*** § 3323. Opioid stewardship fund.** 1. Definitions:

(a) "Opioid stewardship payment" shall mean the total amount to be paid into the opioid stewardship fund for each state fiscal year as set forth in subdivision two of this section.

(b) "Ratable share" shall mean the individual portion of the opioid stewardship payment to be paid by each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York.

(c) Notwithstanding any inconsistent provision of law to the contrary, "distribute" shall mean to deliver a controlled substance other than by administering or dispensing to the ultimate user, including intra-company transfers between any division, affiliate, subsidiary, parent or other entity under complete common ownership and control. For purposes of this section, "distribute" shall not include controlled substances surrendered to reverse distributors, or donated to recipient entities or third-party intermediaries pursuant to the unused prescription drug donation and redispensing program of section two hundred eighty-b of this chapter.

2. Opioid stewardship payment imposed on manufacturers and distributors. All manufacturers and distributors licensed under this article (hereinafter referred to as "licensees"), that sell or distribute opioids in the state of New York shall be required to pay an opioid stewardship payment. On an annual basis, the commissioner shall certify to the state comptroller the amount of all revenues collected from opioid stewardship payments and any penalties imposed. The amount of revenues so certified shall be deposited quarterly into the opioid stewardship fund established pursuant to section ninety-seven-aaaaa of the state finance law. No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section.

3. Determination of opioid stewardship payment. The total opioid stewardship payment amount shall be one hundred million dollars annually, subject to downward adjustments pursuant to subdivision nine of this section.

4. Reports and records. Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall provide to the commissioner a report detailing all opioids sold or distributed by such manufacturer or distributor in the state of New York. Such report shall include:

(a) the manufacturer's or distributor's name, address, phone number, federal Drug Enforcement Agency (DEA) registration number and controlled substance license number issued by the department;

(b) the name, address and DEA registration number of the entity to whom the opioid was sold or distributed;

(c) the date of the sale or distribution of the opioid;

(d) the gross receipt total, in dollars, of all opioids sold or distributed;

(e) the name and National Drug Code (NDC) of the opioid sold or distributed;

(f) the number of containers and the strength and metric quantity of controlled substance in each container of the opioid sold or distributed;

(g) the total number of morphine milligram equivalents (MMEs) sold or distributed; and

(h) any other elements as deemed necessary by the commissioner.

4-a. Initial and future reports. (a) Such information shall be reported annually to the department in such form as defined by the commissioner, provided however that the initial report provided pursuant to subdivision four shall consist of all opioids sold or distributed in the state of New York for the two thousand seventeen calendar year, and must be submitted by August 1, 2018. Subsequent annual reports shall be submitted on April first of each year based on the actual opioid sales and distributions of the prior calendar year.

(b) For the purpose of such annual reporting, MMEs shall be determined pursuant to a formulation to be issued by the department and updated as the department deems appropriate.

5. Determination of ratable share. Each manufacturer and distributor licensed under this article that sells or distributes opioids in the

state of New York shall pay a portion of the total opioid stewardship payment amount. The ratable share shall be calculated as follows:

(a) The total amount of MMEs sold or distributed in the state of New York by the licensee for the preceding calendar year, as reported by the licensee pursuant to subdivision four of this section, shall be divided by the total amount of MME sold in the state of New York by all licensees pursuant to this article to determine the licensee payment percentage. The licensee payment percentage shall be multiplied by the total opioid stewardship payment. The product of such calculation shall be the licensee's ratable share. The department shall have the authority to adjust the total number of a licensee's MMEs to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee, when making such determination and adjust the ratable share accordingly.

(b) The licensee's total amount of MME sold or distributed, as well as the total amount of MME sold or distributed by all licensees under this article, used in the calculation of the ratable share shall not include the MME of those opioids which are: (i) manufactured in New York state, but whose final point of delivery or sale is outside of New York state; (ii) sold or distributed to entities certified to operate pursuant to article thirty-two of the mental hygiene law, or article forty of the public health law; or (iii) the MMEs attributable to buprenorphine, methadone or morphine.

(c) The department shall provide to the licensee, in writing, on or before October fifteenth, two thousand eighteen, the licensee's ratable share for the two thousand seventeen calendar year. Thereafter, the department shall notify the licensee in writing annually on or before October fifteenth of each year based on the opioids sold or distributed for the prior calendar year.

6. Payment of ratable share. The licensee shall make payments quarterly to the department with the first payment of the ratable share, provided that the amount due on January first, two thousand nineteen shall be for the full amount of the first annual payment, with additional payments to be due and owing on the first day of every quarter thereafter.

7. Rebate of ratable share. In any year for which the commissioner determines that a licensee failed to report required information as required by this section, those licensees complying with this section shall receive a reduced assessment of their ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period.

8. Licensee opportunity to appeal. A licensee shall be afforded an opportunity to submit information to the department to justify why the ratable share provided to the licensee, pursuant to paragraph (c) of subdivision five of this section, or amounts paid thereunder are in error or otherwise not warranted. If the department determines thereafter that all or a portion of such ratable share, as determined by the commissioner pursuant to subdivision five of this section, is not warranted, the department may: (a) adjust the ratable share; (b) adjust the assessment of the ratable share in the following year equal to the amount in excess of any overpayment in the prior payment period; or (c) refund amounts paid in error.

9. Department annual review. The department shall annually review the amount of state operating funds spent in the office of alcoholism and substance abuse services (OASAS) budget for opioid prevention, treatment and recovery. The commissioner of OASAS shall certify to the department the amount of annual spending for such services, utilizing available information on patient demographics and the actual cost of services delivered by the state and by state-funded providers. The certification of such spending shall begin in state fiscal year two thousand eighteen-nineteen, and continue annually thereafter. The total amount of such spending shall be provided to the department by the commissioner of OASAS no later than June thirtieth of each year. There shall be no stewardship fund payments beginning on July first in the event state operating funds spent in the OASAS budget for opioid prevention, treatment and recovery in the most recently reported year is equal to or less than state operating funds spent for such purposes in state fiscal year two thousand nine-ten.

10. Penalties. (a) The department may assess a civil penalty in an

amount not to exceed one thousand dollars per day against any licensee that fails to comply with subdivisions four and four-a of this section.

(b) In addition to any other civil or criminal penalty provided by law, where a licensee has failed to pay its ratable share in accordance with subdivision six of this section, the department may also assess a penalty of no less than ten percent and no greater than three hundred percent of the ratable share due from such licensee.

(c) Where the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident.

* NB Repealed June 30, 2029