IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

HEALTHCARE DISTRIBUTION ALLIANCE, Plaintiff, v. HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of New York; and BARBARA D. UNDERWOOD, in her official capacity as the Attorney General of New York, Defendants.	No. _____ **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff Healthcare Distribution Alliance ("HDA"), on behalf of its members, hereby files this complaint against Howard A. Zucker, in his official capacity as Commissioner of Health of New York, and Barbara D. Underwood, in her official capacity as the Attorney General of New York:

NATURE OF THE ACTION

1. HDA seeks a declaration that the New York Opioid Stewardship Act (the "Act")[1] is unconstitutional and an injunction against its enforcement. The Act imposes a punitive surcharge on opioid manufacturers and distributors to finance a $600 million "opioid stewardship fund," accumulated over the course of six years. The Act contains several unprecedented, unfair, and arbitrary features, including:

- It seeks to adjudicate legislatively issues that are at stake in ongoing investigations by the State of New York and lawsuits filed by New York City and New York counties.

[1] A true and correct copy of the Act is attached hereto as Exhibit A. Unless otherwise noted, citations throughout are to the Act.

- The Act imposes retroactive liability for opioid sales taking place over eighteen months before its effective date.
- The Act creates a highly unusual "ratable share" surcharge scheme under which any party's liability depends on the liability assigned to *other* parties. For example, if manufacturers and distributors restructure their transactions to avoid New York, the ratable shares of the remaining entities in New York will increase (even if their conduct remains unchanged). If some entities are able to reduce their surcharges by moving transactions to New Jersey, Pennsylvania, and Connecticut, the financial burden on the remaining entities in New York will increase.
- The Act improperly singles out entities subject to the surcharge to bear liability for a complex public-health epidemic involving myriad actors.
- The Act prohibits a party subject to the surcharge from passing its cost onto any purchaser and imposes a potential penalty of up to $1 million "per incident" for violating this provision. Given the fungibility of money and the multiple factors that go into pharmaceutical pricing, this vague prohibition invites arbitrary enforcement.
- The Act confers untrammeled discretion on the New York Department of Health to interpret and enforce its terms.

2. The Act's core will be codified as Title 2-A of Article 33 of the New York Public Health Law. *See* The New York Senate, *Title 2-A: Opioid Stewardship Act*, https://www.nysenate.gov/legislation/laws/PBH/A33T2-A (last visited July 6, 2018).[2] By its terms, the Act went into effect on July 1, 2018. *Id.*

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this case arises under the statutes and Constitution of the United States.

4. This Court has personal jurisdiction over Defendants because Defendants reside within the Southern District of New York.

5. Venue is proper in this Court because a substantial part of the events giving rise to these claims have occurred or will occur in this district and because Defendants reside in the

[2] The Act also added § 97-aaaaa to the state finance law.

Southern District of New York. *See* 28 U.S.C. §§ 1391(b)(1)–(2). Members of HDA maintain distribution facilities in the Southern District of New York, including in Orange County. The Commissioner of Health and the Attorney General maintain offices in New York County.

PARTIES

6. HDA is a Virginia 501(c)(6) trade association that represents pharmaceutical wholesale distributors. In essence, HDA's members purchase pharmaceutical products from manufacturers, store them securely, and deliver them safely to licensed healthcare providers. HDA members ship approximately 15 million diverse medical products across the nation every day. Its members, in their roles as wholesale distributors, do not manufacture, produce, or prescribe pharmaceutical products, nor do they engage in pharmaceutical research and development. Rather, they simply coordinate receipt and delivery of pharmaceutical products from the manufacturers who develop them and who, in many cases, market them to pharmacies, hospitals, and other dispensers, who provide them when prescribed. A substantial part of HDA's mission is to advocate for its members' interests, including through lobbying and litigation. HDA's principal place of business is in Arlington, Virginia.

7. Howard A. Zucker is the New York Commissioner of Health (the "Commissioner"). The Commissioner serves as the head of the New York Department of Health (the "Department"), N.Y. Pub. Health Law § 206(a) (McKinney 2018), and "enforce[s] the public health law," *id.* § 206(f). Furthermore, the Department is charged with administering the Act. *E.g.*, § 3323(4-a). The Commissioner is a resident of New York and is sued only in his official capacity.

8. Defendant Barbara D. Underwood is the Attorney General of New York. Upon the Commissioner's request, the Attorney General has power to "bring an action for an injunction against any person who violates, disobeys or disregards any term or provision of" the New York

Public Health Law. N.Y. Pub. Health Law § 12 (McKinney 2018). The Attorney General is a resident of New York and is sued only in her official capacity.

9. Defendants and those subject to Defendants' supervision, direction, and/or control are responsible for the enforcement of the Act.

10. In enforcing, administering, and adhering to the Act, Defendants and those subject to Defendants' supervision, direction, and/or control will at all relevant times be acting under color of state law.

BACKGROUND

A. The Act

11. On April 13, 2018, the Governor of New York signed into law the Opioid Stewardship Act, which became effective on July 1, 2018. On June 27, 2018, the Department issued guidance regarding the Act that narrowed and/or clarified the Act in certain respects ("the Guidance").[3]

12. This Complaint is predicated on the Act as implemented by the Guidance.

13. The Act imposes a $600 million surcharge on pharmaceutical manufacturers and wholesale distributors to punish those companies for the opioid epidemic, the roots of which are extraordinarily complex and stretch back decades. The surcharge will be spread over six years, with $100 million paid annually from 2019 through 2024. The first $100 million payment is due on January 1, 2019, and will be assessed on the basis of opioid sales and distributions that occurred in 2017, well before the Act's effective date.

14. The Act's proceeds are to be kept separate from all other state revenues, § 97-aaaaa(2), and will be allocated exclusively to certain state agencies and state-funded agencies "to

[3] A true and correct copy of relevant portions of the Guidance is attached hereto as Exhibit B.

provide opioid treatment, recovery and prevention and education services," as well as "to provide support for the prescription monitoring program registry." § 97-aaaaa(4).

15. The Act's legislative history indicates a clear intent on the part of New York's Governor and legislature to punish pharmaceutical manufacturers and distributors for allegedly "creat[ing]" the opioid epidemic. In urging passage of the Act, Governor Cuomo repeatedly revealed this punitive intent, expressing a desire to "hold pharmaceutical companies accountable for perpetuating the [opioid] epidemic" and to "plac[e] the share of societal costs from opioid use on the manufacturers, producers and distributors who financially gain from the use of these drugs."

16. Perhaps most pointedly, in his 2018 State of the State address, Governor Cuomo expressed his desire "to hold pharmaceutical companies accountable for their role in perpetuating the opioid epidemic." He expressed his plans to join the Attorney General in "tak[ing] enforcement actions against pharmaceutical opioid distributors for breaching their legal duties to monitor, detect and report suspicious orders of prescription opioids," opining that "wholesale distributors . . . have violated their duty by selling large amounts of painkillers that were then diverted for illicit uses, helping to contribute to the opioid epidemic."

17. The Act was promulgated against the backdrop of extensive opioid-related litigation against pharmaceutical manufacturers and distributors, along with other participants in the pharmaceutical supply chain.[4] Through the Attorney General, the State has launched investigations of, among others, pharmaceutical distributors, and New York City and several New York counties have filed opioid-related lawsuits against manufacturers and distributors

[4] There have been over one thousand opioid-related cases filed in both state and federal court in the past year and a half, and there are active investigations by attorneys general across the nation.

seeking hundreds of millions of dollars in damages. The Act circumvents that litigation by legislating the outcomes of those investigations and lawsuits.

18. This punitive intent is further expressed in the Act's retroactive imposition of liability for opioid sales or distributions taking place over eighteen months before the Act's effective date. *See* § 3323(5) (providing that the Department will assess the Act's surcharge for 2017 sales or distributions).

19. Moreover, the Act's funds finance opioid treatment and recovery generally, without distinguishing among legally obtained prescription products, illegally obtained prescription products, and illegal drugs, such as heroin. The Act therefore seeks to make responsible the politically unpopular (and largely out-of-state) class of manufacturers and distributors without regard to any connection to the alleged harms that more clearly involve numerous other actors. HDA and its members are committed to playing a responsible role in addressing the opioid epidemic—many HDA members voluntarily spend tens of millions of dollars every year to this end. But the State has no right to single out distributors for punishment, at least not without due process.

20. The Act's proceeds are derived from surcharges to be paid by opioid manufacturers and distributors licensed under Title II of New York's public health law ("Licensees"). § 3323(2). Pharmacies and other supply chain entities, which prior versions of the Act included, are outside the Act's purview.

21. Each Licensee pays a portion of the opioid fund every year. *Id.* The Department determines the portion of the fund for which each Licensee is responsible (the "Surcharge"). § 3323(5)(c). The Department makes this determination based in part on a formula the Act prescribes (the "Formula"), but regardless of the Formula, the Department may adjust each

Licensee's Surcharge "to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee." § 3323(5)(a). (This Complaint refers to the Formula, its exceptions, and the nature-and-use adjustment as the "Surcharge-Calculation Provision.")

22. The Formula is as follows: Each Licensee's payment corresponds with the percentage of morphine milligram equivalents ("MMEs") it sold or distributed in New York in the prior year. § 3323(5)(a). In other words, to calculate a Licensee's Surcharge, the Department divides the number of MMEs the Licensee sold or distributed by the total number of MMEs all Licensees sold in New York and multiplies the result by $100 million.

23. The Act defines "distribute" as "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." § 3323(1)(c).

24. This Formula excludes MMEs that are (i) manufactured in New York but whose "final point of delivery or sale" is outside New York, (ii) sold to certain exempted facilities, or (iii) attributable to buprenorphine, methadone, or morphine. § 3323(5)(b). The Guidance indicates that the Department will apply the first exemption to all opioids ultimately delivered or sold outside New York. Guidance at 2.

25. Every Licensee's Surcharge depends on the liability assigned to *other* Licensees. For example, if manufacturers and distributors restructure their transactions to avoid New York, the Surcharges of the remaining Licensees will increase. If some Licensees are able to reduce their Surcharges by moving transactions to New Jersey, Pennsylvania, and Connecticut, the financial burden on the remaining Licensees in New York will increase.

26. The Act prohibits Licensees from "pass[ing] the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid." § 3323(2). The Commissioner may impose a penalty of up to $1 million "per incident" for violating this provision. § 3323(10)(c). (This Complaint refers to this as the "Cost-Pass-Through Prohibition.")

27. The Cost-Pass-Through Prohibition and the draconian penalty for violating it further evince a punitive intent on the part of the Governor and the New York Legislature.

B. There Is a Justiciable Dispute Between the Parties

28. The claims raised by HDA in this complaint are fit for judicial decision today, and are not speculative or contingent. The Act requires Licensees to report their 2017 sales or distributions by August 1, 2018. § 3323(4-a)(a). The Department will assess Licensees their Surcharges by October 15, 2018, § 3323(5)(c), and payment of all 2017 Surcharges will be due on January 1, 2019. § 3323(6).

29. HDA has standing to sue on behalf of its members, some of whom are Licensees subject to the Surcharge.

30. HDA's purposes include advancing the common interests of pharmaceutical distributors. HDA fulfills that purpose in part through litigation against governmental authorities to defend HDA's members from damaging laws.

31. The Act injures pharmaceutical distributors engaged in business in New York by subjecting them to reporting requirements, by forcing them to pay the Surcharge, to rearrange their affairs to comply with the Act, and to attempt to adhere to the Act's opaque terms, and by prohibiting them from passing the cost of the Surcharge downstream to purchasers.

32. HDA's claims and relief requested herein do not require the participation of HDA's members.

33. The Act is invalid both on its face and as applied to HDA's members.

CLAIMS FOR RELIEF

Count One—Bill of Attainder

34. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 33 as if fully set forth herein.

35. The Act is an unconstitutional Bill of Attainder in violation of Article I, § 10 of the U.S. Constitution.

36. The Act singles out Licensees for punishment. It does not impose the Surcharge or any similar surcharge on any other entity or person, including prescribing doctors or dispensing providers and pharmacies.[5]

37. The Act prejudges the guilt of the Licensees. It improperly imposes liability for alleged past wrongdoing. *See, e.g.*, § 3323(5) (providing that the Department will assess the Surcharge for 2017 sales). The Act's legislative history makes this clear: in urging passage of the Act, Governor Cuomo repeatedly referred to his desire "to hold pharmaceutical companies accountable for their role in perpetuating the opioid epidemic." The Governor also said he planned to join the Attorney General in "tak[ing] enforcement actions against pharmaceutical opioid distributors for breaching their legal duties to monitor, detect and report suspicious orders of prescription opioids," opining that "wholesale distributors in the U.S. . . . have violated their duty by selling large amounts of painkillers that were then diverted for illicit uses, helping to contribute to the opioid epidemic." The Act is an attempt to punish opioid distributors for past conduct.

[5] The Act's legislative history shows that the Chain Pharmacy Association of New York State convinced the State not to put pharmacies "in the untenable position of paying" the Surcharge, because doing so would be "patently unfair."

38. The Act therefore supplants legislative judgment for judicial determinations. The State of New York has launched investigations of pharmaceutical distributors (and others), and New York City and several New York counties have filed opioid-related lawsuits against manufacturers and distributors alleging hundreds of millions of dollars in damages. The Act seeks to short-circuit the judicial process by legislating the outcomes of these lawsuits. It demands the same recompense as the pending litigation but accomplishes this objective by stripping pharmaceutical manufacturers and distributors of their due process and other legal protections. The New York legislature has decided the total amount due ($600 million), who is responsible (manufacturers and distributors), and how the liability should be apportioned (ratable shares of MMEs). The Act is therefore "trial by legislature."

39. The Act inflicts punishment in the form of the Surcharge. As shown by Governor Cuomo's statements and other portions of the legislative record, the Surcharge's purpose is to punish opioid manufacturers and distributors.

40. The Cost-Pass-Through Prohibition further exposes the legislature's punitive intent, as it makes clear that the legislature intended for manufacturers and distributors alone to bear the cost of the Surcharge. The penalty for violating the Cost-Pass-Through Prohibition makes this clear.

41. As a confiscation and deprivation of property, the Surcharge falls within the historical meaning of legislative punishment.

42. In view of the severity of the Surcharge and of the penalties for violating the Cost-Pass-Through Prohibition, the Act cannot reasonably be said to further a nonpunitive legislative purpose.

43. The Act does not provide for the protection of a jury trial to Surcharge payers.

Count Two—Retroactivity Challenge to Surcharge

44. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 43 as if fully set forth herein.

45. The Due Process Clause of the Fourteenth Amendment prohibits states from imposing liability retroactively, especially when creating a wholly new realm of liability.

46. The Act violates this prohibition by imposing liability on Licensees for opioids sold or distributed over eighteen months before the Act's effective date. Because the Act created a new realm of liability, Licensees had no opportunity at any time during 2017 to alter their behavior in anticipation of the Act. This retroactive liability is severe and interferes significantly with reasonable, investment-backed expectations.

Count Three—Takings Clause

47. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 46 as if fully set forth herein.

48. The Fifth Amendment provides that "private property" shall not "be taken for public use[] without just compensation."

49. The Surcharge constitutes an unconstitutional *per se* taking. It is a confiscation of Licensees' assets. It requires Licensees to transfer $600 million to the "opioid stewardship fund," thereby vesting title to the money in the State.

50. Alternatively to paragraph 49, the Surcharge and the Cost-Pass-Through Prohibition operate together as a regulatory taking, as they deprive distributors of the use of the opioid products they distribute in New York. Distributors use opioid products by selling them. By requiring distributors to pay the Surcharge and forbidding them from passing that added cost along to downstream purchasers, the Act encumbers distributors' ownership interests in those products.

51. Alternatively to paragraphs 49 and 50, the Surcharge and the Cost-Pass-Through Prohibition operate together as a regulatory taking, as they deprive Licensees of the use of the money they pay as Surcharges. The Cost-Pass-Through Prohibition prevents Licensees from passing the Surcharge downstream to purchasers.

52. Alternatively to paragraphs 49, 50, and 51, the Surcharge alone is a regulatory taking, as it deprives Licensees of the use of the cost of the Surcharge.

53. In addition, payment of the Surcharge is an unconstitutional condition to licensure as a controlled-substance distributor or manufacturer. Compliance with the Act is a condition of licensure. *See* N.Y. Pub. Health Law § 3390(4) (McKinney 2018) (providing that the Commissioner may revoke the license of a Licensee who "wilfully or negligently fail[s] to comply with any of the provisions of . . . this article, or the regulations promulgated thereunder"). The Surcharge is not proportional to and bears no nexus to any alleged negative impact of Licensees' activities in New York. The Surcharge is therefore an unconstitutional taking.

54. In addition, compliance with the Cost-Pass-Through Prohibition is an unconstitutional condition to licensure as a controlled-substance distributor or manufacturer. Compliance with the Act is a condition of licensure. *See* N.Y. Pub. Health Law § 3390(4) (McKinney 2018) (providing that the Commissioner may revoke the license of a Licensee who "wilfully or negligently fail[s] to comply with any of the provisions of . . . this article, or the regulations promulgated thereunder"). The Cost-Pass-Through Prohibition forces Licensees to bear the cost of the Surcharge. This cost is not proportional to and bears no nexus to any alleged negative impact of Licensees' activities in New York. The Cost-Pass-Through Prohibition therefore makes the cost of the Surcharge an unconstitutional taking.

Count Four—Substantive Due Process

55. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 54 as if fully set forth herein.

56. The Due Process Clause of the Fourteenth Amendment states that no person shall "be deprived of life, liberty, or property, without due process of law."

57. The Act violates substantive due process by imposing liability on manufacturers and distributors to punish them for alleged past wrongdoing. The legislative history makes clear that the purpose of the bill was to "hold pharmaceutical companies accountable for perpetuating the [opioid] epidemic," the roots of which stretch back twenty years and are predominately tied to activity in the past.

58. The Act singles out certain entities to bear this liability without adequately determining culpability. It forces manufacturers and distributors, but not pharmacies or medical professionals, to pay for alleged harm resulting from a public health problem involving numerous actors.

59. The structure of the Surcharge demonstrates the State's intent to punish manufacturers and distributors for the opioid epidemic. For example, instead of assessing a certain cost per pill, the Act sets the value of the fund at $600 million, regardless of the volume of activity in the present.

60. The Act therefore violates substantive due process by imposing severe liability for alleged past harms without due process and in an arbitrary and capricious manner.

Count Five—Dormant Commerce Clause Challenge to the Cost-Pass-Through Prohibition Based on Extraterritoriality

61. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 60 as if fully set forth herein.

62. The dormant Commerce Clause prevents state statutes from regulating extraterritorial commerce, regardless of that commerce's effects in the state.

63. The Cost-Pass-Through Prohibition directly regulates extraterritorial conduct by prohibiting distributors from passing the cost of the Surcharge "to a purchaser, including the ultimate user of the opioid," regardless of where the opioid is consumed. § 3323(2).

64. The Cost-Pass-Through Prohibition is not limited to opioids that pass through New York. Instead, it is written to encompass transactions with "a purchaser" and with "the ultimate user." *Id.* The Cost-Pass-Through Prohibition therefore applies to (a) opioids that pass through New York and are then distributed, sold, or consumed outside New York and (b) opioids that are manufactured, distributed, sold, and consumed entirely outside New York. In both applications, the Cost-Pass-Through Prohibition regulates transactions that take place outside New York.

65. As to the former application, the Cost-Pass-Through Prohibition regulates extraterritorial transactions downstream from any opioid transaction in New York. It prohibits distributors from passing the cost of the Surcharge along to out-of-state purchasers of opioids distributed in New York, even when those purchasers are one or two steps removed from any New York transaction.

66. As to the latter application, the Cost-Pass-Through Prohibition regulates extraterritorial transactions that are entirely unrelated to New York. It prohibits distributors from passing the cost of the Surcharge along to "*a* purchaser," irrespective of whether the purchaser in question purchases an opioid that a distributor distributed through New York. The Cost-Pass-Through Prohibition therefore prohibits distributors from passing the costs of the Surcharge to purchasers of opioids in transactions entirely outside New York.

67. Finally, the Cost-Pass-Through Prohibition is designed to force and has the effect of forcing distributors to pass the cost of the Surcharge upstream to manufacturers. That is to say, because distributors cannot recoup the Surcharge from downstream purchasers, the Act forces them to seek to recoup the cost of the Surcharge from manufacturers, including out-of-state manufacturers that do not sell directly into New York. In so doing, the Cost-Pass-Through Prohibition has the effect of indirectly imposing on out-of-state manufacturers surcharges that New York cannot impose directly. Those surcharges will then be borne by transactions outside New York, requiring out-of-state parties to pay for the surcharge, in violation of the Commerce Clause.

68. The Act's legislative history confirms the legislature's intent to pass the cost upstream to manufacturers. For example, during a joint legislative hearing, the Deputy Commissioner of the New York Department of Taxation and Finance referred to the legislature's intent that "the cost of . . . treatment programs should be borne, to the extent we can achieve it, on the manufacturers of opioids." She later confirmed that "[i]t's the ultimate goal here to impose a surcharge that will flow to the manufacturers of opioids."

Count Six—Dormant Commerce Clause Challenge Based on Undue Burden

69. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 68 as if fully set forth herein.

70. The Act violates the dormant Commerce Clause because it imposes more than incidental burdens on interstate commerce. The Act also fails to regulate even-handedly or effectuate a legitimate public interest. Finally, the Act imposes a burden on interstate commerce that is excessive in relation to its supposed benefits.

71. The Surcharge and the Cost-Pass-Through Prohibition operate together to burden interstate commerce. The Cost-Pass-Through Prohibition prevents distributors from passing the

cost of the Surcharge downstream to purchasers, thus forcing them to pass its cost upstream to manufacturers, who in turn may pass it on to out-of-state purchasers.

72. Many opioid products distributed in New York are manufactured outside New York. Manufacturers typically do not distribute their products directly into New York; rather, currently, they send their products to distributors outside New York, who in turn deliver them into New York.

73. Many opioid products distributed in New York are distributed by out-of-state distributors (including distributors with facilities both in and outside New York).

74. Therefore, insofar as distributors can pass the cost of the Surcharge upstream, the Act burdens out-of-state manufacturers and the distributors' transactions with them.

75. Furthermore, insofar as distributors are *not* able to pass the cost of the Surcharge upstream, the Act burdens out-of-state distributors with costs that cannot be passed along to downstream purchasers, in New York or elsewhere.

76. Likewise, the Act may lead distributors to cause manufacturers to ship opioid products directly into New York, such that the manufacturers bear the cost of the Surcharge. Insofar as it does, the Act undoes long-established, efficient logistical mechanisms for distributing pharmaceutical products. Instead, the Act favors the use of in-state facilities at a higher cost to the distributor. The Act thus imposes an undue burden on distributors that receive opioid products from manufacturers outside New York.

77. This scheme effectuates no legitimate local public interest. Furthermore, the Cost-Pass-Through Prohibition evinces an intent on behalf of the State to protect in-state interests (namely, the interests of dispensing providers and pharmacies) and to punish primarily out-of-state interests (those of manufacturers and distributors).

78. The effects of this scheme on interstate commerce are more than incidental. The scheme will impose massive costs on out-of-state and interstate transactions.

79. The burden on interstate commerce this scheme poses is clearly excessive in relation to any putative local benefit.

Count Seven—Unconstitutional Vagueness Challenge to Surcharge

80. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 79 as if fully set forth herein.

81. A statute is unconstitutionally vague if it authorizes arbitrary or discriminatory enforcement.

82. The Act allows the Department to alter a Licensee's MME count—and therefore its Surcharge payment—"to account for the nature and use of the product" and "the type of entity purchasing the product." § 3323(5)(a).

83. Furthermore, the Act does not require the Department to explain these alterations, providing only that the Department "shall notify the licensee in writing . . . based on the opioids sold or distributed for the prior calendar year." § 3323(5)(c).

84. The terms "nature and use" and "type of entity" are unconstitutionally broad and allow the Department to alter MME counts arbitrarily and discriminatorily.

85. The Act is further unconstitutionally vague in that it allows the Department to alter MME counts without giving the Licensee notice as to how their counts were reached and how the Surcharge applies.

Count Eight—Unconstitutional Vagueness Challenge to Cost-Pass-Through Prohibition

86. HDA repeats and realleges each and every allegation contained in paragraphs 1 through 85 as if fully set forth herein.

87. A statute is unconstitutionally vague if it fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits.

88. The Cost-Pass-Through Prohibition prohibits distributors from passing the Surcharge's cost "to a purchaser." § 3323(2).

89. Because money is fungible, it is all but impossible to determine whether the Surcharge's cost is passed to a purchaser. Any given increase in any opioid's price may result from myriad business factors. Likewise, any increase in distributors' costs will ultimately be reflected in their products' prices. If the costs of production increase for any reason, drug prices may increase in response.

90. Finally, the Act provides no standards as to how the Department will determine whether a distributor has violated the Cost-Pass-Through Prohibition. The potential penalties of $1 million "per incident" create the risk of astronomical liability and give the Department an improper amount of leeway in implementing this provision, creating an unconstitutional risk of arbitrary and discriminatory enforcement.

* * *

91. The Act's enforcement and administration are and will be under color of state law and violate the constitutional rights, privileges, and immunities of HDA's members. The Act is therefore actionable under 42 U.S.C. § 1983.

92. HDA's members have no adequate remedy at law available against Defendants for the infringement of their constitutional rights.

REQUEST FOR RELIEF

WHEREFORE, HDA respectfully prays that this Court:

(1) declare the Act unconstitutional,

(2) permanently enjoin Defendants and their agents, servants, employees, and all persons in active concert or participation with them from taking any action under or to enforce the Act,

(3) award HDA reasonable attorney's fees and costs pursuant to 42 U.S.C. § 1988, and

(4) grant HDA such additional or different relief as it deems just and proper.

Dated: July 6, 2018

Respectfully submitted,

By: */s/ John Calandra*
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**Admitted in North Carolina. Not yet admitted in the District of Columbia. Supervised by principals who are admitted to the DC bar.*

Exhibit A

TITLE 2-A OPIOID STEWARDSHIP ACT

§ 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.

* * *

§ 2

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

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

* * *

§ 3

The state finance law is amended by adding a new section 97-aaaaa to read as follows:

§ 97-aaaaa. Opioid stewardship fund.

1. There is hereby established in the joint custody of the state comptroller and the commissioner of taxation and finance an account of the miscellaneous special revenue account to be known as the "opioid stewardship fund".

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

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

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

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

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

(ii) Such certificate may be amended from time to time by the director of the budget, upon the recommendation of the commissioner of the office of alcoholism and substance abuse services, and a copy of such amendment shall be filed with the comptroller, the chairman of the senate finance committee and the chairman of the assembly ways and means committee.

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

§ 4 Severability

If any clause, sentence, paragraph, subdivision, or section of this act shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or invalidate the remainder

thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, or section directly involved in the controversy in which such judgment shall have been rendered. It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

§ 5

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

§ 2. Severability clause.

If any clause, sentence, paragraph, subdivision, section or part of this act shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part thereof directly involved in the controversy in which such judgment shall have been rendered. It has hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.

§ 3

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

Exhibit B

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

June 15, 2018

Dear Manufacturers, Distributors, and Importers of Controlled Substances:

Enclosed is the **New York State Opioid Annual Assessment Reporting Guidance** document which defines sales and distribution data reporting requirements under the Opioid Stewardship Act. Transaction data for 2017 is due on August 1, 2018. Additional technical reporting guidance and specifications are available on the Health Commerce System webpage:

1. **New York State Opioid Annual Assessment Reporting Guidance:** https://apps.health.ny.gov/pub/ctrldocs/bne/nyosareportingguidance.pdf
2. **NY Opioid Annual Assessment Technical Report and File Specifications:** https://apps.health.ny.gov/pub/ctrldocs/bne/nyosatechnicalspecifications.html
3. **NY Opioid Assessment Report (Sample Report of uploaded data):** https://apps.health.ny.gov/pub/ctrldocs/bne/nyosareportsample.html
4. **Sample xml Upload File:** https://apps.health.ny.gov/pub/ctrldocs/bne/nyosareportsample.xml
5. **NY Opioid Validation Code:** https://apps.health.ny.gov/pub/ctrldocs/bne/NyOpioidAssessmentReport.xsd
6. **NYS DOH Morphine Milligram Equivalent drug file – available soon:** https://apps.health.ny.gov/pub/ctrldocs/bne/nysdohosandcmme2017.xlsx
7. **NYS Morphine Milligram Equivalent Guidance Document – available soon:** https://apps.health.ny.gov/pub/ctrldocs/bne/nyosammeformulation.pdf

Reports are to be uploaded through the NYS Health Commerce System's Controlled Substance Distribution and Sales Reporting (CSDSR) application. In addition, there will be a manual entry option available to submit required data.

Additional details are available online at www.health.ny.gov/professionals/narcotic. Questions may be sent to osa@health.ny.gov.

Sincerely,

Joshua S. Vinciguerra

Joshua S. Vinciguerra
Director, Bureau of Narcotic Enforcement

New York State Opioid Annual Assessment Reporting Guidance

The Opioid Stewardship Act (OSA) requires New York State Department of Health (NYS DOH) licensed manufacturers and distributors to report transaction information for all opioids sold or distributed to or within New York. The OSA establishes a first-in-the-nation Opioid Stewardship program in which manufacturers, distributors, and importers will help to fund the fight against the opioid epidemic through an assessment. The reported data will form the basis for the assessment to be paid to New York State.

The intent of the OSA is for all manufacturers and distributors to be responsible for their ratable share of opioids sold or distributed into New York. As such, assessments will be based on the initial transaction in the distribution chain when opioids are first sold or distributed within, or into, New York. Opioids subsequently sold or distributed outside of New York or returned for non-use or expiration, will be subtracted from that entity's ratable share. The law states that a penalty may be imposed if a licensee passes any portion of the ratable share to the purchaser, however this is not intended to apply to price increases that are attributable to other ordinary changes in manufacture or distribution costs.

Overview of OSA Annual Reporting Requirements

NYS DOH will calculate ratable shares of the assessment based on certain reported opioid transaction information in morphine milligram equivalents (MME), and will issue invoices for the ratable shares of the assessment to each licensee. Licensees should report the 2017 Calendar Year transactions by August 1, 2018. The Department will provide guidance on when subsequent reports and payments are due for future years.

Reporting shall be in the manner and format specified by NYS DOH as defined below and specified in the **'NY Opioid Annual Yearly Assessment Technical Report and File Specifications'** document available at: nyosatechnicalspecifications.html

Pursuant to Public Health Law §3323(1)(c) "distribute" means to deliver a controlled substance other than by administering or dispensing to the ultimate user, not including drugs surrendered to reverse distributors.

For the purposes of the OSA, "sell" shall not include mere offers or agreements to do the same. The OSA's reporting and assessment requirements apply to completed distribution and sale transactions.

Other exclusions may apply as described in further detail below. Hence, it is possible that the OSA requires a licensee to report its transactions even if the result is that the licensee has no assessable transactions.

Important Note: Failure to report required data may result in a civil penalty of up to $1,000.00 per day, pursuant to Public Health Law §3323(10)(a).

****

Definitions for Required Data Elements:

Reporter DEA Number – DEA registration number of the NYS DOH Controlled Substance licensee authorized to sell or distribute controlled substances to or within NYS. The NYS DOH Controlled Substance licensee must submit a separate report for each DEA number under which it made a reportable transaction during the Transaction Year.

Reporter NY Controlled Substance License – NYS DOH Controlled Substance license number for the entity authorized by NYS to sell or distribute controlled substances to or within NYS. If the license number and associated Reporter DEA Number changed during the transaction year, indicate the license number corresponding with the Reporter DEA Number at the time of the transaction. If more than one license number was on file for the same Reporting DEA number, provide the more recent license number on record for that transaction year.

Transaction Year – The calendar year in which an opioid sale or distribution occurred.

NY Gross Opioid Receipts – The total overall sales in dollars and cents for all opioids sold or distributed to or within NYS, minus opioid returns to the reporter, during the Transaction Year being reported. Do not include any sales from NYS to outside of NYS.

NY Gross Assessable Opioid Receipts – *This shall only apply to the initial transaction in the distribution chain when opioids are sold or distributed to or within NYS.* The total NY Gross Opioid Receipts (defined above), minus sales of opioids which:

A. Are sold to entities certified to operate pursuant to Article 32 of the Mental Hygiene Law or Article 40 of the Public Health Law;
B. Are buprenorphine, methadone, or morphine;
C. Have an MME conversion factor of zero pursuant to the formulation issued by NYS DOH; or
D. Are direct sales to:
    1. Veterinarians;
    2. Federal Veteran Administration Hospital Pharmacies;
    3. Federal Installations (i.e., West Point, Fort Drum, etc.); or
    4. Indian Reservations.

NY Total MMEs – The sum of morphine milligram equivalents for all opioid sales or distributions to or within NYS minus opioid returns to the reporter, during the Transaction Year being reported. Determination of MMEs will be pursuant to the formulation issued by DOH.

NY Total Assessable MMEs – *This shall only apply to the initial transaction in the distribution chain when opioids are sold or distributed to or within NYS.* The NY Total MMEs (defined above) minus those MMEs attributable to sales or distributions excluded as described in 'NY

Gross Assessable Opioid Receipts' parts A-D above equals the NY Total Assessment MMEs. In addition, distribution of MMEs reported by a manufacturer or distributor in the 'NY Total MMEs' above, are excluded from 'NY Total Assessable MMEs' if the sale of the product is to an entity located outside of NYS.

Billing Contact Name – First and last name of individual to be contacted for questions related to invoice.

Billing Contact Phone – Phone number for 'Billing Contact Name'.

Billing Contact Email – Email address for 'Billing Contact Name'.

SFS Customer ID – Customer ID assigned by DOH for invoicing purposes in the Statewide Financial System.

Reporting Contact Name – First and last name of individual to be contacted for questions related to the NY Opioid Assessment data reported.

Reporting Contact Phone – Phone number for 'Reporting Contact Name'.

Reporting Contact Email – Email address for 'Reporting Contact Name'.

Reporter Address – Reporter name and address.

Name (Required)
Address1(Required)
Address2 (Optional)
City (Required)
State (2-digit abbreviation - Required)
Zipcode (Required)
Zipcode + 4 (Optional)
NYS County (Required, see technical document, enter 'Not NY' if non-NYS)

Billing Address – Name and address for invoicing purposes.

Name (Required)
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State (2-digit abbreviation - Required)
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NYS County (Required, see technical document, enter 'Not NY' if non-NYS)

NY Total Distributed Opioid Drug List

Indicate a summary of opioid drugs sold or distributed to or within NYS. Enter one summary row per NDC number sold or distributed. The column headings are defined below:

- **National Drug Code (NDC) numbers** - the 11-digit code identifying the drug.
- **Package size** - Packaging as indicated by the last two digits of the NDC number (the package code). For example, a package code of '02' for a particular labeler's NDC number could = a bottle of 100 tablets. In this example, indicate '100' for the Package Size.
- **NY Total packages** - The total number of packages sold or distributed to or within NYS for that particular NDC number.
- **NY Total MMEs** - Total number of morphine milligram equivalents (MMEs) sold or distributed to or within NYS for that particular NDC number.
- **NY Total Assessable Packages** - The total number of packages sold or distributed to or within NYS for that particular NDC number minus sum of MMEs that are exempt as stated in **NY Total Assessable MMEs** as previously defined.
- **NY Total Assessable MMEs** - Total number of morphine milligram equivalents (MMEs) sold or distributed to or within NYS for that particular NDC number minus the sum of MMEs that are exempt as stated in **NY Total Assessable MMEs** as previously defined.

NY Exempt Opioid Drug List

Provide a list of each NDC Code for opioids sold or distributed to or within NYS that are exempt from the assessment. Exempted Drugs are:

Buprenorphine
Methadone
Morphine
Alfentanil
Sufentanil
Remifentanil
Fentanyl in Solution
Fentanyl Base/Powder

NY Receiving-Associate DEA List

List each receiver/associate DEA Number, their NYS Controlled Substance License Number, if applicable, and the receiver status of that associate. Each associate DEA Number should be listed only once.

- **Receiver DEA Number** - The associate registrant number is a 9-character DEA number identifying the recipient of the opioids with which the transaction took place.
- **Receiver NY Controlled Substance License** - The NY Controlled Substance License Number of the receiver, if applicable. Example: 0309999.
- **Receiver Status** - State whether that receiver/associate entity is included in the assessment. Receiver Status options are limited to the following:
    - **Reportable** - The transaction with this receiver is not exempt from the assessment.
    - **MentalHygeine32Exempt** - The transaction with this receiver is always exempt from the assessment because it is an entity certified to operate pursuant to Article 32 of the Mental Hygiene Law.

- **PublicHealth40Exempt** - The transaction with this receiver is always exempt from the assessment because it is an entity certified to operate pursuant to Article 40 of the Public Health Law.
- **Veterinarian Exempt** - The transaction with this receiver is always exempt from the assessment.
- **FederalVAExempt** - Federal Veteran Administration Hospital Pharmacies. The transaction with this receiver is always exempt from the assessment.
- **OtherGovFedExempt** - Federal Installations (i.e., West Point, Fort Drum, etc.). The transaction with this receiver is always exempt from the assessment.
- **IndianReservationExempt** - The transaction with this receiver is always exempt from the assessment.
- **FinalPOSNonNYExempt** - The transaction with this receiver is always exempt from the assessment because the final point of sale is outside of NYS.

Comments - Please provide any comments or clarifications. This field is limited to 4,000 characters.

IHANS OSA Notification 2

Effective July 1, 2018, pursuant to the Opioid Stewardship Act (OSA), all manufacturers, distributors, and importers that were licensed in New York State (NYS) at any time during the 2017 calendar year, must report transaction information for all opioids sold or distributed within, or into, NYS. Reports must be submitted to the NYS Department of Health's Bureau of Narcotic Enforcement. Please see the attached reporting guidance. Reports must be submitted by August 1, 2018.

New York State Opioid Annual Assessment Reporting Guidance

The Opioid Stewardship Act (OSA) requires New York State Department of Health (NYS DOH) licensed manufacturers and distributors to report transaction information for all opioids sold or distributed to or within New York. The OSA establishes a first-in-the-nation Opioid Stewardship program in which manufacturers, distributors, and importers will help to fund the fight against the opioid epidemic through an assessment. The reported data will form the basis for the assessment to be paid to New York State.

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