

## CONTROLLED SUBSTANCES BOARD

4822 Madison Yards Way  
PO Box 8366  
Madison WI 53708

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Secretary



Email: [dspd@wisconsin.gov](mailto:dspd@wisconsin.gov)  
Voice: 608-266-2112  
FAX: 608-251-3032

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### **GUIDANCE REGARDING THE DESIGNATION OF GABAPENTIN AS A MONITORED PRESCRIPTION DRUG**

#### **Background Facts**

Gabapentin is a prescription medication approved by the U.S. Food and Drug Administration for the treatment of neuropathic pain and epileptic disorders. In recent years, however, Gabapentin has been increasingly encountered by law enforcement, documented in national crime lab reports, reported to poison control centers, and diverted for illicit use. The Researched Abuse, Diversion and Addiction – Related Surveillance (RADARS) System indicates an increase in Gabapentin diversion. The Drug Abuse Warning Network (DAWN) indicates a rise in emergency department visit rates for Gabapentin.

The Wisconsin Controlled Substances Board (CSB) and the Prescription Drug Monitoring Program (PDMP) staff have received requests by health care practitioners and law enforcement to have Gabapentin included in the PDMP. Prescribers have indicated it is beneficial to be aware of a patient having a prescription for Gabapentin prior to prescribing an opioid because, when combined with opioids, there is an increased risk of respiratory depression and opioid-related mortality increases significantly. Gabapentin is sought after for illicit use due to its potentiating opioid effect.

#### **Action Taken**

In response to the facts above, the CSB has adopted Clearinghouse Rule 20-080 relating to designating Gabapentin as a prescription drug having a substantial potential for abuse, and therefore a monitored prescription drug pursuant to Wis. Stat. § 961.385 (1) (ag). Gabapentin is now listed in Wis. Admin. Code § CSB 4.03 (2) as a monitored prescription drug effective September 1, 2021.

#### **Gabapentin Has Not Been Scheduled as a Controlled Substance**

Gabapentin has been designated as a monitored prescription drug, not a controlled substance. A DEA registration number is not required for a practitioner to prescribe Gabapentin, nor is a DEA registration number required for a dispenser to fill a prescription for Gabapentin.

#### **Practical Impact for Many Prescribers and Dispensers of Gabapentin**

Because Gabapentin has been designated a monitored prescription drug, a practitioner now must review a patient's prescription drug history as required by Wis. Admin. Code § CSB 4.105 prior to prescribing Gabapentin. Additionally, dispensers must report into the PDMP as required under Wis. Admin. Code § CSB 4.05 when dispensing Gabapentin.

#### **Exemptions Where the Lack of a DEA Registration Number Causes a Dispensing Reporting Error or Prevents Practitioner Access to the PDMP**

A DEA registration number is currently required information for all submissions to the PDMP. Reporting of Gabapentin without a valid prescriber or pharmacy DEA registration number will trigger a submission error and the record will not be accepted by the PDMP. As a result, a dispenser will be excused from

their duties to report Gabapentin dispensing information, and may void the dispensing record, where one of the following is true:

- The dispenser does not have a DEA registration number.
- The dispenser is attempting to report Gabapentin dispensing data where the prescribing practitioner does not have a DEA number.
- The dispenser is attempting to report Gabapentin dispensing data where the prescribing practitioner has not provided their DEA number with the prescription order.

To emphasize the third bullet point above, dispensers are not obligated to correct Gabapentin dispensing records where the prescriber's DEA number has been omitted from the prescription order. These Gabapentin dispensing records missing a prescriber DEA number may be voided.

Similarly, a DEA registration number is required for a practitioner to access the PDMP system. Because of this, a practitioner who does not have a DEA registration number is exempt from the general requirement to review a patient's prescription drug history report prior to prescribing Gabapentin.

Updated instructions for revising or voiding erroneous submissions of Gabapentin dispensing with missing DEA information is available in the Data Submitter Guide.