

Pharmacy Quality Assurance Commission

PO Box 47852 • Olympia, Washington 98504-7852 Tel: 360-236-4030 • 711 Washington Relay Service

March 4, 2022 Weekly Legislative Review Agenda

Time: 12:00 p.m.

Register for Webinar

ID: 484-649-427 Phone: 914.614.3221

Access Code 532-935-602

Audio PIN: Shown after joining the webinar

Questions contact:

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In accordance with the Open Public Meetings Act, notices were mailed electronically to individuals who requested notification of meetings of the Pharmacy Quality Assurance Commission.

Times and Order: The meeting will begin at 12:00 p.m. and will continue until all agenda items are complete. This agenda is subject to change. Items might not be taken in order of the agenda. Please call 360.236.4834 before the meeting date to confirm the meeting agenda. This meeting will not be recorded.

- 1. Opening
 - a. Member Roll Call
- 2. PQAC Bill Report Review Bills (Information)
 - i. Determine position and action on each bill (Action)
 - ii. Weekly report on actions
- 3. Public Comment Period

Meeting Adjourned/Closed.

Accessibility: This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than five (5) days prior to the meeting. If you would like general information about this meeting, please call (360) 236-4946. If you need assistance with special services, you may leave a message with that request at 1-800-525-0127 or if calling outside Washington State call (360) 236-4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1-877- 833-6341.

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Link to Washington State Legislature Bill Information 2022

Jan 10, 2022 – First day of session.

Feb 3, 2022 – Policy Committee Cutoff.

Feb 7, 2022 – Fiscal Committee Cutoff.

Feb 15, 2022 – House of Origin Cutoff.

Feb 24, 2022 – Policy Committee Cutoff – Opposite House.

Feb 28, 2022 – Fiscal Committee Cutoff – Opposite House.

March 4, 2022 – Opposite House Cutoff. Next cutoff
March 10, 2022 – Sine die. Last day allowed for regular session under state constitution.

TVW - http://www.tvw.org/

| Bills Requiring Active Involvement/Input | | | |
|--|---|---|--|
| Bill # /Companion | Short Title | Brief Description | Committee Action (subject to change) |
| ESHB 1852 | Language requirements for prescription drug labels. | The Pharmacy Quality Assurance Commission (commission) must adopt rules by July 1, 2024 establishing requirements for the purpose of translating prescription drug labels and prescription information. This applies only to outpatient medications dispensed for home use and intended for human use. At a minimum, these rules must require the printing of English and the translated language directions for use on prescription containers/labels and that pharmacies or nonresident pharmacies must provide any additional directions of use, auxiliary warnings, or other information required by the commission in rule. Additionally, these rules must establish: • The languages for which translation is required (must choose at least 15 languages in consultation with the WA State office of Equity and Governor's Interagency Council on Health Disparities and update the list at least every 5 years) • The labels and/or information sheets for which translation is required • The pharmacies and settings to which the translation requirements apply • The procuring/providing process for the translations • Necessary conditions under which a pharmacy must provide translated prescription information • Any signage a pharmacy must post to notify customers of the availability of translated prescription information The commission must also make rules that help administer/implement the translation requirements and rules that establish other accessibility requirements for individuals who are blind, visually impaired, and/or print disabled. Establishes penalties on nonresident pharmacies for violations of these requirements. | HB 1852 Pre-filed: 1/7/2022 Sponsors: Representatives Thai, Cody, Gregerson, Macri, Santos, Slatter, Valdez, Pollet, and Riccelli Introduced: 1/10/2022, referred to House Committee on Health Care & Wellness. ESHB 1852 Floor vote: 2/9/2022, voted to pass (64/32/0/2) Introduced (Senate): 2/11/2022, referred to Senate Health & Long Term Care Committee. Executive session (Senate): 2/21/2022, no action taken Executive session (Senate): 2/23/2022, amendment S4848.1 adopted, passed to Rules for 2 nd reading (2/24) |

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| Bills Requiring | Bills Requiring Active Involvement/Input | | |
|----------------------|--|---|---|
| Bill # /Companion | Short Title | Brief Description | Committee Action (subject to change) |
| | | Recently adopted amendment S4848.1 clarifies that the commission has the goal, but not the responsibility, to include all languages in rule spoken by at least 5% of the state population or 1,000 people in Washington when selecting at least 15 languages for the translation list. | |
| SHB 1675 | Dialysate and dialysis device manufacturers. | SHB 1675 amends RCW 18.64.257 and 69.41.032 (addressing the prescription of legend drugs by dialysis programs) to include additional entities related to dialysis programs and treatment. These entities—dialysis device and/or dialysate manufacturers and wholesalers—are allowed to sell, deliver, possess, and/or dispense dialysis devices or commercially available dialysate directly to dialysis patients. This direct delivery to patients is only allowed for legend drugs and dialysis devices prescribed by "a practitioner acting within the scope of the practitioner's practice" as determined by the commission in rule. SHB 1675 also grants the commission rulemaking authority to implement the bill. | HB 1675 Sponsors: Representatives Bateman, Maycumber, Leavitt, Graham, Dolan, Cody, Griffey, and Riccelli Introduced: 1/10/2022, referred to House Health Care & Wellness Committee. SHB 1675 Floor vote (House): 1/26/2022, Voted to pass (97/0/0/1) Introduced (Senate): 2/1/2022, referred to Senate Health & Long Term Care Committee. Floor vote (Senate): 3/1/2022, voted to pass (48/0/0/1) |
| SHB 1728 | Insulin affordability – Workgroup funding and report deadline. | SHB 1728 would amend RCW 70.14.160 to change the composure of the insulin affordability workgroup and would create a new section pertaining to funding deadlines for that group. The deadline for the submission of the preliminary report "detailing strategies to reduce the cost of and total expenditures" of insulin for patients and the expiration of the section establishing the workgroup is extended from 2020 to 2022. The section expiration date is also extended from 2022 to 2024. A new section (Sec. 2.) is added that makes this act null and void if specific funding is not provided for this act by June 30, 2022. | HB 1728 Sponsors: Representatives Maycumber, Cody, Callan, Eslick, Macri, Ramos, Griffey, Riccelli, and Leavitt; by request of Health Care Authority Introduced: 1/10/2022, referred to House Health Care & Wellness. |
| | | Per Amendment <u>S4806.1</u> , the workgroup is required to develop strategies to provide a once-yearly 30-day emergency supply of insulin to individuals. | SHB 1728 Floor vote: 2/14/2022, voted to pass (97/1/0/0) |

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| Bills Requiring Active Involvement/Input | | | |
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| Bill # /Companion | Short Title | Brief Description | Committee Action (subject to change) |
| | | | Introduced (Senate): 2/16/2022, referred to Senate Health & Long Term Care Committee. Executive session (Senate): 2/23/2022, am. 4806.1 adopted, passed through committee with "do pass" recommendation, placed on second reading by Rules (3/1) |
| HB 2122 | Expanding regulatory authority over cannabinoids. | HB 2122 authorizes the Liquor and Cannabis Board (board) to regulate all cannabinoids that may be impairing, regardless of origin, and would direct the board to adopt rules related to cannabinoid products and Cannabis isolates, except those authorized as a drug by the federal Food and Drug Administration (FDA). This would clarify board jurisdiction over some identified substances and would give the board rulemaking authority for the production, processing, delivery, sale, etc. of hemp and FDA-approved substances. These substances include forms of tetrahydrocannabinol (THC) other than delta-9 THC, which has previously been placed in LCB's jurisdiction. Additional licensing types and fees are created under board jurisdiction. | HB 2122 Sponsors: Representatives Kloba, Ryu, Callan, Wicks, Dolan, and Bateman Introduced: 2/21/2022, referred to House Appropriations Committee. |
| HB 2123 | Quality and safety standards for cannabinoid product testing. | HB 2123 requires the Liquor and Cannabis Board (board) to adjust their regulations regarding cannabinoid definitions, cannabis product testing, and lab standards. This bill adds new sections to the Uniform Controlled Substances Act (RCW 69.50) establishing a THC concentration threshold for sale of products outside marijuana producers, processors, or retailers licensed by the board. A grant program (Section 6) is created to aid local governments in enforcing the new sales thresholds. Section 5 of the bill establishes a scientific panel tasked with reviewing data and regulations pertaining to the definitions of "impairing," "artificial cannabinoids," and "synthetically derived cannabinoids." The panel is also tasked with providing recommendations on potential manufacturing, extracting, and synthesizing methods and safety guidelines for cannabinoids, all to be included in a findings report to be submitted by December 1, 2022 | HB 2123 Sponsors: Representatives MacEwen, Springer, Young, Robertson, Vick, Chapman, Corry, and Walen Introduced: 2/22/2022, referred to House Appropriations Committee. |

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| Bills Requiring Active Involvement/Input | | | |
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| Bill # /Companion | Short Title | Brief Description | Committee Action (subject to change) |
| SSB 5753 AMH HCW H2831.1 | Enhancing the capacity of health profession boards, commissions, and advisory committees. | SSB 5753 modifies membership and quorum requirements for 18 regulatory bodies including the Pharmacy Quality Assurance Commission (commission). Section 15 of the bill grants the commission authority to designate a presiding officer—either the secretary or their designee—to conduct disciplinary proceedings under the commission's jurisdiction in place of an administrative law judge. The presiding officer shall not vote on or make any final decisions in cases where clinical expertise is necessary. Functions performed in accordance with chapter 34.05 RCW. Section 17 of the bill adds a new section to chapter 18.64 RCW and grants the commission authority to appoint members of panels with at least three members. Minimum quorum for such panels is three. SSB 5753 also amends the membership composure and function of regulatory bodies in the following way: • Removes U.S. citizenship as a prerequisite to serve on boards, commissions, or committees (13 regulatory bodies affected). • Reclassifies some boards, commissions, and committees as Class 5 Groups under chapter 43.03 RCW (11 regulatory bodies affected). • Quorum rules adjusted/created/updated for various boards, commissions, and committees (12 regulatory bodies affected). Per amendment AMH HCW POOL 022, adopted into SSB 5753 on February 23, 2022: • The executive director for the Pharmacy Quality Assurance Commission is no longer required to be a licensed pharmacist. • The executive director for the Nursing Care Quality Assurance Commission is no longer required to be a graduate of an approved nursing education program (must still be a college/university graduate), nor required to be currently licensed as a registered nurse | SB 5753 Sponsors: Senators Robinson and Lovick Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. SSB 5753 Floor vote: 2/2/2022, voted to pass (36/11/0/2) Public hearing (House): 2/16/2022 Executive session (House): 2/23/2022, amendment POOL 022 added, moved through committee with a "do pass" recommendation Floor vote (House): 3/1/2022, voted to pass (57/41/0/0) |

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| Additional Bills to Watch (Not in PQAC Jurisdiction) | | | |
|--|---|--|--|
| Bill # /Companion | Short Title | Committee Action (subject to change) | |
| E2SHB 1181 | Suicide prevention programs for veterans and military members | HB 1181 Sponsors: Orwall, Boehnke, Callan, Leavitt, Davis, Dolan, Valdez, Young, Riccelli, Lekanoff, Barkis, Peterson, Shewake, Bronoske, Macri, and Morgan Introduced (House): 1/13/2022, referred to House Housing, Human Services & Veterans Committee. E2SHB 1181 Floor vote (House): 2/15/2022, voted to pass (97/0/0/1) Introduced (Senate): 2/18/2022, referred to Senate Human Services, Reentry & Rehabilitation Committee. Public hearing (Senate): 2/22/2022 Executive session (Senate): 2/24/2022, moved through committee with "do pass" recommendation (with amendments), referred to Ways & Means. Public hearing (Senate): 2/26/2022 Executive session (Senate): 2/28/2022, moved through committee with "do pass" recommendation, passed to Rules Committee and placed on second reading (3/2) | |
| SHB 1813 | Pharmacy choice – Pharmacy benefit manager rules. | HB 1813 Sponsors: Representatives Schmick, Macri, Graham, and Chambers Introduced: 1/10/2022, referred to House Health Care & Wellness Committee SHB 1813 Floor vote: 2/11/2022, voted to pass (95//0/0/3) Introduced (Senate): 2/15/2022, referred to Senate Health & Long Term Care Committee Division track – Monitoring for amendments | |
| SHB 1821 | Definition of established relationship for purposes of audio-only telemedicine. | HB 1821 Sponsors: Representatives Schmick, Riccelli, Cody, and Graham Introduced: 1/10/2022 and referred to House Committee on Health Care & Wellness. SHB 1821 Floor vote: 2/8/2022, voted to pass (95/0/0/3) Introduced (Senate): 2/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing (Senate): 2/21/2022 Executive session (Senate): 2/23/2022, amendment \$\frac{54814.1}{2}\$ adopted, passed to Rules for 2nd reading (2/24) Floor vote (Senate): 3/1/2022, voted to pass (49/0/0/0) | |

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| Additional Bills to Watch (Not in PQAC Jurisdiction) | | | |
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| Bill # /Companion | Short Title | Committee Action (subject to change) | |
| <u>HB 1874</u> | Reducing licensing barriers for those with previous arrest. | HB 1874 Sponsors: Representatives Vick, Dufault, Hoff, Jacobsen, Leavitt, Simmons, Corry, Senn, Peterson, Goodman, Riccelli, Davis, Macri, and Young Introduced: 1/11/2022, referred to House Consumer Protection & Business Committee. Floor vote: 1/26/2022, Voted to pass (96/1/0/1) Floor vote (Senate): 3/1/2022, voted to pass (49/0/0/0) | |
| 2SSB 5532 | Prescription drug affordability board. | SB 5532 Sponsors: Senators Keiser, Robinson, Conway, Hasegawa, Pedersen, Randall, Stanford, and Wilson, C. Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. 2SSB 5532 Floor vote: 2/9/2022, voted to pass (47/0/0/2) Executive session (House): 2/28/2022, moved through Appropriations Committee with "do pass" recommendation (with amendments). Referred to Rules Committee and placed on second reading (3/1). Division track – Monitoring for amendments | |
| SSB 5546 | Insulin affordability – Monthly insurance copay cap | SB 5546 Sponsors: Senators Keiser and Van De Wege Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. SSB 5546 Floor vote: 2/8/2022, voted to pass (48/1/0/0) Floor vote (House): 2/26/2022, voted to pass (85/10/0/3). Signatures: Signed by Senate President (3/1), signed by House Speaker (3/1), delivered to Governor for signature (3/2) | |
| SSB 5765 | Relating to the practice of midwifery. | SB 5765 Sponsors: Senators Randall, Keiser, Conway, Das, Hasegawa, Lovelett, Mullet, Robinson, Saldaña, Stanford, Trudeau, Wilson, C. Introduced: 1/11/2022, referred to Senate Health & Long Term Care Committee. SSB 5765 Floor vote: 2/14/2022, voted to pass (27/20/0/2) Executive session (House): 2/23/2022, moved through Health Care & Wellness Committee with "do pass" recommendation (with amendments), referred to Rules Committee and placed on second reading (2/26). | |

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| Additional Bills | Additional Bills to Watch (Not in PQAC Jurisdiction) | | |
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| Bill # /Companion | Short Title | Committee Action (subject to change) | |
| SSB 5794 | Behavior health condition prescription drug coverage. | SB 5794 Sponsors: Senators Dhingra, Kuderer, Frockt, Hasegawa, Lovelett, Randall, Van De Wege, and Wilson, C. Introduced: 1/11/2022, referred to Senate Health & Long Term Care Committee. SSB 5794 Floor vote: 2/11/2022, voted to pass (49/0/0/0) Introduced (House): 2/14/2022, referred to House Health Care & Wellness Committee. Division track – Monitoring for amendments | |

| Dead/dormant | Dead/dormant Bills (relevant if needed to pass the budget) | | |
|----------------------|--|--|--|
| Bill # /Companion | Short Title | Bill Summary | |
| 2SHB 1668 | Expanding regulatory authority over cannabinoids. | 2SHB 1668 would authorize the Liquor and Cannabis Board (board) to regulate all cannabinoids that may be impairing, regardless of origin, and would direct the board to adopt rules related to cannabinoid products and Cannabis isolates, except those authorized as a drug by the federal Food and Drug Administration (FDA). | |
| | | This would move jurisdiction over some identified substances from the Pharmacy Quality Assurance Commission (PQAC) to the Liquor and Cannabis Board (LCB) and would give the LCB rulemaking authority for the production, processing, delivery, sale, etc. of hemp and FDA-approved substances. These substances include forms of tetrahydrocannabinol (THC) other than delta-9 THC, which has previously been placed in LCB's jurisdiction. | |
| HB 1863 | Authorizing the prescriptive authority of psychologists. | The bill adds psychologists to the list of professions able to prescribe medication, if a currently licensed psychologist meets the certain criteria. The bill also excludes opioids from medication that may be prescribed, requires the Examining Board of Psychology to work with the medical commission when creating administrative rules establishing standards for certifying prescribing psychologists, and adds a 10 th board member and a requirement one of the board members must be an expert in psychotropic prescribing. | |
| PSSB 5660 | Establishment of a psilocybin board. | This bill creates a system in which individuals aged 21 or older may consume psilocybin products for purposes of wellness, provided that the consumption takes place within licensed service centers, under the supervision of licensed facilitators, and using products created and tested by manufacturers and testers licensed by the Washington State Department of Health (DOH). | |
| | | The bill also: | |

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| Dead/dormant Bills (relevant if needed to pass the budget) | | | |
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| Bill # /Companion | Short Title | Bill Summary | |
| | | Establishes a misdemeanor offense for falsification of identification and establishes civil penalties for violations of psilocybin rules. Preempts local jurisdictions from establishing local licenses or taxes related to the manufacturing or sale of psilocybin. Prohibits an employer from discriminating against, requiring testing for, or discharging an employee for receiving psilocybin services | |
| <u>SB 5743</u> | Designating kratom as a controlled substance. | SB 5743 amends RCW 69.50.204 to classify mitragynine and 7-hyroxymitragynine, substances commonly known as kratom, as Schedule I drugs. A new section is added to justify the decision via emergency declaration: "This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately." | |
| SB 5767 | Regulating hemp-derived cannabinoids. | The bill requires LCB to adjust their regulations regarding cannabinoids and cannabis product testing, and lab standards. This includes LCB regulation regarding flower lots, batch testing; and laboratory testing standards that require certain tests to be completed on each flower lot, such as moisture analysis, foreign matter screening, microbial, mycotoxins and others. This bill adds several definitions and defines different types of cannabinoids. The bill may require the department to amend 246-70 WAC, depending on what LCB would need to change in their rules. We may need to amend our chapter regarding heavy metal screening and mycotoxin screening depending on how it affects | |
| SB 5941 | The Washington Kratom Consumer Protection Act | LCB's rulemaking. SB 5941—the Washington Kratom Consumer Protection Act—adds a new chapter to Title 69 RCW for the purpose of regulating the preparation, distribution, or sale of kratom products. Kratom products are defined in Section 2.5 as "products that contain any part of the leaf of the plant <i>Mitragyna speciose</i> or kratom extract, and are intended for human ingestion." Section 3 of the HB 5941 prohibits kratom processors—those who sell, prepare, manufacture, distribute, or maintain kratom products—from using "dangerous nonkratom substances" in kratom products and establishes additive thresholds for such products. Kratom processors may not distribute or sell kratom products to individuals under 21 years of age (Section 4), and Section 5 establishes fines that may be imposed for violations of Sections 3 and 4. Section 6 of SB 5941 grants the department rulemaking authority related to kratom products to establish 1) testing standards for safe human consumption, 2) accurate labeling standards, and 3) other rules deemed necessary to administer the new chapter. Sections 1 through 6 are intended to comprise the new chapter in Title 69 RCW, which will take effect on January 1, 2023. | |

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| Dead/dormant | Dead/dormant Bills (relevant if needed to pass the budget) | | |
|----------------------|--|--------------------------------------|--|
| Bill # /Companion | Short Title | Bill Summary | |
| | Related to the practice of optometry. | Non-jurisdiction/division track bill | |

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