

1 condition that places the infant at a high risk for development of
2 necrotizing enterocolitis.

3 § 12. Section 4303 of the insurance law is amended by adding a new
4 subsection (oo) to read as follows:

5 (oo) A medical expense indemnity corporation, a hospital service
6 corporation or a health service corporation that provides coverage for
7 hospital, surgical or medical care shall provide the following coverage
8 for pasteurized donor human milk (PDHM), which may include fortifiers as
9 medically indicated, for inpatient use, for which a licensed medical
10 practitioner has issued an order for an infant who is medically or phys-
11 ically unable to receive maternal breast milk or participate in breast
12 feeding or whose mother is medically or physically unable to produce
13 maternal breast milk at all or in sufficient quantities or participate
14 in breast feeding despite optimal lactation support. Such infant shall:
15 (i) have a documented birth weight of less than one thousand five
16 hundred grams; or (ii) have a congenital or acquired condition that
17 places the infant at a high risk for development of necrotizing entero-
18 colitis.

19 § 13. This act shall take effect immediately.

20

PART NN

21 Section 1. Article 33 of the public health law is amended by adding a
22 new title 2-A to read as follows:

TITLE 2-A

OPIOID STEWARDSHIP ACT

Section 3323. Opioid stewardship fund.

§ 3323. Opioid stewardship fund. 1. Definitions:

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

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

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

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

1 or such licensee shall be subject to penalties pursuant to subdivision
2 ten of this section.

3 3. Determination of opioid stewardship payment. The total opioid
4 stewardship payment amount shall be one hundred million dollars annual-
5 ly, subject to downward adjustments pursuant to subdivision nine of this
6 section.

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

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

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

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

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

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

22 (f) the number of containers and the strength and metric quantity of
23 controlled substance in each container of the opioid sold or distrib-
24 uted;

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

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

28 4-a. Initial and future reports. (a) Such information shall be
29 reported annually to the department in such form as defined by the
30 commissioner, provided however that the initial report provided pursuant
31 to subdivision four shall consist of all opioids sold or distributed in
32 the state of New York for the two thousand seventeen calendar year, and
33 must be submitted by August 1, 2018. Subsequent annual reports shall be
34 submitted on April first of each year based on the actual opioid sales
35 and distributions of the prior calendar year.

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

39 5. Determination of ratable share. Each manufacturer and distributor
40 licensed under this article that sells or distributes opioids in the
41 state of New York shall pay a portion of the total opioid stewardship
42 payment amount. The ratable share shall be calculated as follows:

43 (a) The total amount of MMEs sold or distributed in the state of New
44 York by the licensee for the preceding calendar year, as reported by the
45 licensee pursuant to subdivision four of this section, shall be divided
46 by the total amount of MME sold in the state of New York by all licen-
47 sees pursuant to this article to determine the licensee payment percent-
48 age. The licensee payment percentage shall be multiplied by the total
49 opioid stewardship payment. The product of such calculation shall be
50 the licensee's ratable share. The department shall have the authority
51 to adjust the total number of a licensee's MMEs to account for the
52 nature and use of the product, as well as the type of entity purchasing
53 the product from the licensee, when making such determination and adjust
54 the ratable share accordingly.

55 (b) The licensee's total amount of MME sold or distributed, as well as
56 the total amount of MME sold or distributed by all licensees under this

1 article, used in the calculation of the ratable share shall not include
2 the MME of those opioids which are: (i) manufactured in New York state,
3 but whose final point of delivery or sale is outside of New York state;
4 (ii) sold or distributed to entities certified to operate pursuant to
5 article thirty-two of the mental hygiene law, or article forty of the
6 public health law; or (iii) the MMEs attributable to buprenorphine,
7 methadone or morphine.

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

14 6. Payment of ratable share. The licensee shall make payments quarter-
15 ly to the department with the first payment of the ratable share,
16 provided that the amount due on January first, two thousand nineteen
17 shall be for the full amount of the first annual payment, with addi-
18 tional payments to be due and owing on the first day of every quarter
19 thereafter.

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

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

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

53 10. Penalties. (a) The department may assess a civil penalty in an
54 amount not to exceed one thousand dollars per day against any licensee
55 that fails to comply with subdivisions four and four-a of this section.

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

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

9 § 2. Subdivision 1 of section 3316 of the public health law is amended
10 by adding a new paragraph (c) to read as follows:

11 (c) is unlikely during the period of his or her license to complete
12 the reports or to pay the ratable share required by title two-A of this
13 article on or before the required date. Prior evidence of non-compliance
14 shall constitute substantial evidence of such.

15 § 3. The state finance law is amended by adding a new section 97-aaaaa
16 to read as follows:

17 § 97-aaaaa. Opioid stewardship fund. 1. There is hereby established
18 in the joint custody of the state comptroller and the commissioner of
19 taxation and finance an account of the miscellaneous special revenue
20 account to be known as the "opioid stewardship fund".

21 2. Moneys in opioid stewardship fund shall be kept separate and shall
22 not be commingled with any other moneys in the custody of the state
23 comptroller and the commissioner of taxation and finance.

24 3. The opioid stewardship fund shall consist of moneys appropriated
25 for the purpose of such account, moneys transferred to such account
26 pursuant to law, contributions consisting of promises or grants of any
27 money or property of any kind or value, or any other thing of value,
28 including grants or other financial assistance from any agency of
29 government and moneys required by the provisions of this section or any
30 other law to be paid into or credited to this account.

31 4. Moneys of the opioid stewardship fund, when allocated, shall be
32 available, subject to the approval of the director of the budget, to
33 support programs operated by the New York state office of alcoholism and
34 substance abuse services or agencies certified, authorized, approved or
35 otherwise funded by the New York state office of alcoholism and
36 substance abuse services to provide opioid treatment, recovery and
37 prevention and education services; and to provide support for the
38 prescription monitoring program registry as established pursuant to
39 section thirty-three hundred forty-three-a of the public health law.

40 5. At the request of the budget director, the state comptroller shall
41 transfer moneys to support the costs of opioid treatment, recovery,
42 prevention, education services, and other related programs, from the
43 opioid stewardship fund to any other fund of the state to support this
44 purpose.

45 6. (i) Notwithstanding the provisions of any general or special law,
46 no moneys shall be available from the opioid stewardship fund until a
47 certificate of allocation and a schedule of amounts to be available
48 therefor shall have been issued by the director of the budget, upon the
49 recommendation of the commissioner of the office of alcoholism and
50 substance abuse services, and a copy of such certificate filed with the
51 comptroller, the chairman of the senate finance committee and the chair-
52 man of the assembly ways and means committee.

53 (ii) Such certificate may be amended from time to time by the director
54 of the budget, upon the recommendation of the commissioner of the office
55 of alcoholism and substance abuse services, and a copy of such amendment

1 shall be filed with the comptroller, the chairman of the senate finance
2 committee and the chairman of the assembly ways and means committee.

3 7. The moneys, when allocated, shall be paid out of the opioid
4 stewardship fund, pursuant to subdivision four of this section, and
5 subject to the approval of the director of the budget, on the audit and
6 warrant of the comptroller on vouchers certified or approved by (i) the
7 commissioner of the office of alcoholism and substance abuse services or
8 his or her designee; or (ii) the commissioner of the department of
9 health or his or her designee.

10 § 4. Severability. If any clause, sentence, paragraph, subdivision, or
11 section of this act shall be adjudged by any court of competent juris-
12 diction to be invalid, such judgment shall not affect, impair, or inval-
13 idate the remainder thereof, but shall be confined in its operation to
14 the clause, sentence, paragraph, subdivision, or section directly
15 involved in the controversy in which such judgment shall have been
16 rendered. It is hereby declared to be the intent of the legislature that
17 this act would have been enacted even if such invalid provisions had not
18 been included herein.

19 § 5. This act shall take effect July 1, 2018 and shall expire and be
20 deemed to be repealed on June 30, 2024, provided that, effective imme-
21 diately, the addition, amendment and/or repeal of any rule or regulation
22 necessary for the implementation of this act on its effective date are
23 authorized to be made and completed on or before such effective date.

24 § 2. Severability clause. If any clause, sentence, paragraph, subdivi-
25 sion, section or part of this act shall be adjudged by any court of
26 competent jurisdiction to be invalid, such judgment shall not affect,
27 impair, or invalidate the remainder thereof, but shall be confined in
28 its operation to the clause, sentence, paragraph, subdivision, section
29 or part thereof directly involved in the controversy in which such judg-
30 ment shall have been rendered. It has hereby declared to be the intent
31 of the legislature that this act would have been enacted even if such
32 invalid provisions had not been included herein.

33 § 3. This act shall take effect immediately provided, however, that
34 the applicable effective date of Parts A through NN of this act shall be
35 as specifically set forth in the last section of such Parts.