MARCH 2023

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

NarxCare Scores – A Refresher

Narx Scores are provided by the Iowa Prescription Monitoring Program (PMP) as part of a patient's NarxCare report. Narx Scores provide an additional tool to help providers evaluate a patient's risk profile. Currently, there are four different scores available: Narcotic, Sedative, Stimulant, and Unintentional Overdose Risk. Scores range from 000 to 999 and reflect past patient exposure to narcotics (opioids), sedatives, and stimulants, with higher scores representing a relatively higher risk of overdose or potential misuse. Other factors used to calculate Narx Scores include the number of prescribers and pharmacies, co-prescribed drugs, overlapping prescription days, and the quantity and doses of medication dispensed. The number in the third position (00X) represents the number of active prescriptions under that category. For example, a Narcotic Narx Score of 234 would indicate that a patient has four active narcotic prescriptions.

In an average patient population, Narx Scores will be low for most patients, with 75% of scores being less than 200. In this sample patient population, approximately 5% of scores will be more than 500, while approximately 1% will be greater than 650. It is important to note that the Narcotic Score may contribute to the Sedative Score and vice versa. As a result, a patient may have a Narcotic Score even when they have not been prescribed a narcotic. Of note, there is no "normal" score, and scores should be evaluated on a patient-by-patient basis. A high Narx Score is not necessarily an indication of abuse, and scores alone cannot be used to determine the appropriateness or misuse of medications. Rather, scores are intended to provide clinical guidance and generate patient-provider discussions. Scores are not intended to be used in isolation or as a replacement for clinical decision making.

National Pharmacy Compliance News
A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

DATA-Waiver Program Eliminated

To increase access to buprenorphine for the treatment of opioid use disorder, the "DATA-Waiver Program" has been eliminated. On December 29, 2022, Congress signed the Consolidated Appropriations Act of 2023 (the Act), promulgating the following changes:

- A DATA-Waiver registration [or X-DEA number] is no longer required to treat patients with buprenorphine [or to prescribe buprenorphine] for opioid use disorder.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for opioid use disorder with buprenorphine.
- The Act does not impact existing state laws or regulations that may be applicable.

A pharmacist is still required to exercise sound professional judgment when determining the legitimacy of a controlled substance (CS) prescription.

CS Reconciliation

The Iowa Board of Pharmacy's new rule (657 Iowa Administrative Code (IAC) 10.20), which became effective July 6, 2022, provides various mechanisms whereby a pharmacy can ensure the accountability of the Schedule III-V substances it maintains. In addition to a perpetual inventory for all Schedule III-V substances, pharmacies have the option to conduct a documented audit and reconciliation every six months or document cycle counts every 90 days, so long as all CS are counted during each 90-day period. Within these two accountability measures is the expectation for reconciliation of discrepancies that are discovered. Pharmacies should be reminded that conducting a reconciliation on any discrepancy includes an evaluation, investigation, or review of the situation to determine the source of the discrepancy. A reconciliation does not simply mean making a manual correction to the record to match the on-hand count. Board inspections and investigations may include a review of such audits or cycle counts, and pharmacies will be expected to provide documentation of the action taken in response to any discrepancy found as part of the audit or cycle count and reconciliation.

Rules Recently Adopted by the Board – PMP Updates

At its January meeting, the Board adopted rulemaking that implements changes made to the PMP Advisory Council enacted during the 2022 Iowa Legislative session (House File 2201). The Iowa Code changes converted the council from governor appointed to Board appointed; adjusted the minimum composition of the council membership; and directed the Board to adopt rules on matters pertaining

to council membership, including terms of appointment and quorum. The adopted rules provide a list of professionals or individuals who may serve on the council; set an appointment term of three years, which may be extended no more than two additional terms and expires on June 30 of the third year of the term; set a quorum at three council members; and provide conditions for termination of an appointment.

The rulemaking also clarified that only opioid antagonists intended to reverse an opioid-related overdose are required to be reported to the PMP. Questions have been raised related to other opioid antagonist products, such as Contrave®, and reporting requirements. The amendment seeks to clarify that opioid antagonists that are not intended for overdose reversal are not required to be reported to the PMP.

The rules were published in the February 8, 2023 *Iowa Administrative Bulletin* with an effective date of March 15, 2023.

Basic Alarm System/Video Surveillance Requirements – Reminder of July 6, 2023 Implementation Deadline

Each community pharmacy located in Iowa that holds a general pharmacy license is reminded of the coming implementation deadline for the Board's new subrule IAC 657—6.7(5), which was adopted by the Board in May 2022. The requirements, most of which became effective on July 6, 2022, require implementation of policies and procedures to ensure appropriate physical security and monitoring of the pharmacy to prevent unauthorized access to prescription drugs, including CS, and pharmacy records. Components included in the monitoring requirements that were given a delayed enforcement date were the utilization of basic alarm and video surveillance systems. These required components must be in place no later than July 6, 2023. The pharmacy's policies and procedures related to the use of basic alarm and video surveillance systems must establish the retention of documentation of activities or recordings retained from the systems, as well as contingencies when the systems are temporarily unavailable.

USP Chapters <795> and <797> Revisions Finalized; Enforceable November 2023

Pursuant to Board rules 657 IAC 20.3 for nonsterile compounding and 20.4 for sterile compounding, pharmacies located in Iowa are required to follow the "current revision" of the applicable United States Pharmacopeia (USP) chapter standards (Chapter <795> for nonsterile compounding and Chapter <797> for sterile compounding). USP published proposed revisions in 2018, but the revisions were appealed in 2020. After further review and consideration, USP published its final revision for General Chapters <795> and <797> on November 1, 2022. The revised standards will become "official" and enforceable on November 1, 2023. Although the standards will not be enforceable until November 1, 2023, pharmacies are encouraged to adopt the revised standards early where possible. The Board

will continue to remain flexible with compounders who are working toward compliance with the new revised standards, which may not align with the current official version of 2014.

Fraudulent Prescriptions – What to Watch Out for

Fraudulent prescriptions are a constant concern for pharmacists and increasingly difficult to identify. However, action taken by Drug Enforcement Administration (DEA) against a pharmacy in Florida provides valuable insight and guidance for pharmacies in this practice area (86 *Federal Register* 72694/December 22, 2021). The DEA case emphasized that "red flags are circumstances surrounding a prescription that cause a pharmacist to take pause, including signs of diversion or the potential for patient harm." Red flags addressed in this case included:

- Cocktail medications – DEA found that dispensing cocktail medications requires documentation of investigation and resolution.
- Improper dosing for pain management – DEA's expert asserted that proper pain management for patients receiving both long-acting and short-acting opioids is to use larger, scheduled doses of long-acting opioids for control of chronic pain with smaller, as-needed doses of short-acting opioids for breakthrough pain.
- Long distances traveled – although the distances traveled in this case, ranging between 30 to 50 miles round trip, were not ultimately impactful in this case, this can still be a factor that is considered when completing an assessment for legitimacy.
- Payment in cash – cash payments are especially suspicious when the patient utilizes a third-party payer for other prescriptions but pays cash for a CS prescription.
- Price gouging – when a patient insists on filling their CS prescriptions at a suspicious pharmacy that charges inflated prices for the substances, it may indicate the prescriptions are fraudulent and that the suspicious pharmacy may be aware of the illegitimacy of the prescriptions.

DEA Administrator Anne Milgram noted that the presence of a red flag does not prohibit a pharmacist from filling a prescription, but it "means that there is a potential concern with the prescription, which the pharmacist must address and resolve, and . . . make a record of its resolution, assuming it is resolvable."

Pharmacist License Renewal – CE Requirements

As a condition for license renewal, pharmacists must complete at least 30 hours of continuing education (CE). Required specific Accreditation Council for Pharmacy Education (ACPE)-accredited topics include the following:

- patient/medication safety (ACPE topic designator "05") – two hours;
- pharmacy law (ACPE topic designator "03") – two hours;

- drug therapy (ACPE topic designators “01” or “02”) – 15 hours; and
- immunization, if engaged in the administration of immunizations (ACPE topic designator “06”) – one hour.

The Board conducts random audits of pharmacist license renewals each year to ensure compliance with these requirements. If you are selected for a CE audit and your National Association of Boards of Pharmacy® CPE Monitor® records indicate insufficient hours, you will receive a notice from Board staff with a request for documentation or evidence of completion of the required CE. Pharmacists are encouraged to routinely review CPE Monitor (for the applicable renewal period) to ensure that all CE is recorded and compliant.

Podcast: BOP What, Why & How

Following each Iowa Board of Pharmacy meeting, the Iowa Pharmacy Association (IPA) hosts the *BOP What, Why & How* podcast. This podcast explains “what” actions were taken by the Board, “why” the Board took those actions, and “how” pharmacy practice in Iowa is affected.

This podcast is recorded in collaboration with IPA and Board staff and can be downloaded wherever you listen to podcasts. Members of IPA can obtain law CE included with membership. CE credit may also be purchased without IPA membership.

To subscribe to the podcast, access recent episodes, and learn how to obtain CE credit, scan the QR code or visit *www.iarx.org/bop_podcast.*

The Iowa Board of Pharmacy News is published by the Iowa 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 official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Andrew Funk, PharmD - State News Editor
Lemrey “Al” Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Megan Pellegrini - Publications and Editorial Manager

400 SW 8th St, Suite E | Des Moines, IA 50309-4688 | Tel: 515/281-5944
Fax: 515/281-4609 | pharmacy.iowa.gov