ASSEMBLY, No. 3917

STATE OF NEW JERSEY

218th LEGISLATURE

INTRODUCED MAY 7, 2018

Sponsored by:
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SYNOPSIS

Requires pharmaceutical manufacturers and wholesale distributors to annually report certain manufacturing and dispensing information concerning prescription opioid drugs, medication-assisted treatment drugs, and opioid antidote drugs.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 1/25/2019)

AN ACT concerning opioid drugs and supplementing Title 24 of the Revised Statutes.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. a. As used in this section:

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Medication-assisted treatment drug" means any drug used to assist with recovery from a substance use disorder. The term shall include naltrexone, buprenorphine, methadone, and any other drug as may be designated by the director by regulation.

"Opioid antidote drug" means any drug, regardless of dosage amount or method of administration, which has been approved by the United States Food and Drug Administration (FDA) for the treatment of an opioid overdose. "Opioid antidote drug" includes, but is not limited to, naloxone hydrochloride, in any dosage amount, which is administered through nasal spray or any other FDA-approved means or methods.

b. (1) Each pharmaceutical manufacturer that manufactures prescription opioid drugs, medication-assisted treatment drugs, or opioid antidote drugs for sale or distribution in New Jersey shall report to the division the name, strength, and number of doses of each prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug that it manufactured for sale or distribution in New Jersey, as well as the zip code of the location where the drug was ultimately delivered for sale or dispensing, in each year of the 10-year period immediately preceding the effective date of this act. Thereafter, the manufacturer shall annually report to the division the name, strength, and number of doses of each prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug that it manufactured for sale or distribution in New Jersey, along with the zip code of the location where the drug was ultimately delivered for sale or dispensing, during the preceding year.

(2) Each wholesale distributor of prescription opioid drugs, medication-assisted treatment drugs, or opioid antidote drugs that are sold or dispensed in New Jersey shall annually report to the division the name, strength, and number of doses of each prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug that it distributed for sale or dispensing in New Jersey, as well as the zip code of the location where the drug was ultimately delivered for sale or dispensing, in each year of the 10-year period immediately preceding the effective date of this act. Thereafter, the wholesale distributor shall annually report to the

division the name, strength, and number of doses of each prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug that it distributed for sale or dispensing in New Jersey, as well as the zip code of the location where the drug was ultimately delivered for sale or dispensing, during the preceding year.

c. The division shall take measures to verify the accuracy of the data reported pursuant to subsection b. of this section, including, but not limited to, requiring a pharmaceutical manufacturer or wholesale distributor to submit the relevant data to a third-party auditor for an independent analysis at the pharmaceutical manufacturer's or wholesale distributor's expense.

d. The division shall review the data reported pursuant to subsection b. of this section to determine, for each year for which data is reported:

(1) the total number of doses of prescription opioid drugs, medication-assisted treatment drugs, and opioid antidote drugs sold or distributed in the State;

(2) the specific number of doses for each formulation of a prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug based on the drug's name and strength; and

(3) the percentage of the total number of doses of prescription opioid drugs, medication-assisted treatment drugs, and opioid antidote drugs, and the percentage of the number of doses for each formulation of a drug based on its name and strength, attributable to each pharmaceutical manufacturer and each wholesale distributor.

The division shall make all such information available on the division's Internet website.

e. (1) A pharmaceutical manufacturer or wholesale distributor that fails to report the data required pursuant to subsection b. of this section, or that fails to obtain a third party audit of a given year's reported data at the request of the division pursuant to subsection c. of this section, shall be liable to a civil penalty of up to $250,000 for each year for which it has failed to report the required data or for which it has failed to obtain a third party audit at the request of the division. The civil penalty may be reassessed against the pharmaceutical manufacturer or wholesale distributor on an annual basis until such time as the data for the year that is the subject of the violation is reported, or until the requested third party audit for the year that is the subject of the violation is completed and submitted to the division, except that the maximum civil penalty that may be assessed for the violation shall double in each consecutive year during which the violation continues.

(2) A pharmaceutical manufacturer or wholesale distributor shall be liable to a civil penalty of $1,000 for each dose of a prescription opioid drug, medication-assisted treatment drug, and opioid antidote drug that is not accurately reported to the division

pursuant to subsection b. of this section, unless the director, in the director's discretion, waives such penalty for good cause shown.

f. A civil penalty imposed pursuant to subsection e. of this section may be collected with costs in a civil action by a summary proceeding instituted by the director in a court of competent jurisdiction pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.). Penalties recovered for violations of this section shall be remitted to the Division of Mental Health and Addiction Services in the Department of Health and expended on substance use disorder prevention and treatment programs.

2. The Director of the Division of Consumer Affairs in the Department of Law and Public Safety, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), shall adopt rules and regulations as shall be necessary to effectuate the provisions of this act.

3. This act shall take effect 180 days after the date of enactment, except that the Division of Consumer Affairs in the Department of Law and Public Safety may take any administrative action in advance as shall be necessary for the implementation of this act.

STATEMENT

This bill requires pharmaceutical manufacturers and wholesale distributors of prescription opioid drugs, medication-assisted treatment drugs, and opioid antidote drugs that are sold or distributed in New Jersey to report to the Division of Consumer Affairs in the Department of Law and Public Safety the name, strength, and number of doses of each prescription opioid drug that it manufactured or distributed for sale or dispensing in New Jersey in each year, as well as the zip code of the location where the drug was ultimately delivered for sale or dispensing. Pharmaceutical manufacturers and wholesale distributors will additionally be required to report this information for each of the 10 years immediately preceding the effective date of the bill. The division will be required to verify the accuracy of the reported data, and may require manufacturers and wholesale distributors to obtain a third-party audit of the reported data at their own expense.

The division will be required to review the data, determine the total number of doses of prescription opioid drugs, medication-assisted treatment drugs, and opioid antidote drugs distributed in New Jersey each year based on name and strength of the drug, and the percentage of that total that is attributable to each manufacturer

and wholesale distributor in the State. This information will be made available on the division's website.

The division will be permitted to impose certain civil penalties for violations of the bill. A manufacturer or wholesale distributor that fails to report the required data or that fails to obtain a third party audit at the division's request will be liable to a civil penalty of up to $250,000 for each year that it fails to report the required data or complete a requested audit; the division may continue to assess penalties for a given violation on an annual basis until such time as the violation is corrected, with the maximum amount that may be assessed for the penalty doubling in each consecutive year that the violation continues. A manufacturer or wholesale distributor will further be liable to a civil penalty of $1,000 for each dose of a prescription opioid drug, medication-assisted treatment drug, or opioid antidote drug that is not accurately reported, unless the penalty is waived by the Director of the Division of Consumer Affairs for good cause shown.

Civil penalties assessed under the bill may be collected, with costs, in a civil action by a summary proceeding instituted by the director in a court of competent jurisdiction. Penalties recovered for violations of the bill will be remitted to the Division of Mental Health and Addiction Services in the Department of Health and expended on substance use disorder prevention and treatment programs.