

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 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)

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)

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.

- **MentalHygiene32Exempt** - 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.