10/20/2021 Pharmacy Ex. Bd. - After item H ADD: Guidance Document Regarding the Designation of Gabapentin as a Monitored Prescription Drug

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request: Adam Barr, Executive Director, Controlled Substances Board		**2) Date when request submitted:** 10/15/21 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting
3) Name of Board, Committee, Council, Sections: Pharmacy Examining Board		
4) Meeting Date: 10/20/21	**5) Attachments:** ☒ Yes ☐ No	**6) How should the item be titled on the agenda page?** Guidance Document Regarding the Designation of Gabapentin as a Monitored Prescription Drug
7) Place Item in: ☒ Open Session ☐ Closed Session	**8) Is an appearance before the Board being scheduled?** *(If yes, please complete Appearance Request for Non-DSPS Staff)* ☐ Yes ☐ No	**9) Name of Case Advisor(s), if required:**

10) Describe the issue and action that should be addressed:

Review and provide feedback on Controlled Substances Board guidance document regarding the designation of Gabapentin as a monitored prescription drug.

11) Authorization

Adam Barr — 10/15/21

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

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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.

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 Most 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 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.

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.