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Board Members

Assembly Bill 474

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Nevada Assembly Bill (AB) 474 was indeed the start of a new era for prescribing controlled substances (CS). Any time there are changes within the law, it may create some confusion and require clarification. A newly approved regulation of the Nevada State Board of Pharmacy, effective on June 26, 2018, provides information to clarify and expand sections of the bill.

The first matter of business was to define the terms "acute pain" and "course of treatment." Legislative Counsel Bureau (LCB) File No. R047-18 defines "acute pain" as "pain that has an abrupt onset and is caused by injury or another cause that is not ongoing. The term does not include chronic pain or pain that is being treated as part of care for cancer, palliative care, hospice care or other end-of-life care."

LCB File No. R047-18 defines "course of treatment" as "all treatment of a patient for a particular disease or symptom of a disease, including, without limitation, a new treatment initiated by any practitioner for a disease or symptom for which the patient was previously receiving treatment." The intent of defining "acute care" and "course of treatment" was to help prescribers and other health care professionals understand the initial prescription policies outlined in AB 474.

Nevada Revised Statutes (NRS) 639.23911, Chapter 605, Page 4431, AB 474, Section 53, requires a practitioner to obtain informed written consent from a patient prior to issuing a CS prescription. How does this work in a group practice where a patient may see a number of practitioners within the practice? LCB File No. R047-18 provides guidance for what can be included as obtaining informed written consent:

1. Viewing informed written consent . . . previously given by the patient and stored on a database maintained by the practitioner or a group of practitioners with which the practitioner is associated; and
2. Immediately before prescribing the controlled substance, discussing the provisions of the informed written consent . . . with the patient, allowing the patient to ask questions about those provisions and answering those questions.

Similarly, there were questions presented to the Board about the prescription medication agreement, how it can be obtained from the patient, and when a practitioner or group of practitioners are allowed to share the consent. As part of the new regulations, a patient may enter into a prescription medication agreement with a group of practitioners in satisfaction of the requirements of NRS 639.23914, Chapter 605, Page 4433, AB 474, Section 56. In addition, this section of the law is satisfied if the patient enters into an agreement with a member or another agent of the group who has the authority to enter into the agreement on behalf of the group. Furthermore, if a practitioner or group of practitioners enters into a prescription medication agreement with a patient before issuing a prescription for which such an agreement is required, the prescribing practitioner must review the

continued on page 4

National Pharmacy Compliance News

October 2018

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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.*

continued from page 1

agreement immediately before issuing the prescription and update the agreement if necessary.

To prescribe a CS to a patient, the prescriber must review his or her medical history and perform a physical examination on the patient. A practitioner must make a good faith effort to obtain and review the medical records of the patient, as required by NRS 639.23912, Chapter 605, Page 4431, AB 474, Section 54. Does this mean that all medical records of a patient must be reviewed by any practitioner who intends to prescribe a CS to the patient? Does this also mean that a full physical examination must be performed by a practitioner on a patient if the practitioner intends to prescribe a CS to the patient? The new regulation states that a practitioner has met this requirement if the practitioner makes an effort to obtain all medical records, which in the professional judgment of the practitioner are necessary to determine whether to prescribe a CS listed in Schedule II, III, and/or IV to the patient. The practitioner conducting the review of the medical records and physical examination of a patient shall target the review and examination to the condition causing the pain of the patient. In determining whether a medical record is necessary to make such a determination, a practitioner may consider:

1. The time needed to provide care to the patient;
2. The nature of the practice of the practitioner; and
3. If the benefit of prescribing the CS without obtaining the medical record outweighs the risk of doing so.

Finally, AB 474 states that when a practitioner is reviewing a patient's prescription monitoring program report, or any other sources, and determines that the patient has been issued the same CS that provides ongoing treatment for the same condition, the practitioner shall not prescribe the same CS for the same condition. However, the Board does not construe NRS 639.23507 to prohibit a practitioner from:

1. Prescribing a CS to a patient who has been issued another prescription for a different CS;
2. Increasing the dosage of a CS that has been prescribed to a patient; or
3. Prescribing a CS for the purpose of:
   a. Continuing the same course of treatment for which the patient has previously been prescribed the same CS; or
   b. Replacing doses of the CS that have been lost, stolen, or destroyed.

These approved regulations are from the Board and can be reviewed in more detail on the Board's official website and by accessing the links below.

- AB 474 is available at *https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5735/Text.*
- LCB File No. R047-18 is available at *https://www.leg.state.nv.us/Register/2018Register/R047-18AP.pdf.*

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