



# Oregon State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **No. 608 – A Message From the Board’s New Executive Director, Joseph “Joe” Schnabel, PharmD, RPh, BCPS**

I am excited to have been selected as the executive director of the Oregon State Board of Pharmacy and to work with Board members and staff who are committed to protecting the public health, safety, and welfare of Oregonians. I would like to thank Marcus “Marc” Watt, RPh, who led the Board through many changes in pharmacy practice that have enhanced the ability of pharmacists and technicians to make a positive impact on patient care and public health.

Since graduating from Oregon State University (OSU) and Purdue University, I have spent the last 31 years working at Salem Hospital as the clinical pharmacy manager and director of pharmacy. It was difficult to leave the challenging and fast-paced hospital environment and even more so, the great coworkers and friends that I had the privilege to work with over the years.

My service as a Board member from 1993 through 2001 has helped me understand the important role the Board has in serving the public and the profession. I also learned that behind the scenes are dedicated Board staff who work hard to implement Board actions and serve the nearly 30,000 licensees and registrants. I am happy to be part of this great team! While on the Board, I served as chair of the Collaborative Drug Therapy Management Task Force, which provided structure and legitimacy to pharmacists working collaboratively with physicians on managing drug therapies for patients in all practice settings. Another landmark of my years on the Board was working to implement the Oregon Death with Dignity Act and the process for transmitting and filling prescriptions written under the Act.

Priorities for my leadership as executive director will include building on the Public Health and Pharmacy Formulary Advisory Committee process, leading the

development and implementation of a comprehensive strategic plan, and continuing to improve service to the public and our licensees. The practice of pharmacy in Oregon is widely seen as progressive in providing patient-centered pharmacy care and the Board’s goal is to continue to regulate sensibly in order to achieve the best outcomes for our patients.

## **No. 609 EPT – Clarity for Pharmacists and Practitioners**

*By Michael Sidener and Justin Chen, 2019 PharmD Candidates, OSU College of Pharmacy, in coordination with the HIV/STD/TB Section of OHA*

Oregon is in the midst of an epidemic of sexually transmitted infections (STIs). Over the past decade, rates of gonorrhea and chlamydia have increased exponentially. Expedited partner therapy (EPT), the practice of prescribing or dispensing an antibiotic for the treatment of an STI to the partner of a patient without first examining that partner, represents a critical public health intervention to reduce the transmission of gonorrhea and chlamydia in Oregon. The first-line strategy for managing partners of patients diagnosed with gonorrhea or chlamydia is to have all exposed sex partners evaluated, tested, and treated for STIs by a health care provider. EPT represents an alternative partner management strategy for patients’ partners for whom prompt medical evaluation and treatment cannot otherwise be ensured. In a large community-randomized trial conducted throughout Washington State, implementation of EPT resulted in a 10% reduction in the prevalence of chlamydia and incidence of gonorrhea among women.

EPT was authorized by the Oregon State Legislature in 2009 and implemented under Oregon Revised Statute (ORS) 676.350. The purpose and procedure for providing EPT prescriptions are outlined in Oregon Administrative Rules (OAR) 855-041-4000 and 855-041-4005. The Oregon Health Authority (OHA) publishes the EPT

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# National Pharmacy Compliance News

May 2019



**NABPF**

National Association of Boards  
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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

## **FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach**

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

## **FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements**

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

## **Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse**

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD<sup>®</sup> Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at [www.nabp.pharmacy](http://www.nabp.pharmacy).

### ***New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade***

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

### ***FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls***

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

### ***FDA Releases Two Draft Guidances Related to REMS Programs***

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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protocol for health care providers, which indicates that EPT may be provided to the patient and made available to his or her partner(s). This means it is legal for a clinician to evaluate his or her patient and determine that the patient and partner(s) require antibiotic treatment. The clinician can then issue prescriptions to treat the patient and partner(s). The clinician may directly dispense the medication to the patient for the patient and his or her partner(s), maintaining appropriate dispensing records, or provide prescriptions to be filled at a pharmacy.

A health care provider may prescribe EPT by submitting a prescription that contains the words “expedited partner therapy” or “EPT” electronically, verbally, or in writing to a pharmacy. Providers may write a prescription in the name of the partner (if it is known) or using a generic name, such as “EPT Patient.” The patient or partner(s) may then present the prescription to the pharmacy to get it filled. However, the provider does not often know the name of the patient’s partner(s), and electronic medical record systems may not allow prescriptions to be submitted electronically for unnamed partners. A prescriber may issue an EPT prescription in the name of the patient that includes separate doses for each unnamed partner. When a pharmacy receives an EPT prescription for a patient and his or her partner(s), the pharmacy shall process and dispense a unique prescription to each individual patient. A prescription for EPT is valid even without the name of the intended recipient. Note that an EPT prescription is valid for 30 days and is not refillable.

EPT prescriptions can be dispensed using “EPT Patient” in lieu of a name on the dispensed medication label. A pharmacist shall ask about known allergies but is not required to collect the EPT patient’s or partners’ names, addresses, contact information, or demographics. The pharmacist shall provide counseling and written drug information to patients filling EPT prescriptions with additional drug information for their partners. EPT is not currently covered by insurance if the EPT prescription is not filled by the partner for whom the medication is intended. Licensed providers who prescribe/dispense EPT and pharmacists who dispense EPT, in accordance with

ORS 676.350 and OAR 855-041-4000 through 855-041-4005, are following legal, evidence-based practice. The most up-to-date EPT guidelines, including the drugs permitted, can be found on OHA’s STD Prevention [website](#).

### **No. 610 Fee Increases**

Per the [notice sent to licensees](#) on November 13, 2018, the Board included fee increases in its 2019-2021 operational budget request. Governor Kate Brown and the legislature have since approved the proposed increase in fees. The Board operates solely on licensing and miscellaneous fees. The last overall fee increases for the Board were in 2001. There was a fee increase in 2011-2013 for a number of categories; however, the majority of these were reversed in 2013 back to the 2001 rates due to an unanticipated high ending balance, and the temporary fee reduction process has continued. Since then, biennial licensure was implemented beginning in 2015 without a fee adjustment for pharmacists, certified pharmacy technicians (CPTs), and pharmacy technicians, who have all received a two-year license for the price of a one-year license. New fees for these categories will not impact current licensees until their next renewal in 2020 (for CPTs) or 2021 (for pharmacists). Any new applicants in these categories and all other categories for new and renewing licensees/registrants are projected to be impacted on or after July 1, 2019, when new rules will go into effect. The Board has published a notice for a rulemaking hearing for Wednesday, May 22, 2019, to receive public comment on the proposed changes. Visit the Board’s [website](#) for more information.

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