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Circular Letter: BHPL-DCP 17-5-101

TO: Massachusetts Pharmacies

FROM: James G. Lavery
Director, Bureau of Health Professions Licensure 

DATE: May 10, 2017

RE: Changes to the Prescription Monitoring Program (PMP) Reporting Requirements

The purpose of this circular letter is to inform Massachusetts pharmacies of recent changes to the reporting requirements for the Prescription Monitoring Program (PMP). Per legislative mandate, the Commissioner of Public Health has designated Gabapentin as an additional drug for the purposes of reporting to the PMP. This letter outlines the steps, divided into two phases, needed to fulfill the state law requirement to submit all dispensed Gabapentin, a Schedule VI medication, prescriptions into the PMP via the PMP Clearinghouse. Pharmacies will need to comply with the first phase of this requirement by August 1, 2017. Additional changes in reporting requirements are also detailed in this correspondence.

Background

As you know, state law requires each pharmacy that dispenses a controlled substance in Schedule II to V, or a substance classified as an additional drug by DPH, must submit information for each such prescription dispensed to DPH for the purposes of monitoring prescribing and dispensing.

By enacting Section 69 of Chapter 52 of the Acts of 2016 the Massachusetts legislature required DPH to promulgate regulations to classify Gabapentin and its chemical equivalents as additional drugs for the purposes of section 24A. Regulation changes to 105 CMR 700.000 (*Implementation of M.G.L. c. 94C*), promulgated on May 5, 2017, include criteria for the classification of additional drugs. For the purposes of reporting to the PMP, Gabapentin, including its chemical equivalents, has been classified as an additional drug according to the criteria enumerated in 700.012(C)(7).

Data Reporting Requirements

The Department has updated the PMP "Data Submission Dispenser Guide" (Version 3.0) to include guidance on how to report Gabapentin into the PMP Clearinghouse. Each pharmacy is required to collect data for dispensed Gabapentin prescriptions in accordance with the ASAP 4.2 specifications, including

Customer ID. The Guide is updated on a regular basis, including in the event the Department classifies further “additional drugs.” The Guide may be found at:
<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/drug-control/pmp/data-submission.html>.

Compliance Timeline

Compliance with the requirement to report Gabapentin into the PMP Clearinghouse will occur in two implementation phases:

- 1) **Phase 1-Reporting All ASAP Requirements Except Customer ID:** By **August 1, 2017**, all Massachusetts pharmacies are required to report the ASAP-required dispensing information outlined in the Data Submission Guide into the PMP Clearinghouse, except for the “AIR – Additional Information Reporting” data, commonly referred to as the Customer ID.

Each designated data submitter should confirm that the pharmacy is reporting Gabapentin by emailing the PMP Program at mapmp.dph@state.ma.us. Please note that non-compliance with this requirement may result in notification to the Board of Registration in Pharmacy.

- 2) **Phase 2-Reporting Customer ID Reporting:** The Department understands pharmacies may need more time to work with their respective vendors to make necessary changes to their Purchase of Sale (POS) systems to collect Customer IDs for Gabapentin prescriptions. To allow for POS system updates, pharmacies are not required to report Customer ID data until **August 1, 2018**. Please note that non-compliance with this requirement after August 1, 2018 may result in notification to the Board of Registration in Pharmacy.

Pharmacies that are able to implement both phases of these requirements before the stated deadlines are ***strongly encouraged*** to do so. Information entered into the PMP Clearinghouse is critical to users of the Massachusetts Prescription Awareness Tool (MassPAT) as a consideration in their clinical decision-making. By viewing a patient’s prescription history in the system, a provider can avoid duplication of drug therapy and coordinate care by communicating with other providers to improve clinical outcomes and overall patient health. Utilizing MassPAT can also enable early identification of potential prescription drug misuse, abuse or diversion and trigger early intervention.

Waivers

The Department may issue a waiver to a pharmacy that is unable to meet these requirements due to unforeseen challenges. Please visit the Department’s website and review the “Massachusetts Request for Temporary Waiver of Daily Data Submission- Gabapentin” waiver form for more information.

Reporting Considerations

We understand that some prescribers of Gabapentin may not have a personal Drug Enforcement Administration (DEA) number. The Data Submission Dispenser Guide has been updated to make “PRE02” conditional in the event that a prescriber does not have a personal DEA number. This is the only condition in which the PRE02 does not need to be populated with a personal DEA number.

Additional Reporting Changes

Please note that the Data Submission Guide also includes the following noteworthy changes that apply to all controlled substances in Schedule II to V, or a substance classified as an additional drug by DPH,

dispensed by a pharmacy. All pharmacies are expected to come into compliance with these changes by August 1, 2017, with the exception of Customer ID collection for Gabapentin as discussed in Phase 2-Reporting above:

- Customer ID must be collected at pick-up only.
- Customer ID must be collected for refills.
- Prescriber NPI must be submitted in each record.

Resources

More information on Gabapentin reporting is available at: www.mass.gov/dph/dcp/pmp. On this site, you will find information on upcoming educational webinars on this change, along with other recent PMP-related enhancements.

If you have any questions, please email the PMP Program at mapmp.dph@state.ma.us.