November 2018

News

Delaware State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Legislation Signed into Law

Governor John Carney has signed a number of bills into law that will have an impact on pharmacy. Below is a synopsis of each bill, the date it was signed into law, and a link to the full text of the bill.

- **House Bill (HB) 441 synopsis:** Because of the delay in the prior authorization process by pharmacy benefits managers (PBMs), many patients end up waiting days or weeks for medications to be filled that are prescribed on an emergency basis or for medications that have been previously prescribed for chronic and long-term conditions that must go through the prior authorization process again. To reduce the delays and hardships of this waiting process, this bill will put into place specified time tables to fill emergency prescriptions and make subsequent prior authorizations for chronic and long-term conditions filled more readily.

  This bill was signed into law on August 28, 2018, and can be reviewed in full at *https://legis.delaware.gov/json/BillDetail/GenerateHtmlDocumentEngrossment?engrossmentId=13194&docTypeId=6.*
- **HB 425 synopsis:** This act establishes that a contract between a PBM and a pharmacy may not prohibit a pharmacy or pharmacist from doing any of the following:
  1. Providing an insured person with information regarding the retail price of a prescription drug or the amount of the cost share for which the insured person is responsible for paying for a prescription drug.
  2. Discussing information with an insured person that regards the retail price of a prescription drug or the amount of the cost share for which the insured person is responsible for paying for a prescription drug.
  3. If a more a ordable, therapeutically equivalent prescription drug is available, selling the more a ordable, therapeutically equivalent prescription drug to the insured person.

  In some cases, contracts between PBMs and pharmacies have provisions that prohibit pharmacies or pharmacists from informing consumers that they have options related to a prescription drug they want to buy and that a prescription drug could be purchased at a lower cost if consumers paid out of pocket rather than through their health insurance plan. These provisions are often known as "gag clauses." At least seven states have enacted laws prohibiting these gag clauses. This bill was signed into law on August 28, 2018, and can be reviewed in full at *https://legis.delaware.gov/json/BillDetail/GenerateHtmlDocumentEngrossment?engrossmentId=13165&docTypeId=6.*
- **HB 331 synopsis:** This bill creates regulations concerning the use, distribution, and education of benzodiazepine and non-benzodiazepine hypnotics. It requires practitioners to obtain consent from a minor's parent or guardian prior to prescribing these drugs and requires the pharmacist to include a cautionary statement explaining the risks associated with the long-term use of these drugs. This bill was signed into law on September 4, 2018, and can be reviewed in full at *https://legis.delaware.gov/json/BillDetail/GenerateHtmlDocumentEngrossment?engrossmentId=2931&docTypeId=6.*
- **Senate Bill 157 synopsis:** Expedited partner therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with a sexually transmitted disease without clinical assessment of the partners. In August 2006, the Centers for Disease Control and Prevention recommended EPT as an evidence-based option to manage chlamydial infections and gonorrhea by treating index patients' sex partners to prevent reinfection and curtail further transmission. As of July 2017, EPT is permissible in 41 states. This act makes EPT clearly permissible in Delaware and requires health care professionals to provide information developed by the Delaware Department of Health

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National Pharmacy Compliance News

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NABPF
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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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and Social Services when providing EPT. This act provides immunity to health care practitioners and pharmacists acting in compliance with the statute and also provides immunity to health care practitioners who do not provide EPT and pharmacists who do not fill a prescription written under this statute if doing so would violate any of the laws that govern pharmacies and pharmacists. This act also makes technical corrections to the definitions section to correct a reference and to conform existing law to the standards of the Delaware Legislative Drafting Manual.

This bill was signed into law on August 29, 2018, and can be reviewed in full at *https://legis.delaware.gov/json/BillDetail/GenerateHtmlDocumentEngrossment?engrossmentId=2965&docTypeId=6.*

Community and Hospital PIC Annual Self-Inspection Report Reminder

The pharmacist-in-charge (PIC) self-inspection report for all Delaware pharmacies must be completed by February 1, 2019. The report must be completed and signed by the PIC. The report does **not** need to be sent in to the Delaware State Board of Pharmacy, but must be kept in a manner in which it is readily retrievable for Board inspectors.

The form is available on the Board's website at *https://dprfi es.delaware.gov/pharmacy/Pharmacist-in-Charge_Self-Inspection.pdf.*

Board Legislative Committee Meetings

Just a reminder, the Board's legislative committee meets on the fir t Wednesday of each month immediately following the Board meeting. Currently, the committee is working on updating the entire state pharmacy statute. The meetings are open to the public and give an opportunity for comment.

The *Delaware State Board of Pharmacy News* is published by the Delaware State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the officia views, opinions, or policies of NABPF or the Board unless expressly so stated.

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