

## Pharmacy Quality Assurance Commission

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## February 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

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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
  - a. 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.

March 10, 2022 – Sine die. Last day allowed for regular session under state constitution.

TVW - <a href="http://www.tvw.org/">http://www.tvw.org/</a>

<b>Bills Requiring</b>	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
<u>HB 1852</u> / <u>SB</u>	Language	Starting on January 1, 2023, a licensed pharmacy or nonresident pharmacy must	HB 1852		
<u>5840</u>	requirements for	provide translated directions upon request for use and side effects of	Pre-filed: 1/7/2022		
	prescription drug	prescription drugs. The Pharmacy Quality Assurance Commission	Sponsors: Representatives		
SHB 1852	labels.	(commission) is charged with determining the languages for which translation	Thai, Cody, Gregerson, Macri,		
		is required, and fifteen (15) languages must be chosen. The commission will	Santos, Slatter, Valdez, Pollet,		
		build the list of languages based on the percent of the population of Washington			
		that speaks the language, and this list must be reassessed and updated every five			
		(5) years. The commission is also responsible for making the translations of	referred to House Committee		
		directions for use and common side effects and developing signage to notify the	on Health Care & Wellness.		
		public of the availability of translation services.	Public hearing: 1/17/2022		
			Executive session: 1/26/2022,		
		Licensed pharmacies and nonresident pharmacies are not required to provide	no action taken.		
		their own translated directions to patients, either within or beyond the list of	CHD 1053		
		fifteen languages determined by the committee. Pharmacies may provide their	SHB 1852		
		own translated directions for use and side effects but are only responsible for	Executive session: 1/31/2022,		
		the accuracy of the English language directions.	Moved through committee with "do pass"		
		Substitute Bill	recommendation		
		Removes the general requirements for a pharmacy and nonresident	recommendation		
		pharmacy to provide translated directions for use and side effects when	SB 5840		
		requested by a patient, patient representative, or prescriber and instead	Sponsors: Senators Keiser,		
		requires the Pharmacy Quality Assurance Commission (Commission) to	Das, Hasegawa, Robinson,		
		adopt rules establishing the requirements for the translation of	Wilson, C.		
		prescription drug labels and prescription information by July 1, 2024. At			

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Bills Requiring	Bills Requiring Active Involvement/Input			
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)	
		a minimum the rules must require translation of directions for use and auxiliary warnings and must establish:  The languages for which translation is required The elements of the prescription drug label or other information that must be translated The pharmacies and settings that the requirements apply to; o the process for procuring or providing the translations When a pharmacy or nonresident pharmacy must provide the translated prescription information Any signage that a pharmacy must post to notify consumers of the availability of translated prescription information Modifies the requirements for the selection of the languages for which translation is required, so that the Commission must select up to 15 languages, must consult with the Office of Equity and Governor's Interagency Counsel on Health Disparities, and must reassess the languages at least every 10 years rather than five Authorizes the Commission to adopt rules establishing other accessibility requirements for individuals who are blind, low vision, or otherwise print disabled for prescription drug labels and prescription information Specifies that the requirements apply only to outpatient prescriptions dispensed for home use that are intended for human use and do not apply to prepackaged emergency medications or opioid overdose reversal medications distributed pursuant to statutory requirements for hospital emergency departments and certain licensed or certified behavioral health facilities Authorizes the Commission to take enforcement action against a nonresident pharmacy for failure to comply with these requirements Removes liability related provisions Defines "auxiliary warning."	Introduced: 1/12/2022, referred to Senate Health & Long Term Care Committee.	

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Bills Requiring	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
HB 1675/ SB 5507 SHB 1675	Dialysate and dialysis devices.	HB 1675/SB 5507 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 are manufacturers of commercially available dialysate, manufacturers' agents acting on behalf of the manufacturer, and dialysis devices used by home dialysis patients. The inclusion of these entities would allow dialysis product manufacturers to sell, deliver, possess, and/or dispense dialysis devices and associated legend drugs—particularly commercially available dialysate—directly to dialysis patients.  Under the proposed act, dialysis product manufacturers and agents representing those manufacturers would be exempt from PQAC licensure if they are shipping commercially available dialysate used by home dialysis patients.  Substitute Bill  Replaced "manufacturer of commercially available dialysate and 11 dialysis devices used by home dialysis patients, or a manufacturer's 12 agent acting on behalf of such manufacturer," with "a manufacturer, or a wholesaler"  Added language to apply only to practitioners acting within their scope of practice  Added subsections to grant the commission rulemaking authority	HB 1675 Pre-filed: 12/20/2021 Sponsors: Representatives Bateman, Maycumber, Leavitt, Graham, Dolan, Cody, Griffey, and Riccelli Introduced: 1/10/2022, referred to House Health Care & Wellness Committee. Public hearing: 1/12/2022 Executive session: 1/19/2022, substitute bill SHB 1675 introduced  SHB 1675 Executive session: 1/19/2022, Moved through committee with "do pass" recommendation 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.  SB 5507 Pre-filed: 12/7/2021 Sponsors: Senators Keiser, Muzzall, Lovick, and Wilson, C.		

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Bills Requiring	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
			Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee		
SB 5546 SSB 5546	Insulin affordability.	SB 5546 amends Washington state law pertaining to insulin affordability and the operations of the insulin work group (RCW 70.14.160). Section 1 of the bill amends language in RCW 48.43.780 to reduce the amount health plan enrollees must pay for a 30-day supply of prescription insulin drugs, from \$100 to \$35. This section also amends the date after which issued or renewed health plans must comply with the price change from January 1, 2021 to January 1, 2023.  Section 3 of the bill addresses the insulin work group established in RCW 70.14.160 and HB 2662. The bill does not affect the number or type of representatives serving on the work group but expands the scope of the strategies considered in reducing insulin costs for individuals. Section 3.2(b) is an added subsection that requires the work group to design and review strategies for providing a once yearly 30-day supply of insulin to individuals on an emergency basis. This section also extends the deadline by which the work group must submit a preliminary report to the governor and legislature from December 1, 2020 to December 1, 2022.  Substitute Bill  Section 3 of SB 5546 removed, Section 4 becomes Section 3  No longer amends RCW 70.14.160	SB 5546 Pre-filed: 12/16/2021 Sponsors: Senators Keiser and Van De Wege Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing: 1/19/2022 Executive session: 1/21/2022, no action taken. 1/24/2022, replaced with SSB 5546.  SSB 5546 Executive session: 1/24/2022, Moved through committee with "do pass" recommendation, referred to Senate Ways & Means Committee. Executive session: 1/25/2022, referred to Senate Rules Committee for second reading.		
HB 1728	Insulin affordability – Workgroup funding and report deadline.	1728 HB would amend RCW 70.14.160 and create a new section pertaining to the insulin affordability workgroup. 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	HB 1728 Pre-filed: 1/3/2022 Sponsors: Representatives Maycumber, Cody, Callan, Eslick, Macri, Ramos, Griffey, Riccelli, and Leavitt; by		

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Bills Requiring	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
		added that makes this act null and void if specific funding is not provided for this act by June 30, 2022.	request of Health Care Authority Introduced: 1/10/2022, referred to House Committee on Health Care & Wellness. Public hearing: 1/10/2022 Executive session: 1/19/2022, moved through committee with a "do pass" recommendation, referred to House Appropriations Committee Public hearing (appropriations): 1/27/2022 Executive session: 2/1/2022, executive action taken		
SB 5547 / HB 1668 SHB 1668	Expanding regulatory authority over cannabinoids.	SB 5547/HB 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). These substances include forms of tetrahydrocannabinol (THC) other than delta-9 THC, which has previously been placed in LCB's jurisdiction.	SB 5547 Pre-filed: 12/16/2021 Sponsors: Senators Keiser and Schoesler Introduced: 1/10/2022, referred to Senate Labor, Commerce & Tribal Affairs Committee. Public hearing: 1/20/2022 Executive session: 2/2/2022, no action taken		
		Substitute Bill  • Additional language included (Sections 10 and 11) to include artificial and synthetic cannabinoid contents as a condition for taxing/regulating	HB 1668 Pre-filed: 12/20/2021		

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Bills Requiring	Active Involvem	ent/Input	
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)
		<ul> <li>"marijuana concentrates, useable marijuana, or marijuana-infused products."</li> <li>Section 6.1(o) – LCB given rulemaking authority for production, processing, delivery, sale, etc. of hemp and FDA-approved products</li> </ul>	Sponsors: Representatives Kloba, Wylie, and Young Introduced: 1/10/2022, referred to Senate Labor, Commerce & Tribal Affairs Committee. Public hearing: 1/13/2022 Executive session: 1/21/2022, no action taken. 1/25/2022, executive action taken (four amendments adopted).  SHB 1668 Executive session: 1/25/2022, moved through committee with a "do pass" recommendation. Referred to appropriations (1/27/2022)
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 LCB's rulemaking.	SB 5767 Sponsors: Senators Stanford, Rivers, and Hasegawa Introduced: 1/11/2022, referred to Senate Labor, Commerce & Tribal Affairs Committee. Public hearing: 1/20/2022
<u>SB 5753</u>	Enhancing the capacity of	It modifies membership and quorum requirements for the following regulatory bodies: Dental Quality Assurance Commission, the Veterinary Board of	<u>SB 5753</u> Pre-filed: 1/7/2022

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<b>Bills Requiring</b>	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
SSB 5753	health profession boards, commissions, and advisory committees.	Governors, the Board of Physical Therapy, the Board of Massage, and the Board of Nursing Home Administrators. It authorizes the Pharmacy Commission to use the same regulatory delegation for facilities enforcement that it currently does for pharmacy professionals. It harmonizes all boards and commissions as Class 5 Groups under Chapter 43.03 RCW. And finally, the bill removes US citizenship as a prerequisite to serve on boards, commissions, or committees.  SSB 5753	Sponsor: Senator Robinson Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing: 1/21/2022 Executive session: 1/24/2022, replaced with SSB 5753.		
		<ul> <li>Removal of the U.S. Citizen requirement for serving.</li> <li>It modifies membership and quorum requirements for the following regulatory bodies: The Dental Quality Assurance Commission, the Veterinary Board of Governors, the Board of Physical Therapy, the Board of Massage, and the Board of Nursing Home Administrators.</li> <li>The bill authorizes the Pharmacy Commission to use the same regulatory delegation for facilities enforcement that it currently does for pharmacy professionals.</li> <li>The bill harmonizes all boards and commissions as Class 5 Groups under Chapter 43.03 RCW.</li> </ul>	Executive session: 1/24/2022, moved through committee with a "do pass" recommendation, passed to Senate Rules Committee Second reading: 1/28/2022 (Rules Committee)		
SB 5660 PSSB 5660	Establishment of a psilocybin board.	This bill creates a system similar to Oregon Measure 109 in which, following an 18-month program development period, 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). It directs DOH to (including, but not limited to):  • Establish a Washington Psilocybin Advisory Board with 20-23 members appointed by the Governor or designated by statute to provide advice and recommendations to DOH related to this new statute.  • Publish information relating to the safety and efficacy of psilocybin Povelop a program by January 1, 2024 to regulate psilocybin products	SB 5660 Pre-filed: 1/5/2022 Sponsors: Senators Salomon, Lovelett, Kuderer, Pedersen, Saldaña, Trudeau, and Wellman Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing: 2/2/2022 @ 8:00 a.m.		

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Bills Requiring	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
		<ul> <li>Adopt requirements and guidelines for psilocybin services</li> <li>Establish a code of conduct, education standards, and guidelines for psilocybin facilitators</li> <li>Establish quality and safety standards for psilocybin products</li> <li>Establishes regulations and location guidelines for licensure of psilocybin businesses</li> </ul>			
		<ul> <li>Establishes a misdemeanor offense for falsification of identification and establishes civil penalties for violations of psilocybin rules.</li> <li>Preempts local jurisdictions from establishing local licenses or taxes related to the manufacturing or sale of psilocybin.</li> <li>Prohibits an employer from discriminating against, requiring testing for, or discharging an employee for receiving psilocybin services</li> </ul>			
SB 5743	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 5743 Pre-filed: 1/7/2022 Sponsor: Senator Honeyford Introduced: 1/10/2022, referred to Senate Law & Justice Committee.		
SB 5941	The Washington Kratom Consumer Protection Act	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	SB 5941 Sponsor: Senator Honeyford Introduced: 1/25/2022, referred to Senate Law & Justice Committee.		

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Bills Requiring	Bills Requiring Active Involvement/Input				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
		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.			
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 following criteria:  • Successfully complete a qualifying master's degree, which includes psychopharmacology studies and supervised experience treating patients and prescribing medication (Sec 3 (2)(c));  • Successfully complete an 80-hour supervised clinical experience in physical assessment (Sec 3 (2)(d));  • Successfully complete a postdoctoral prescribing psychology fellowship of a minimum 500 hours and 100 individual patients (Sec 3 (2)(e)); and  • Pass a relevant examination (Sec 3 (2)(f)).  The bill also:  • Excludes opioids from medication that may be prescribed (Sec 4(4))  • Requires the Examining Board of Psychology to work with the medical commission when creating administrative rules establishing standards for certifying prescribing psychologists (Sec 6(4)(c)).  • Sec 5 also adds a 10 <sup>th</sup> board member and a requirement one of the board members must be an expert in psychotropic prescribing.  • Currently, there are seven professional and two public board members; SB 5753 proposes adding two additional public members	HB 1863 Pre-filed: 1/7/2022 Sponsors: Representatives Macri, Goodman, and Simmons Introduced: 1/10/2022, referred to the House Health Care & Wellness Committee.		

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Additional Bil	ls to Watch (Not i	n PQAC Jurisdiction)	
Bill # /Companion	Short Title	Committee Action (subject to change)	
SB 5532 / HB 1671 SSB 5532	Prescription drug affordability board.	SB 5532 Pre-filed: 12/10/2021 Sponsors: Senators Keiser, Robinson, Conway, Hasegawa, Pedersen, Randall, Stanford, and Wilson, C. Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing: 1/19/2022 Executive session: 1/24/2022, no action taken.  HB 1671 Pre-filed: 12/20/2021 Sponsor: Representatives Riccelli, Leavitt, Bateman, Valdez, Cody, Macri, Paul, Simmons, Chopp, Tharinger, Kloba, Pollet, Ormsby, Harris-Talley, and Taylor. Introduced: 1/10/2022, referred to House Health Care & Wellness Committee.  SSB 5532 Executive session: 1/28/2022, moved through committee with a "do pass" recommendation, referred to Senate Ways & Means Committee (1/31/2022)	
HB 1813 / SB 5811	Pharmacy choice  — Pharmacy benefit manager rules.	Division track – Monitoring for amendments  HB 1813 Pre-filed: 1/6/2022 Sponsors: Representatives Schmick, Macri, Graham, and Chambers Introduced: 1/10/2022, referred to House Health Care & Wellness Committee Public hearing: 1/24/2022 Executive session: 2/2/2022, action taken  SB 5811 Sponsors: Senator Rivers, Keiser, and Short Introduced: 1/11/2022, referred to Senate Health & Long Term Care Committee.  Division track – Monitoring for amendments	

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Additional Bil	lls to Watch (Not i	in PQAC Jurisdiction)
Bill # /Companion	Short Title	Committee Action (subject to change)
HB 1821 SHB 1821	Definition of established relationship for purposes of audio-only telemedicine.	HB 1821 Pre-filed: 1/6/2022 Sponsors: Representatives Schmick, Riccelli, Cody, and Graham Introduced: 1/10/2022 and referred to House Committee on Health Care & Wellness. Public hearing: 1/17/2022 Executive session: 1/26/2022  SHB 1821 Executive session: 1/26/2022, moved through committee with a "do pass" recommendation. Referred to Rules 2 Review (1/27/2022) Second reading: 2/1/2022
SB 5765 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. Public hearing: 1/26/2022 Executive session: 1/28/2022 @ 8:00 a.m.  SSB 5765 Executive session: 1/28/2022, moved through committee with a "do pass" recommendation. Referred to Senate Rules Committee for second reading (1/31/2022)
<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. Public hearing: 1/17/2022 Executive session: 1/20/2022, moved through committee with a "do pass" recommendation Second reading: 1/25/2022, rule suspended and placed on third reading Floor vote: 1/26/2022, Voted to pass (96/1/0/1) Introduced (Senate): 2/1/2022, referred to House Business, Financial Services & Trade Committee.

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Additional Bil	Additional Bills to Watch (Not in PQAC Jurisdiction)		
Bill # /Companion	Short Title	Committee Action (subject to change)	
SB 5542	Related to the practice of optometry.	SB 5542 Pre-filed: 12/14/2021 Sponsors: Senators Cleveland, Rivers, Conway, Lovick, and Robinson Introduced: 1/10/2022, referred to Senate Health & Long Term Care Committee. Public hearing: 1/26/2022 Executive session: 2/2/2022, action taken	
SB 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. Public hearing: 1/28/2022 Executive session: 2/2/2022, action taken  Division track – Monitoring for amendments	

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