains excise tax.

(h) **Commercial fishing privileges.** Sales or exchanges of commercial fishing privileges, as defined in RCW 82.87.050, are exempt from capital gains excise tax.

(i) **Goodwill in an auto dealership.** Sales or exchanges of goodwill received from the sale of an auto dealership licensed under chapter 46.70 RCW whose activities are subject to chapter 46.96 RCW are exempt from capital gains excise tax. However, long-term capital gain from sales or exchanges of goodwill in other types of businesses are not exempt from capital gains excise tax.

(5) **Deductions.** To obtain your Washington capital gains, you may deduct certain amounts from the measure of your adjusted capital gain, subject to the following guidelines. RCW 82.87.060.

(a) **Standard deduction.**

(i) Individuals other than spouses or state-registered domestic partners are entitled to deduct $250,000 from their Washington capital gains.

(ii) Spouses and state-registered domestic partners are limited to a total standard deduction of $250,000, regardless of whether they file joint or separate returns. In the case of spouses or domestic partners filing separate returns, the deduction may be split in whatever manner the spouses or partners choose, so long as the total claimed deduction does not exceed $250,000.

(b) **Charitable donation deduction.** A taxpayer may take a deduction from their Washington capital gains for certain charitable donations to one or more qualified organizations during a tax year. See subsection (2) of this rule for "qualified organization" definition.

(i) **Deduction amount; limitation.** The charitable donation deduction equals the difference between the taxpayer's total qualifying donations minus $250,000. The maximum charitable donation deduction in a year is $100,000 per tax return, regardless of the taxpayer's filing status. Thus, in the case of one joint tax return, the maximum chari-

table donation deduction is $100,000 although the return is filed by two individuals.

(ii) **Donor-advised funds; indirect donations through intermediaries.** Generally, a donor-advised fund is a separately identified account that is maintained and operated by a nonprofit organization, and each account is composed of donations that are made by individual donors. Although the nonprofit organization has legal control over it, individual donors maintain advisory privileges with respect to the distribution of funds and management of the account's assets. If you donate to a donor-advised fund or a similar intermediary charitable vehicle, that intermediary, or in case of a donor advised fund, the organization that owns or controls the fund, must qualify as a qualified organization under RCW 82.87.080. The organization to which you make the donation, and not the organization where the donation ends up, determines whether you donated to a qualified organization.

Example 24: Qualifying charitable donations by a couple.

Facts: Chris and Hannah are a married couple. They file a joint return for federal tax purposes, and therefore also file a joint capital gains excise tax return. See RCW 82.87.120. However, they maintain some separate funds consisting of separate property (rather than community property). In 2024, each spouse made charitable donations to qualified organizations using their separate funds. Chris made donations totaling $290,000, and Hannah made donations totaling $400,000.

Result: The maximum charitable donation deduction in a year is $100,000 per tax return. Thus, the total charitable donation deduction the couple can take on their joint capital gains excise tax return is $100,000, even though the sum of the spouses' donations exceeded $250,000 by more than $100,000.

Example 25: Nonqualifying charitable donation.

Facts: Jimmy donates $350,000 to the Global Wildlife Fund (GWF) every year. GWF is an international nonprofit organization that aims to conserve endangered species. Its global headquarters is in Sweden. GWF has a U.S. headquarters in Washington, D.C., and has no presence in Washington state. Jimmy claims a $100,000 charitable donation deduction on his capital gains excise tax return.

Result: The facts indicate that GWF is not principally directed or managed within Washington state. Therefore, Jimmy is not eligible for the charitable donation deduction for his donation to GWF, because GWF is not a qualified organization under RCW 82.87.080.

(c) **Qualified family-owned small business deduction.** You may deduct the amount of adjusted capital gain derived in the taxable year from your sale or transfer of a qualified family-owned small business, subject to all the following requirements. RCW 82.87.070.

(i) The sale or transfer must be a sale of substantially all the business's assets or a transfer of substantially all of your interest in the business. A transfer of substantially all the business's assets, means a sale of at least 90 percent of the business's real property and tangible and intangible personal property, measured by fair market value. A sale of substantially all of your interest in the business, means a transfer of at least 90 percent of your interest in the business.

(ii) You must have held a qualifying interest in the qualified family-owned small business for at least five years immediately preceding the sale or transfer. A mere change in form of the business, i.e., where no change in beneficial ownership of the business has oc-

curred, including no change in the proportion of beneficial ownership in the business, does not interrupt this required holding period.

(iii) You, or your family, or both, must have materially participated in operating the business for at least five of the 10 years immediately preceding the sale or transfer, unless the sale or transfer was to a member of your family. A mere change in form of the business, i.e., where no change in beneficial ownership of the business has occurred, including no change in the proportion of beneficial ownership in the business, does not interrupt this required participation period.

(iv) The business's worldwide gross revenue cannot have exceeded $10,000,000 in the 12-month period immediately preceding the sale or transfer.

(6) **Allocation of long-term capital gains and losses.** Allocation is the method for determining which long-term capital gains and losses to include in computing a taxpayer's Washington capital gains.

(a) **Tangible personal property.** You must allocate to Washington long-term capital gain or loss from a sale of tangible personal property in two situations:

(i) The tangible personal property was located in Washington at the time of the sale or exchange, i.e., the tangible personal property was physically present in Washington at the time the sale or exchange occurred; or

(ii) The tangible personal property was not located in Washington at the time of the sale or exchange, but the transaction had each of the following characteristics:

(A) The property was located in Washington at any time during the year in which the sale or exchange occurred or in the immediately preceding year;

(B) The taxpayer was a Washington resident at the time the sale or exchange occurred; and

(C) The taxpayer was not subject to the payment of an income or excise tax legally imposed on the long-term capital gain by another taxing jurisdiction. If the sale generated a loss, this element is met if the loss is not included in the taxpayer's income or excise tax base in another taxing jurisdiction. RCW 82.87.100.

Example 26: Allocation of gain from tangible personal property.

Facts: Michael is domiciled in Washington. His home is in Seattle, and he resides there year-round. In October 2024, Michael decides to sell a coin collection he inherited two years ago. In December, Michael brings the coins to Nevada, which does not have an income tax and does not impose excise taxes on occasional sales. While in Nevada, Michael sells the coin collection and the sale results in a $100,000 long-term capital gain.

Result: Michael's $100,000 long-term capital gain from the sale is allocated to Washington for purposes of the capital gains excise tax. Although he sold the coins in Nevada, they were located in Washington during the year in which the sale occurred, Michael was a Washington resident at the time the sale occurred, and Michael was not subject to an income or excise tax on the sale of the coins in another taxing jurisdiction.

(b) **Intangible personal property.** You must allocate to Washington long-term capital gain or loss from a sale or exchange of intangible personal property if you were domiciled in Washington at the time the sale or exchange occurred. RCW 82.87.100.

(c) **Determinations of domicile.**

(i) Determination of intent, burden of proof. An intention to make a place of abode one's domicile is determined by facts and circumstances on a case-by-case basis. The department will review the factors and some may be given more weight than others depending on the facts and circumstances. The following is a nonexclusive list of factors the department will consider in evaluating an individual's domicile:

- Length of time spent in a location;
- Expressed intent;
- Place of business, profession, or employment;
- Location of bank accounts;
- Residence and address for federal income and state tax purposes;
- Sites of personal and real property owned by the individual;
- State of motor vehicle and other personal property registration;
- State of motor vehicle driver's license;
- Location of schools attended by children;
- State of voter registration;
- Location of professional or business licenses;
- Payment of in-state tuition;
- Location from where financial transactions originate;
- Claiming of residence in a state for purposes of obtaining a hunting or fishing license, eligibility to hold public office, eligibility for obtaining a property tax benefit (such as a homestead exemption), or for judicial actions;
- Mailing address.

Individuals may submit to the department a request for a ruling on where the department considers individuals to be domiciled for purposes of this tax.

(ii) Continuation and change of domicile. Your domicile, once established, is presumed to continue. Therefore, if you have been domiciled in Washington, you will have the burden of proving your domicile has changed to a location outside of Washington. To establish a new domicile, you must be physically present at the new place of intended domicile and have an intention to make that new place your permanent home. This means that, for instance, selling your former home or acquiring a new one is not conclusive in establishing domicile.

(iii) Domicile of spouses, state-registered domestic partners, children. The department will presume that the domicile of spouses or state-registered domestic partners are the same. The department will also presume that a child's domicile is the same as the domicile of the child's parents until the child is no longer dependent and establishes his or her own separate domicile. If the parents have separate domiciles, the department will presume that the domicile of the child is the domicile of the parent with whom the child spends more time in the tax year.

(iv) Exceptions. Federal law may apply to service members in determination of domicile. Generally, under Title 50 U.S.C. § 571 (residence for tax purposes under the Servicemembers' Civil Relief Act), a member of the armed forces does not acquire a new domicile solely because that individual was stationed elsewhere during a period of active duty.

(d) **Credit for taxes paid to other taxing jurisdictions.** Taxpayers may be entitled to a credit against capital gains excise tax equal to the amount of any legally imposed income or excise tax paid by the taxpayer to another taxing jurisdiction on capital gains derived from

capital assets within the other taxing jurisdiction. See RCW 82.87.100. In no case may the credit under this subsection (c) exceed the individual's capital gains excise tax liability on the capital assets for the tax year in which the individual claims this credit. Entitlement to this credit requires the following:

(i) Another taxing jurisdiction legally imposed an income or excise tax on capital gain included in the taxpayer's Washington capital gains;

(ii) The taxpayer in fact paid the tax imposed by the other taxing jurisdiction before the taxpayer filed their Washington capital gains excise tax return on which the credit is claimed; and

(iii) The gain taxed by the other jurisdiction arose from the sale or exchange of a capital asset within the other taxing jurisdiction. For this purpose, the department will presume that long-term capital gain from sales or exchanges of intangible personal property are within the other taxing jurisdiction if the other taxing jurisdiction legally imposed tax on the long-term capital gain derived from the sale or exchange of the intangible personal property.

Example 27: Allocation of gain from intangible property and credit for other taxes paid.

Facts: Julie is a Washington domiciliary and owns a second home in New York. During 2025, she resided in New York for eight months and in Washington the other four months. Julie is a casual investor. In 2025, Julie sold her investment in cryptocurrency to online buyers. The sale generated long-term capital gain for Julie. Under New York law, Julie is treated as a statutory resident even though she was domiciled in Washington. As a statutory resident, Julie is required to remit to New York income tax on the income she earned from the sale of the cryptocurrency. Julie pays the New York tax and files a Washington capital gains excise tax return, claiming a credit for the income tax paid to New York on the sale of the cryptocurrency.

Result: Because Julie was domiciled in Washington at the time the sale or exchange occurred, the gain from her sale is allocated to Washington. However, because New York legally imposed income tax on Julie's sale of cryptocurrency and Julie remitted income tax on the sale to New York, Julie is entitled to a credit against Washington capital gains excise tax equal to the New York tax Julie paid on the transaction.

(e) **Allocation and sourcing of gains or losses from pass-through entities.** The allocation method for gains and losses is the same whether you owned the property directly or indirectly through a pass-through or disregarded entity.

Example 28: Allocation of passed through gain from intangible property.

Facts: Jack is domiciled in Washington. He is a 50 percent shareholder of Invest Corp., an S corporation. Invest Corp. is a long-time shareholder of Fictional Co. In 2025, Invest Corp. sells its Fictional Co. shares, resulting in long-term capital gain, 50 percent of which is passed through to Jack for federal income tax purposes.

Result: The long-term capital gain from the sale of the Fictional Co. stock is allocated to Washington because the stock is intangible personal property and the taxpayer, Jack, was domiciled in Washington at the time the sale occurred.