

# New York State Department of Health Opioid Excise Tax Annual Report Guidance

Article 20-D of New York State Tax Law establishes an Opioid Excise Tax. In compliance with Tax Law §498, each registrant (such as a manufacturer, wholesaler, or outsourcing facility) shall provide an annual report to the Department of Health detailing all opioids sold into or within New York State.

**This guidance document refers to the Department of Health’s annual reporting requirements only. It does not address the quarterly tax return filings required by Tax Law §498. For additional information on the Opioid Excise Tax, visit the Department of Taxation and Finance’s webpage at <https://www.tax.ny.gov/bus/oet/oetidx.htm>.**

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## Required Reporters

All registrants as defined by Tax Law §497 must report annually to the Department of Health detailed information on all opioids sold by such registrant into or within New York State:

- Any person, firm, corporation or association that holds and transfers title to an opioid unit and:
  - Is required to be registered with the New York State Education Department (NYSED) as a wholesaler, manufacturer, or outsourcing facility pursuant to §6808 or §6808-b of the education law, **or**
  - Would be required to be registered with the New York State Education Department (NYSED) as a wholesaler, manufacturer, or outsourcing facility pursuant to such §6808-b but for the exception in subdivision two of such section, **or**
  - Is required to be registered with the New York State Department of Health (DOH) as a manufacturer or distributor of a controlled substance pursuant to PHL §3310.

## Report Requirements

One report should be submitted for all registrants that operate under one corporate Taxpayer Identification Number (TIN). For example, if a reporting entity has multiple DEA registration numbers, NYS Education Department registration numbers and/or NYS DOH Controlled Substance License numbers associated with the same corporate TIN, then the opioid transaction detail should all be included in one report.

All transactions (including sales, returns, credits, and cancellations) of a finished opioid unit by a registrant into or within New York State must be reported.

The annual report to DOH should include:

- First and subsequent opioid transactions into or within New York State
- Transactions to all purchasers; including programs operated pursuant to Mental Hygiene Law Article 32 and Public Health Law Article 40
- Transactions of opioids for veterinary use

Transactions that do not need to be reported:

- Buprenorphine
- Methadone
- Morphine
- Active Pharmaceutical Ingredients, Raw Materials and Bulk Powders
- Sales to a purchaser outside of New York State when the opioid unit will be used or consumed outside of New York State

Submission of reports reflecting no activity are not required, but they will be accepted.

**In accordance with Tax Law Article 20-D, annual reports to NYSDOH must include the following information:**

**IDENTIFYING INFORMATION**

- Taxpayer Identification Number
  - Transaction Reporting Year
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**REGISTRANT INFORMATION**

- Registrant Corporate Name
  - Corporate Address
  - Corporate E-mail
  - Corporate Phone Number
  - DEA Registration Number(s), if applicable
  - DOH Controlled Substance (CS) License Number(s), if applicable
  - NYSED Registration Number(s), if applicable
  - Licensee Corporate Name
  - Submitter Name and Contact Information
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**INFORMATION FOR ALL OPIOID TRANSACTIONS**

- Seller Transaction ID
- Seller Invoice Number
- Seller DEA Number, CS License Number, SED Registration Number (where applicable)
- Buyer DEA Registration Number
- Buyer DOH CS License Number, if applicable
- Buyer DEA Name
- Buyer DEA Address
- Buyer Type
- Transaction Date
- Transaction Type
- Original Sale Date, returns only
- Original Sale Invoice, returns only
- Gross Receipt Total for Each Transaction
- First Sale Indicator
- 11-digit National Drug Code (NDC)
- Name of Opioid
- Strength Per Unit
- Units Per Saleable Container
- Number of Containers of Opioid for Each Transaction
- Total Metric Quantity
- MME Conversion Factor
- Total Morphine Milligram Equivalent (MME) for Each Transaction
- Wholesale Acquisition Cost (WAC) Threshold Exceeded (is WAC greater than or equal to \$0.50)

## Reporting Instructions

The NYS DOH Opioid Excise Tax Annual Report must be submitted through the New York State Health Commerce System (HCS). Organizations must have a representative with an active HCS account that is linked to their reporting organization to submit their report through the **Controlled Substance Distribution and Sales Reporting (CSDSR) application**. The representative must have the Opioid Annual Report Data Submitter role under their reporting organization to submit the report.

If your organization does not currently hold a NYS DOH Controlled Substance License then you will not be able to access the CSDSR application. Please send an email to [mme@health.ny.gov](mailto:mme@health.ny.gov) for assistance.

Instructions for establishing a new HCS account can be found in Appendix B.

### **Timeline**

The first annual report must be submitted to DOH by **August 20, 2020** for transactions occurring between July 1, 2019 and December 31, 2019.

Subsequent annual reports will be due on **April 20** of each year for transactions occurring during the preceding calendar year (January 1 through December 31). For example, all reportable opioid transactions occurring January 1, 2020 through December 31, 2020 must be included on a registrant's annual report submitted to DOH by April 20, 2021.

Corrections to any reportable opioid transactions from a prior reporting year must be included on a full file re-submission of that annual report.

### **Submission Format**

Submission of the annual report will be by XML (or by XML simulated workbook). The file specifications and data field definitions can be found at:

[https://www.health.ny.gov/professionals/narcotic/opioid\\_excise\\_tax.htm](https://www.health.ny.gov/professionals/narcotic/opioid_excise_tax.htm)

An Excel submission template, which includes instructions on generating an XML file, is available for registrants if Excel can support the number of transactions being reported.

## Appendix A. Calculating Morphine Milligram Equivalent (MME)

In its annual report, registrants must report the total number of MME of each opioid transaction into or within New York State. The MME Conversion Table<sup>1</sup> is available at [NDC MME Table](#) and includes the 9-digit National Drug Code (NDC), strength per unit, and MME conversion factor for the opioid. If an NDC is not found on the MME conversion table, please send an email to [mme@health.ny.gov](mailto:mme@health.ny.gov) and include “Drug Not Found” in the subject line of the e-mail.

The formula for calculating the MME is as follows:

**Multiply: # of units x strength per unit x MME conversion factor**

- **Unit:** a single finished dosage form of an opioid, such as a pill, tablet, capsule, suppository, transdermal patch, buccal film, milliliter of liquid, milligram of topical preparation, or any other form.
- **Strength per Unit:** amount of opioid in a unit measured by weight, volume, concentration or other metric.
- **MME Conversion Factor:** reference standard of a particular opioid, as it relates in potency to morphine as determined by the commissioner of health.
- **MME:** a unit multiplied by its strength per unit multiplied by the MME conversion factor
- **Saleable Container:** the container of product introduced into commerce by the manufacturer and intended for sale to a dispenser.

**Example for the calculation of MME for tablets, capsules, and other solid dosage forms:** For 5mg hydrocodone tablets, the current conversion factor listed on the MME conversion Table is 1 MME.

- *For one bottle of 500 tablets, the calculation of MMEs is:*  
 $500 \text{ tablets} \times 5\text{mg} \times 1 \text{ MME} = 2,500 \text{ MMEs per bottle}$
- *For the distribution of 20 bottles each containing 2,500 MME:*  
 $20 \text{ bottles} \times 2,500 \text{ MME per bottle} = 50,000 \text{ Total MMEs}$

**Example for the calculation of MME for liquids:** For a 50mg/mL meperidine hydrochloride solution, the current conversion factor listed on the MME conversion table is 0.1 MME.

- *For a box of 25 x 0.5mL ampules, the quantity = 12.5mL*  
 $12.5\text{mL} \times 50\text{mg} \times 0.1 = 62.5 \text{ MMEs per box}$

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<sup>1</sup> The MME Conversion Table is the exclusive source for calculating MME for the purposes of the Opioid Excise Tax and is only intended to be used for such purpose. The MME Conversion Table is not to be used for any clinical evaluation or clinical decision-making purposes. The MME Conversion Table is updated periodically.

- *For the distribution of 40 boxes each containing 62.5 MME:*  
40 boxes x 62.5 MME = 2,500 Total MMEs

**Example for the calculation of MME for a transdermal patch:** For a 75mcg/hour patch, the current conversion factor listed on the MME conversion table is 7.2 MME.

- *For a box with 5 x 1 patch, the quantity = 5 patches*  
5 patches x 75mcg x 7.2 = 2,700 MME per box
- *For the distribution of 60 boxes each containing 2700 MME:*  
60 boxes x 2,700 MME = 162,000 Total MMEs

## Appendix B. Creating a New HCS Account

An application for a new Health Commerce System (HCS) account may be obtained by e-mailing a request to [narcotic@health.ny.gov](mailto:narcotic@health.ny.gov). Include the information as specified below.

1. In the e-mail subject heading state: "HCS Application Request - OET"
2. In the body of the e-mail include:
  - **Company information**
    - Company Name
    - Mailing Address
    - Telephone Number
    - Fax Number
    - Bureau of Narcotic Enforcement Controlled Substance License Number
    - DEA Registration Number
  - **A "Director" for the online account must be designated:**
    - The full First name, Middle name, Last name
    - Title
    - Date of Birth
    - E-mail address
    - Telephone Number
    - HCS User ID – if this person already has an HCS account, but needs the account linked to this organization
  - **The Director may authorize other persons ("Coordinators") to establish separate HCS accounts, if desired:**
    - The full First name, Middle name, Last name
    - Date of Birth
    - E-mail address
    - Telephone Number
    - HCS User ID - if this person already has an HCS account, but needs the account linked to this organization
3. Once the Department has received your request, the necessary HCS application forms will be e-mailed to you. Follow the instructions provided and retain a copy for your records. The Commerce Accounts Management Unit (CAMU) will process your account registration from this point forward.

*\*Coordinators may be added or removed by a Director at any time.*

For assistance accessing an HCS account, contact the Commerce Accounts Management Unit (CAMU) at 866-592-1890 or see the links at the bottom of the HCS webpage: <https://commerce.health.state.ny.us/>.

**IMPORTANT:** Creating a new HCS account requires an original notarized form to be mailed back to CAMU. Please allow several weeks to establish a new HCS account.



## **Appendix C. Additional Information on Opioid Excise Tax**

Visit the links below for more information on the Opioid Excise Tax.

- Tax Law Article 20-D, Excise Tax on Sale of Opioids:  
<https://www.nysenate.gov/legislation/laws/TAX/A20-D>
- Department of Taxation and Finance Opioid Excise Tax webpage:  
<https://www.tax.ny.gov/bus/oet/oetidx.htm>