DISPENSATION DATA SUBMISSION WAIVER POLICY


A dispenser or pharmacy shall submit all information required under section 7 (b) of the Act to the system no later than the close of the subsequent business day after dispensing a controlled substance.

DEFINITIONS:

"Dispense." To deliver a controlled substance, other drug or device to a patient by or pursuant to the lawful order of a prescriber.

"Dispenser." A person lawfully authorized to dispense in this Commonwealth, including mail order and Internet sales of pharmaceuticals. The term does not include any of the following:

(1) A licensed health care facility that distributes the controlled substance for the purpose of administration in the licensed health care facility.
(2) A correctional facility or its contractors if the confined person cannot lawfully visit a prescriber outside the correctional facility without being escorted by a corrections officer.
(3) An authorized person who administers a controlled substance, other drug or device.
(4) A wholesale distributor of a controlled substance.
(5) A licensed provider in the LIFE program.
(6) A provider of hospice as defined in the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.
(7) A prescriber at a licensed health care facility if the quantity of controlled substances dispensed is limited to an amount adequate to treat the patient for a maximum of five days and does not allow for a refill.
(8) A veterinarian.

"Pharmacy." As defined in the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

POLICY:

“Zero Reports”:
If a pharmacy has not dispensed any schedule II, III, IV, and V controlled substances on a given business day, it must file a zero report for no dispensation by the close of the subsequent business day or it will be considered non-compliant.

“Waiver from Submitting Zero Reports”:
(1) Dispensers or pharmacies that dispense less than five prescriptions for schedule II, III, IV, and V controlled substances per month may apply for a waiver from submitting zero reports.
(2) Application for waivers only exempt dispensers or pharmacies from submitting zero reports; it does not exempt dispensers or pharmacies from any other rule in the Act.
“Waiver from Submitting Data as required by PA PDMP”:
Dispensers or pharmacies that do not currently dispense any schedule II, III, IV, and V controlled substances in the Commonwealth of Pennsylvania or do not fit under the definition of “dispenser” as defined in the Act may apply for a waiver from submitting data.

(1) The dispenser or pharmacy needs to provide evidence or sufficient justification to Pennsylvania’s Prescription Drug Monitoring Program that the dispenser or pharmacy does not dispense monitored prescription drugs.

(2) The waiver form can be downloaded from the Pennsylvania’s Prescription Drug Monitoring Program (PDMP) Office website: www.doh.pa.gov/PDMP.

(3) The PDMP office will make its best effort to respond to waiver requests within 30 days from the date a completed application is received by the PDMP office. Upon initial review a preliminary waiver may be issued until an official response is completed.

(4) The PDMP office reserves the right to reject or void the waiver at any time for any reason, including but not limited to the discovery of evidence contradicting a dispenser or pharmacy’s attestation.

(5) If the waiver application is denied or the granted exemption expires, the license holder is responsible for collecting and submitting data as required by the Act.

(6) A dispenser or pharmacy previously granted a waiver that begins dispensing controlled substances must do the following to remain in compliance with Pennsylvania’s PDMP reporting requirements:
   a. Submit the controlled substance prescription data no later than the subsequent business day after dispensation.
   b. Provide a written notification of the change in reporting to the PDMP office via mail or e-mail within 15 days

(7) Annual resubmission of the waiver forms must be submitted to the PA PDMP office by June 1st of each calendar year. The annual waiver applies to dispensers and pharmacies and shall include evidence and justification that the dispenser or pharmacy does not dispense any controlled substances or dispenses less than five prescriptions for controlled substances per month.

“Waiver from submitting electronic data reports”:
Dispensers or pharmacies that are required to submit data to the PA PDMP system but wish to submit data using the Universal Claim Paper Form (UCF) may apply for a waiver for the electronic data reporting requirement based on the good cause exception as defined under the Act. An explanation and/or proof of the circumstances must be included as a separate attachment.