2019 Legislative Report

Oregon Society of Health Systems Pharmacists

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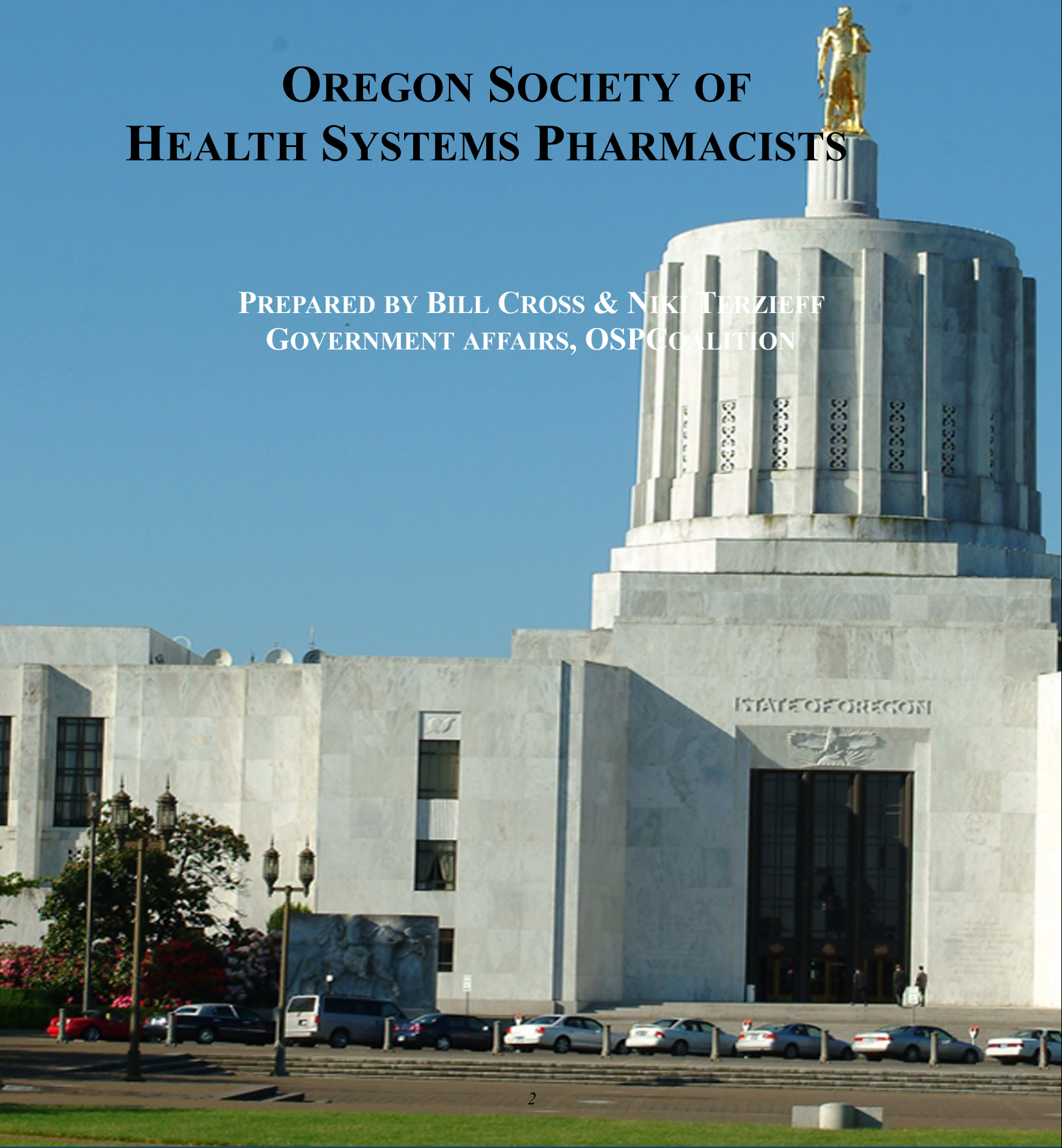

GENERAL SUMMARY

"One of the most dramatic ends to a legislative session in Oregon history"

The reports of this past Legislative Session are wild and wide-ranging…and nearly all true. Democrats would like to remind Oregonians of the good things they were able to do. Republicans would like to remind Oregonians of the bad things they were able to stop. The Governor's office would like to remind Oregonians that she is in fact a part of the process.

As the session began a cloud loomed. Democrats controlled all three branches of policy making government. A Super-Majority in both chambers seeded fear and anxiety well before the legislature convened. With the anticipation of being put through the wringer, Republicans and conservative interests braced for the worst and prepared for a six month stretch of battle. That mindset came through loud and clear as the months progressed. This session was packed full of avoidance, interruptions, threats, admonishments…all of which culminated to help underscore the partisan mess that Americans feel they are suffering under (regardless of which side of the aisle you're on).

It would have been very difficult for you to have missed some word about the Senate Republican Walk Out, the Timber Unity Movement, the threats on the lives of Oregon State Troopers and the standstill to which Oregon's government ground into in June. It would have been slightly easier for you to have missed the engagement of the Governor in the first round of negotiations, when progressive-backed legislation being proposed met its demise without a single vote by an elected official. And even more easily missed would be the work that the House of Representatives - considered the "junior" chamber - plodded on with, quietly and discreetly.

Major packages in housing and tenant protection reforms passed; providing a clearer guide as to when and how prices and housing-stock should fluctuate. Paid Family Leave, a long-awaited program by progressives, was negotiated and became law. A decade's worth of work finally resulted in a simple and straightforward clean air and water negotiation. PERS reform, Public education funding, reforms on Death with Dignity, healthcare delivery systems, cannabis and hemp programs and more silently moved along. Despite so many progressive policies passing, the majority party took slings and arrows from its far reaching left; disappointed that they didn't muscle even more progressive policy wins.

The impact of the overarching narrative, this being one of the most dramatic sessions, is truly yet to be seen. Will the walk out and vitriol only cement the view of the public that government is

broken? Will the civil law suit brought forward to determine whether or not the Senate Republicans will be able to use a denial of quorum again? Should the Governor call a special session, and if so, on which topic? We encourage you to stay engaged and alert with your advocacy team to find out. We'd be remiss if we didn't mention the passing of stateswoman Jackie Winters, who dedicated her life to service, indelibly improved Oregon and will be profoundly missed in the legislature and beyond.

OOJLC Legislative Priorities

For the past seven years, OSHP and OSPA have worked together on advocacy issues through the OSPA/OSHP Joint Legislative Council (OOJLC) which directs a combined approach to legislative issues. The OOJLC works in collaboration with the Oregon Pharmacy Coalition to consolidate discussion points and determine the most efficient process for decision-making and action with respect to pharmacy issues in Oregon. The Coalition assists OSPA and OSHP in identifying the key issues important to our practices, creating workgroups to meet with legislators, and monitoring important legislative concerns. This collaborative relationship has led to a very successful approach to the legislative session with regard to pharmacy interests.

At least once a month during the legislative session the OOJLC conducts the business of legislative oversight and engagement in advocacy. January and February meetings kicked off the session with an examination of the work we knew was ahead of us: continued efforts on PBM reforms, the Governor's Opioid task force, drug take-back programs and keeping an eye on the proposals from the 2018 Pricing Transparency task force.

What we did not anticipate, despite attempting to save bandwidth for outside proposals, was the sheer volume of interest in pharmacy issues. In what can only be described as an out-sized interest, the Oregon State Pharmacy Coalition found itself spread thin and in some uncomfortable positions this last session. Prescribing of insulin and supplies, mandates for label readers for the visually impaired and label translation software showed up with force and moved decidedly through the process. Other items, such as pricing reports, prescribing and dispensing of pseudoephedrine or the threat of importing drugs from Canada in order to contain costs received much attention and created new advocacy needs.

We do not believe the attention and interest in pharmacy, pharmacists and the interplay within the healthcare delivery system is going to relent. We need your voice. The items below and reported on within were only successful (or mitigated) by the time and attention of your colleagues in pharmacy. Please attend our coalition meetings as we get underway for 2020.

Some of the more significant legislation that OOJLC played an active role in during the 2019 Legislative Session included:

Establishes Basic Fair Practices for PBMs

HB 2185 establishes new restrictions on PBMs which will help protect pharmacies and their patients from abuses.
• Allows patients the option to use a local pharmacy instead of mandating use of a mail order pharmacy.
• Allows local Oregon pharmacies to mail or deliver prescriptions to their patients.
• Ensures a pharmacist can alert a patient that a prescription could be purchased at a lower cost if paid out of pocket rather than purchasing through the PBM benefit plan.
• Defines specialty drugs to drugs which cannot be supplied to patients through a retail pharmacy.
• Allows Oregon long term care pharmacies the ability to dispense needed urgent drugs to fragile patients in nursing homes.
• Prevents PBMs from paying 340B pharmacies differently from other similar pharmacies in their networks.
• Creates rules and enforcement provisions requiring PBMs to pay pharmacies, at minimum, their acquisition price for a drug.
• Eliminates retroactive additional fees clawed back after payments from PBMs to pharmacies have already been paid.

This legislation builds on efforts over the past four sessions to address this mostly unregulated industry. PBMs have abused this power by not only slashing reimbursement rates but are actively trying to disadvantage pharmacies in their network so that patients must go to their PBM owned pharmacies.

Introduced at the request of OSPA and OSHP, HB 2185C was unanimously approved by both the House and the Senate and was signed into law by the governor.

Establishes a Drug Take Back Program
HB 3273 established a drug take-back program to allow for the safe disposal of prescription drugs. The bill requires manufacturers of certain drugs that are sold within this state to participate in the drug take-back program and the Board of Pharmacy is authorized to assess fines of up to $10,000 each day a covered manufacturer does not participate. A take-back program operator must be organized as a 501(c)(3) entity and submit its plan to the Department of Environmental Quality for approval for the collection and disposal of drugs.

The covered manufacturers will be required to pay all program costs including the costs of the collection kiosks and disposal services. HB 3273 establishes the criteria for authorized collectors, drop-off sites covered drug collection events and disposal of covered drugs. The bill also requires the program orperators to promote public outreach and education about safe disposal of drugs. The program is voluntary for pharmacies and preempts local jurisdiction programs. The measure requires the program operator to establish at least one drop-off site in each county in this state and per population center, plus an additional drop-off site for every 50,000 residents of the city or town located within a population center. DEQ will be authorized to enter into an agreement with the Board of Pharmacy to inspect the drop-off sites. The

measure also provides DEQ with enforcement authority and allows it to establish fees to pay for the program administration.

OSPA and OSHP were a part of coalition of organizations that supported the measure because increasing the number, convenience and visibility of prescription drug collection sites in Oregon will help decrease access to unused medications that can be found in households, protect Oregon's water quality and allevuiate public safety budgets.

HB 3273 passed in the House by a 57 to 3 vote and unanimously in the Senate.

Prescribing and Dispensing Insulin

SB 9 permits pharmacists to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies. Most importantly, the measure requires health benefit plans and medical assistance programs to provide payment or reimbursement for emergency refills of insulin and associated insulin-related devices and supplies.

In October, 2018, the Board of Pharmacy adopted rules that establish a pharmacist's authority to prescribe drugs and devices approved by the Board's formulary and via protocols recommended by the Advisory Committee. That included insulin and insulin-related devices and supplies. So, while pharmacists can already prescribe and dispense emergency refills and associated insulin-related devices and supplies, there is no statutory requirement that insurers reimburse them for their services related to prescriptions for emergency refills and related devices and supplies. What is not so welcome in the bill is a training requirement which, when the Board of Pharmacy adopted the rule, was not added as the Board determined that pharmacists have the education and competency to prescribe insulin.

SB 9 was approved by a vote of 56 to 3 in the House and a unanimous vote in the Senate. The bill went into effect upon the signature of the governor.

Governor's Opioid Epidemic Task Force Bill

HB 2257 is a result of the Governor's Opioid Epidemic Task Force activity. It establishes a pilot program to treat pregnant individuals suffering from substance use disorders (SUD) and enhances access for individuals receiving treatment for SUD services that are publicly funded. The measure also establishes accreditation standards for SUD programs and improves use of the state's prescription drug monitoring program (PDMP).

Unfortunately, the language regarding the PDMP provisions added a requirement that pharmacies report "the diagnosis code used by the practitioner and the reason for the prescription." This poses a compliance challenge to pharmacies which must report to the PDMP within 72 hours after dispensing a Schedule 2 through 4 drug prescription as the diagnosis code is not required to be included in the prescription nor is there any information as to the "reason for" which is not a medical term. OSPA and OSHP pointed out that getting that information from the providers'

offices within 72 hours will be difficult and put pharmacies in jeopardy of failing to comply with current law. At earlier meetings where this clause was drafted, both the sponsor and PDMP representatives stated that the diagnosis would only be required to be reported if it was known and clearly indicated on the prescription. Pharmacists would not be expected to call to find out diagnosis codes, nor would prescriber be required to put it on the prescription. And, with regard to "reason for" which is not a medical term, nor documented, everyone agreed to remove it, yet the final language included it. This concern was made part of the legislative public record and that the sponsors of the measure stated that they would introduce a bill in 2020 to remedy this if it can't be done by rule.

OSPA and OSHP were generally supportive of the measure but concerned about the PDMP provisions. HB 2257 passed 45-12 in the House and unanimously in the Senate.

Other Bills of Interest

Prescription Drug Price Increase Notification Requirements

HB 2658 requires prescription drug manufacturers to report to the Department of Consumer and Business Services the planned increase in the price of a prescription drug at least 60 days before the date of the increase. In 2018, the Legislature approved HB 4004 which created the Oregon Prescription Drug Price Transparency program and requires manufacturers to file annual reports for each drug with a net yearly price increase of 10 percent or more if the drug costs at least $100 for a month's supply. HB 2658 specifies that the 60-day reporting requirement applies to brand name drugs for which there is a cumulative increase of 10 percent and generic drugs for which there was a cumulative increase of 25 percent or more. The report will include: the date the increase will become effective; the current price of the drug; the dollar amount of the planned price increase; a statement of whether the price increase is necessitated by a change or improvements to the drug; and the year the drug became available for sale in the U.S.

As members of the Oregon Coalition for Affordable Prescriptions, OSPA and OSHP supported the adoption of HB 2658. Approved by both chambers and signed by the governor, the measure will apply to price increases implemented on or after July 1, 2019.

Drug Importation

HB 2689 & SB 409 would have established a state-administered whole drug importation program managed by the Oregon Health Authority to purchase high-cost drugs from wholesalers who purchase drugs in Canada. As of January, 2019, 12 states had introduced similar legislation in an effort to increase price competition in the U.S., and drugs purchased by the program would be distributed to retail pharmacies and outlets.

Although the drug-importation proposal is a well-meaning policy aimed at enhancing consumer access to medications, a goal OSPA and OSHP fully support, the unintended consequences outweigh any potential benefit. We opposed the bills for concerns regarding safety include the following: a lack of likely cost savings, the inability to ensure safety, the irreversibility of damage to patients of inevitable counterfeits, the inability to hold foreign criminal actors accountable when they traffic in counterfeits, a potential additional liability for dispensing a counterfeit medicine that harms a patient, and the loss of integrity in the Drug Supply Chain Security System known commonly as "track and trace."

Both HB 2689 and SB 409 were advanced out the House and Senate Health Care committees respectively but did not make it out of Ways and Means. This issue will likely receive further attention over the next several sessions.

Prescription Readers for Visually Impaired Customers

HB 2935 requires pharmacies to provide access to prescription readers for blind and visually impaired customers effective January 1, 2020. Pharmacists will need to ensure that the prescription label is compatible with the reader. The measure defines "a person who is blind", exempts institutional drug outlets and states that a "prescription reader" means a device that is designed to audibly convey the information contained on the label of a prescription drug. The Board of Pharmacy is directed to adopt rules to implement the legislation.

OSPA and OSHP did not take an official position on the bill but did express concerns about the costs imposed on pharmacies to provide this service as well as apparently there is only one vendor for prescription readers and uncertainty about how the product is being marketed to pharmacies. The measure passed 41-19 in the House and 19-9 in the Senate and has been signed into law by the Governor.

Prescribing and Dispensing Pseudoephedrine

HB 2303 would have allowed pharmacists to prescribe and dispense pseudoephedrine products. It would have required individuals buying such products to be over 18 years of age and to provide government-issued photo identification and directs the pharmacist to run a search for the purchaser using the PDMP. It would have limited the transfer of pseudoephedrine to 9 grams per individual in a 30-day period and directed the Board of Pharmacy to adopt rules to implement the legislation.

The House-approved version of HB 2303 would have required the use of the National Precursor Log Exchange (NPLEx) as opposed to the PDMP. However, the Senate-approved version amended the bill to require the use of the PDMP. It passed in the Senate but died in the House during the closing days of the session. OSPA and OSHP were neutral on the proposed legislation.

Prescription Label Translation Policy

SB 698 requires the pharmacies to provide prescription drug labels and inserts in both English and a language the patient can understand. It directs Board of Pharmacy to adopt rules to require that prescription drugs be labeled in English and other language upon request of a practitioner, patient or patient representative. The measure allows the board to determine prescription drugs for which an additional informational insert in English and other language may be included and requires that labels and informational inserts be available in at least 14 languages other than English. The board will update available languages at least once every 10 years. Institutional drug outlets are exempt from the requirements. The board will adopt rules to require pharmacy to post signage regarding patients' right to free, competent oral interpretation and translation services.

OSPA and OSHP took no official position on the bill but communicated concerns about the mandated costs, the short timeline for implementation and the availability of the technology to provide a label that is readable written in both English and the patient's language. The bill sponsors did agree to change the operative date from January 1, 2020 to January 1, 2021. SB 698 passed and was signed into law by the Governor.

Task Force on Fair Pricing of Prescription Drugs Legislation

SB 872 would have implemented several of the Task Force on Fair Pricing of Prescription Drugs recommendations regarding transparency for drug prices across the entire supply chain of pharmaceutical products. Of most interest to OSPA and OSHP were provisions that would: require carriers to provide written notice of at least 60 days in advance of a change to the prescription drug formulary that will adversely affect the enrollee; establish a consumer's right to be educated about all means available to reduce the cost for a prescribed drug; require insurers, pharmacy benefit managers and third party administrators to apply toward any deductible or out-of-pocket maximum imposed under a consumer's pharmacy benefit the price paid by a consumer to purchase a prescription drug covered by the pharmacy benefit regardless of whether the consumer used the pharmacy benefit to purchase the drug; requires pharmacy benefit managers to report to DCBS and plan sponsors with specific information regarding rebates, reimbursements, fees, and incentives paid for drugs by manufacturers, insurers, and pharmacies; and, requires manufacturers who advertise a prescription drug to disclose the wholesale price paid by pharmacies located in the state.

While OSPA and OSHP took no official position on SB 872, a number of the other stakeholders who were a part of the task force opposed the bill that was referred to Ways and Means. It finally came out of Ways and Means the least weekend of the session but never made it to the Senate floor for a vote. More to come next session!

Removing Barriers to Naloxone Access

SB 910 removes barriers to accessing naloxone and methadone by making naloxone kits more reality available and giving local authorities flexibility to waive methadone clinic siting restrictions. The bill allows pharmacists to offer to prescribe and provide naloxone kits when dispensing an opiate or opioid prescription and authorizes the Board of Pharmacy to establish by

rule appropriate does that pharmacists may prescribe. Pharmacies, health care professionals and pharmacists will be allowed to distribute multiple naloxone kits to social service agencies and other people, who work with individuals who have experienced an opiate overdose, for redistribution to individuals, or family members of individuals, likely to experience an opiate overdose. The measure also contains a requirement that retail and hospital outpatient pharmacies provide written notice that naloxone and necessary supplies are available at the pharmacy.

OSPA and OSHP monitored the bill which passed both chambers and has been signed into law. It will take effect on the 91st day following adjournment sine die.

Prior Authorization Legislation

SB 139 and SB 249 addressed prior authorization. SB 249, which passed and was signed into law, prohibits certain unfair claim settlement practices by health insurers making prior authorization determinations. The measure prohibits health insurers from engaging in a pattern or practice of refusing to approve requests for prior authorization of covered items without just cause.

SB 139 would have required health insurers to approve prescription drug prior authorization requests for a consecutive 12-month period if the use of the drug is based on clinical evidence and the patient continues to be insured during the 12-month period. It would have required insurers to establish prior authorization and step therapy protocols that are evidence-based and updated based on new evidence and research. The measure would have allowed providers who have requested prior authorization or utilization management exceptions to exercise enrollee's internal appeal and external review rights upon request to the enrollee. Sponsored by the Oregon Medical Association, the bill was more contentious and died in Ways and Means.

OSPA and OSHP monitored both bills.

Opioid Taxation

HB 3192 would have imposed an assessment of $0.01 per morphine milligram equivalent per year on each manufacturer of prescription opioids dispensed in Oregon for use in the prevention, treatment, and safe recovery from opioid addiction and other substance use disorders.

OSPA and OSHP monitored this bill which died in the House Revenue Committee.

Drug Substitution Bills

HB 2753, HB 2754 and HB 2755 would have required pharmacists to substitute a prescribed brand name drug with a generic name drug product and to substitute a prescribed biological product with an interchangeable biological product.

OSPA and OSHP opposed these measures which died in House Health Care.

This report has been prepared by OOJLC's government affairs advocates Bill Cross and Niki Terzieff.