State Opioid Taxes

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Misuse and abuse of both prescription and illicit opioids have led to a national epidemic. Perhaps inspired by the trend to tax tobacco, alcohol, and even soda, some policymakers have been drawn to the idea of taxing prescription opioids.¹ To deter opioid use and defray some of the costs resulting from the abuse of both prescription and illicit opioids, state legislatures are considering new laws that impose a tax or substantial fee² on opioid manufacturers and distributors.

¹ Alex Brill, “State Opioid Taxes: Economic & Health Policy Implications,” at 10 (Jan. 2019) (Brill White Paper). In 2015 the economic impact of the opioid epidemic was estimated at $504 billion, which consisted of $431.7 billion in mortality costs and $72.3 billion in non-mortality costs (health, productivity, and criminal justice). Id. at 5; Alex Brill and Scott Ganz, “The Geographic Variation in the Cost of the Opioid Crisis,” American Enterprise Institute, at 4 (Mar. 2018).

² States have various approaches for imposing these charges. For ease of reference, this article may refer to such charges as a tax although they may technically be a fee, license, surcharge, etc.
To date New York, Delaware, and Minnesota have enacted such measures, and over 15 states have considered similar legislation during the last three years. The enacted measures (and a number of the proposals) take different approaches to the nature and structure of the tax, which means that the compliance demands and approaches required of taxpayers are also likely to differ. The purpose of this article is to review the laws in these three states and to offer some observations on the compliance requirements facing taxpayers.

Approaches to Opioid Taxation

The approaches taken by the states in the enacted measures and proposals from 2017-2019 include excise taxes, value-based taxes, gross receipts taxes, and substantial license fees. The enacted measures are discussed further below.

3 Brill White Paper, supra note 1, at 7. Abuse of prescription opioids is no longer the main problem, because the use of cheaper, illicit opioids on the rise. Nonetheless, most new heroin users started out misusing prescription painkillers. Id. at 2 (“Only slightly more than one-third of people who misuse prescription painkillers are prescribed them by a doctor.”); American Society of Addiction Medicine, “Opioid Addiction: 2016 Facts & Figures”; and Elizabeth Y. Schiller and Oren J. Mechanic, “Opioid Overdose,” National Center for Biotechnology Information (updated Mar. 2, 2019) (“The majority of the opioid deaths are attributable to the use of heroin and synthetic opiates other than methadone. Heroin, at about $2 a bag, is up to 10-fold cheaper than prescription opioid medications for street purchase, which cost on average $1 per milligram.”).


6 See supra note 5.

7 An MME is the “conversion factor used to calculate the strength of an opioid using morphine dosage as the comparative unit of measure.” Del. Code Ann. tit. 16, section 4802B(4).

8 An MME is a single dosage form of an opioid multiplied by its strength per unit multiplied by the morphine milligram equivalent conversion factor. N.Y. Tax Law section 497(6).

9 Similar legislation was considered in: Alaska, California (2017), Idaho, Maine (2017), Massachusetts, Montana, and New Jersey.

10 Kentucky defined a dose as “a single pill, capsule, ampule, liquid, or other form of administration available as a single unit.” H.B. 337, section 1(6) (Ky. 2018).

11 In 2019 similar legislation was considered in California, Maine, and Rhode Island.
New York

Structure of Tax

Effective July 1, 2019, the New York excise tax on opioids is imposed against opioid registrants on first sales in the state. A registrant is any person, firm, corporation, or association that holds and transfers title to an opioid unit and:

- Is required to register with the state Department of Health (DOH) as a manufacturer or distributor of a controlled substance (DOH registrant);
- Is required to register with the state Department of Education (DOE) as a wholesaler, manufacturer, or outsourcing facility (DOE registrant);
- Is a nonresident establishment excepted from registration with the DOE under state education law.

The tax is intended to apply to anyone who manufactures or distributes controlled substances or possesses drugs for some purpose other than personal use or to facilitate an intracompany transfer (for nonresidents). It is imposed at the point of first sale by a registrant in the state. First sale is defined as “any transfer of title to an opioid unit for consideration where actual or constructive possession of such opioid unit is transferred by a registrant holding title to such opioid unit to a purchaser or its designee” in New York for the first time. A sale does not include the transfer of an opioid unit in accordance with a prescription to an ultimate consumer or the transfer of an opioid unit from a manufacturer in New York to a purchaser outside New York when it will be used or consumed outside the state. All sales of opioid units in New York are presumed to be a first sale and taxable, and the burden of proof is on the registrant to establish that a sale was not a first sale.

Tax Rates and Compliance

The tax is imposed at $0.0025 on each MME with a wholesale acquisition cost of less than $0.50 per unit, or $0.0150 on each MME with a wholesale acquisition cost of $0.50 or more per unit. The DOH provides an opioid drug list and an MME conversion table to assist with the calculation.

All registrants liable for the opioid tax are required to file an excise tax return with the Commissioner of Taxation and Finance. The return is required to include total MMEs subject to the tax; wholesale acquisition costs of opioids subject to tax; and the amount of tax due. The first return is due January 21, 2020, and will include sales for the period July 1, 2019, through December 31, 2019. Subsequent returns will be due quarterly on the 20th of the month following the end of the calendar quarter. Returns must be filed through the department’s opioid excise tax web file application. Registrants will be able to claim a credit on later returns for tax previously paid on canceled purchases or for tax paid on sales of opioid units that were later distributed.

\[\text{Note}\ 27\]


N.Y. Tax Law section 497(f).

The DOH registration requirement is triggered when a person, firm, corporation, or association manufactures or distributes a controlled substance within New York. N.Y. Pub. Health Law section 3310(1). All opioids covered under the tax are included in the definition of controlled substance. N.Y. Tax Law section 497(a); and N.Y. Pub. Health Law sections 3302(5), 3306(b).

The DOE registration requirement is triggered when a person, firm, corporation, or association that possesses drugs for the purpose of compounding, dispensing, retailing, wholesaling, manufacturing, or offering drugs for sale at retail or wholesale. N.Y. Educ. Law section 6808(1).

Nonresident establishments are excepted from registration when the potential registration requirement is for intracompany transfers between a division, affiliate, subsidiary, parent, or other entity under complete common ownership and control. Id. section 6808-b(2).

Drugs are broadly defined to include all opioids covered under the New York Opioid Excise Tax. Id. section 6802(7).

N.Y. Tax Law section 498(a).
outside New York for use and consumption outside the state.\(^{30}\)

The tax requires that all sales slips, invoices, receipts, or other statements or memoranda of sale from any sale or purchase of opioid units by registrants be retained for six years after their related return due date.\(^{31}\) Records must be sufficient to determine the number of units and MME for the units, and they must be suitable to determine the amount of tax due. Records must state either the address from which the units are shipped or delivered and the address to which the units are shipped or delivered or where physical possession of the units is transferred.\(^{32}\)

DOH Annual Report

The new law imposes a reporting requirement to the DOH.\(^{33}\) The first report is due on July 20, 2020, and must include transaction information from July 1, 2019, through December 31, 2019.\(^{34}\) Subsequent reports will be due annually on April 20 and include transaction information for the preceding calendar year.\(^{35}\) For current DOH registrants, this report is an expanded version of the DOH controlled substance electronic monthly report.\(^{36}\) For DOE registrants, this is a new reporting requirement.

Like the current monthly DOH report, the annual report must include the:

- registrant’s name, address, phone number, DEA registration number, and state identifying information;
- buyer’s name, address, and DEA registration number;
- date of sale;
- gross receipts for each opioid sold;
- name and national drug code (NDC) of the opioid sold;
- transaction details; and
- total number of MMEs sold.\(^{37}\)

New York enacted the Opioid Stewardship Act in 2018. The measure imposed a tax like the one described above except that it prohibited opioid manufacturers and distributors from passing the costs of the tax to downstream purchasers.\(^{38}\) Before the law took effect, a federal district court determined the tax was unconstitutional because the law’s passthrough provision violated the commerce clause.\(^{39}\) The current version does not prevent manufacturers and distributors from passing the tax forward.\(^{40}\)

Delaware

Tax Structure and Rates

Delaware’s new law imposes an impact fee on opioid manufacturers. The law was effective upon enactment, June 12, 2019,\(^{41}\) and is scheduled to expire on January 1, 2025.\(^{42}\) The fee is imposed on opioid manufacturers, defined as persons “engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription opioid drug, but does not include a person who is engaged in the preparation and dispensing of a drug pursuant to a prescription.”\(^{43}\) A manufacturer must pay the impact fee if it dispenses more than 100,000 MMEs of prescription opioid products in the state in a quarter.\(^{44}\) The fee is imposed on both in-state and out-of-state opioid manufacturers and is based on opioids dispensed in the state.\(^{45}\) The fee is calculated at $0.0100 per MME for a prescription

\(^{30}\) N.Y. Tax Law section 498(c).

\(^{31}\) N.Y. Tax Law section 498(d).

\(^{32}\) Id.

\(^{33}\) N.Y. Tax Law section 498(g).

\(^{34}\) Supra note 24.

\(^{35}\) Id.


\(^{37}\) N.Y. Tax Law section 498(g); and N.Y. Comp. Codes R. and Regs. tit. 10, section 80.23(f).

\(^{38}\) See supra note 4.

\(^{39}\) Id.

\(^{40}\) See N.Y. Tax Law section 498 (providing no restrictive language as in the prior version).

\(^{41}\) Delaware S.B. 34. The state estimates that the impact fee will generate more than $8 million over a three-year period, with funds being used to subsidize enrollment in residential treatment programs for uninsured and underinsured individuals, expanding treatment options, and conducting treatment research. Staff, “House Passes Bill That Will Tax Opioid Companies With Revenues Used for Treatment, Research,” Delaware Business Now, May 16, 2019.

\(^{42}\) S.B. 34, 150th Gen. Assemb. section 3 (Del. 2019).

\(^{43}\) Del. Code Ann. tit. 16, section 4802B(3).

\(^{44}\) Del. Code Ann. tit. 16, section 4804B(a).

\(^{45}\) Del. Code Ann. tit. 16, section 4801B(8).
opiodispensed and reported in the Prescription Monitoring Program (PMP), or $0.0025 per MME for a prescription opioid that is a generic substitution.54

Tax Compliance

Based on information obtained from the PMP, the secretary of state will calculate the total impact fee due from each manufacturer on a quarterly basis and invoice the manufacturer beginning with the close of the first full quarter after the effective date of the act (September 30, 2019).48 The payment is due one month after the date of the invoice.49 Manufacturers can request a hearing with the secretary of state to dispute the invoice amount.50

Under the PMP, Delaware pharmacies and practitioners (and out-of-state pharmacies that deliver, ship, or mail into Delaware) that dispense controlled substances are required to electronically submit data pertaining to the sale of all Schedule II, III, IV, and V controlled substances on a daily basis, with limited exceptions.51 The reports must include the NDC for each prescription.52 The NDC is a unique number that contains a labeler code identifying the manufacturer, repackager, or distributor for each prescription.53 The secretary of state will use these reports to calculate each manufacturer’s impact fee. The fee does not place any new or additional reporting or compliance requirements on pharmacies, practitioners, manufacturers, repackers, or distributors beyond the existing PMP requirements.

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54 A PMP is a program established in Del. Code Ann. tit. 16 section 4798. Id. section 4802B(6).
57 Del. Code Ann. tit. 16, section 4804B(e). Failing to pay by the due date results in a penalty of $100 per day or 10 percent of the impact fee due, whichever is greater, with interest tacked on at a rate of 1 percent a month. Id. section 4804B(f).
58 Del. Code Ann. tit. 16, section 4804B(g).
60 “Frequently Asked Questions,” supra note 51.
61 21 C.F.R. section 207.33(b)(i), (c) (July 15, 2019).

Minnesota

Minnesota enacted the opiate product registration fee on May 22, 2019; it became effective July 1.55 The registration fee is $250,000 for any opiate manufacturer that sells, delivers, or distributes 2 million or more units of an opiate within or into the state annually.56 Following are definitions relevant to the new law (section references are to Minnesota Statutes Annotated):

- Manufacturer: “a manufacturer licensed under section 151.252 that is engaged in the manufacturing of an opiate”;
- Wholesaler: “a wholesale drug distributor licensed under section 151.47 that is engaged in the wholesale drug distribution of an opiate”;
- Opiate: “any opiate-containing controlled substance listed in section 152.02, subdivisions 3 to 5, which is distributed, delivered, sold, or dispensed into or within this state”; and
- One unit: “equals one tablet, capsule, patch, syringe, milliliter, or gram.”

Beginning March 1, 2020, manufacturers and wholesalers must report to the Board of Pharmacy “every sale, delivery, or other distribution within or into this state of any opiate that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person” permitted to possess controlled substances.58 The report is made annually by March 1 and contains data for the prior calendar year.59 Pharmacies are similarly required to report “any intracompany delivery or distribution into this state . . . to the extent that those deliveries and distributions are not reported” by a licensed wholesaler.60 By April 1 of each year, the Board of Pharmacy must notify a manufacturer that the manufacturer has met the threshold and thus is required to remit the
registration fee. Manufacturers have 30 days from the date of notification to dispute the board’s determination; however, the registration fee still must be paid, pending the outcome of the dispute. The new law also substantially increased the license fees imposed on manufacturers of opiate-containing substances to $55,000.

Observations

New York, Delaware, and Minnesota are the first states to enact legislation designed to offset costs related to the abuse of prescription and illicit opioids. More states are likely to follow, and it will be important for affected entities to track the state changes and identify the potential impact to the organization.

Becoming compliant with the new state legislation will require additional time and resources. Taxpayers should consider the following steps in preparing to comply with existing laws and new proposals.

Develop a Cross-Functional Approach

Manufacturers should evaluate which departments will be responsible for compliance. Coordination between tax, accounting, regulatory, sales, and other functions will be necessary to track the requirements, obtain the correct data, and comply with varied state rules. In some instances, such as with the New York tax, the indirect or state and local tax department may take the lead with coordination from the business units, which can provide the necessary detailed transaction data. However, for Delaware, the accounting department may be responsible for paying the bill sent by the state but will need to coordinate with other departments to confirm the accuracy of the fee. For states like Minnesota that have a license fee based on a gross amount, the accounting or regulatory department may be responsible for compliance. In all cases, close coordination with the company’s regulatory department will be imperative.

Develop a Compliance Strategy

Once data needs, information gaps, and the location of the responsibility are determined, procedures with controls are necessary. These controls will likely vary based on the type of opioid levy enacted by the state (e.g., tax vs. fee). These compliance procedures will likely include strategies for determining the amount of tax due, reporting the tax, and preparing associated documentation, registrations, and reports that may be required by states. For states with fees, procedures should be developed for confirming that the state’s determinations are correct.

Identify Issues That Require Additional Clarification

As companies begin to apply the new laws, it is likely that unanswered questions will arise for each state, such as how to handle returns, destroyed product, and subsequent dispositions outside the state. Companies should be prepared to provide comments to states and obtain required answers in order to comply.

Identify Compliance Information Gaps

Each state has a different reporting requirement that will require interaction with many parties to determine if the information is available in the company’s current system and can be made available to the compliance function. For example, with New York, which is a transaction-based tax, sales into the state must be tracked to determine the tax due. With the Delaware fee, manufacturers must be able to obtain and understand the data associated with the opioids in the PMP system. This data is input by pharmacies and practitioners, not the manufacturer. This will present challenges relating to data verification and other third-party reporting issues. In all cases, manufacturers should evaluate what data is needed for compliance and compare that with what data is readily available. To the extent needed information is not available, manufacturers should develop plans to close the information gaps.

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63 Minn. Stat. Ann. section 151.065(subd. 1), (subd. 3).
Monitor State Developments

As new states enact legislation, companies need to develop a plan to monitor the new developments and set processes in place to prepare for new filings and payment requirements.

Conclusion

New York, Delaware, and Minnesota have enacted legislation to counter the costs associated with the abuse of prescription and illicit opioids. In the coming months, it is expected that more states will enact similar legislation — whether in the form of a tax, a fee, or a licensing requirement. Because of the variety of laws enacted regarding opioids, each state will necessarily have varying compliance issues that will challenge taxpayers.