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| Center for health information and analysis |
| Data Specification Manual |
| 957 CMR 2.00:  Payer Reporting of Prescription Drug Rebates |
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| **March 19, 2018** |

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**Summary of Changes**

* Updated file submission schedule. Please note change in deadlines.
* Revised the number of years included in the data submission. Payers shall report preliminary data for calendar year 2017, and final data for calendar year 2016.
* Removed Commonwealth Care from the Insurance Categories.

**Introduction**

M.G.L. c. 12C, § 16(a) requires that the Center for Health Information and Analysis (CHIA) “publish an annual report based on the information submitted under sections 8, 9 and 10 … [and] compare the costs and cost trends with the health care cost growth benchmark established by the health policy commission.”

Effective July 1, 2016, M.G.L. c. 12C, § 16(a) is amended to require that CHIA “consider the effect of drug rebates and other price concessions in the aggregate without disclosure of any product or manufacturer-specific rebate or price concession information, and without limiting or otherwise affecting the confidential or proprietary nature of any rebate or price” when detailing cost growth trends in its annual report.

Pursuant to Administrative Bulletin 17-03, CHIA is requiring payers to submit a prescription drug rebate data file. This data will permit consideration of the effect of prescription drug rebates and other pharmaceutical manufacturer price concessions on aggregate cost growth trends. This Data Specification Manual provides additional technical details to assist payers in reporting and filing prescription drug rebate data. Prescription drug rebate files will contain different record types, including:

* Payer summary information and comments
* Member Months, by Massachusetts residency or approved approximation
* Pharmacy Expenditures, by insurance category and brand status
* Prescription Drug Rebates, by insurance category and brand status
* Pharmacy Benefit Manager (PBM) contract summary information

**File Submission Instructions and Schedule**

Payers shall complete and submit to CHIA two data templates as part of the prescription drug rebate data reporting. The first template, the “Rebate Data Template”, will contain all aggregate member month, expenditure, and prescription drug rebate data. The second template, the “PBM Contract Data Template”, will contain summary information on each payer’s PBM contracts. Payers can find both data submission templates available on CHIA’s website at the following location: <http://www.chiamass.gov/prescription-drug-rebate-data-submission>. Payers shall submit this information on an annual basis. In 2018, payers will submit prescription drug rebate data for CYs 2016 and 2017.

For 2018 data reporting, CHIA will publish prescription drug rebate data at the aggregate level (e.g., total by brand status and insurance category) and will not publish prescription drug rebate data at the payer or pharmacy benefit manager (PBM) level.

If a payer is unable to report any data elements included in this data specification, the payer must notify CHIA in writing (email notification is sufficient). The payer should exhaust all opportunities to obtain the required data elements from their pharmacy benefit manager (PBM) before submitting notification to CHIA. In such instances, CHIA will work with the payer to develop modified data specifications that accommodate the payer’s data limitations and allow CHIA to fulfill its statutory obligations.

Payers shall submit prescription drug rebate information in accordance with regulation 957 CMR 2.00 on the following schedule:

|  |  |
| --- | --- |
| **Prescription Drug Rebate Filing Schedule** | |
| **Date** | **Files Due** |
| Friday, June 1, 2018 | **Prescription Drug Rebate Data**   * CY 2016 Final * CY 2017 Preliminary |

Payers shall submit Excel files with prescription drug rebate data via email. Data should be submitted to [Erin.Bonney@MassMail.State.MA.US](mailto:Erin.Bonney@MassMail.State.MA.US). Payers should copy their regular CHIA contact for TME data submissions when submitting the prescription drug rebate information. Additional information on file submission conventions can be found in Appendix A.

Following submission of the prescription drug rebate data, a payer’s Chief Financial Officer or equivalent must sign and return the data verification statement provided in Appendix B of this Data Specification manual to CHIA within ten days. A payer’s filing is not complete until the data verification statement has been received by CHIA.

**Data Submission**

**Overview**

In accordance with M.G.L. c. 12C, § 16(a) and Administrative Bulletin 17-03, payers must report prescription drug rebate information at an aggregate level. Unlike TME reporting, payers are not required to submit prescription drug rebate information at either the physician group or zip code levels. A payer’s filing is not complete until both rebate data and PBM contract data have been successfully submitted to CHIA.

**Rebate Data Specifications**

Payer Org ID: The CHIA-assigned organization ID for the payer or carrier submitting the file.

Payer Name: The name of the payer or carrier submitting the file.

Insurance Category: The insurance category that is being reported. All available insurance categories are listed below. Payers shall report for all insurance categories for which they have business. Payers reporting under the “Other” category will be asked in quality assurance to identify the type of insurance reflected in this category.

| **Insurance Category** |
| --- |
| Commercial |
| Medicare Advantage |
| Standalone Medicare Prescription Drug Plan |
| Medicaid Managed Care (MCO) |
| Senior Care Options (SCO) |
| One Care |
| Program of All-Inclusive Care for the Elderly (PACE) |
| Other |

Member Population: Payers must define the population of covered members for all data provided in this data filing as members that are covered under policies sitused in the state of Massachusetts. If payers are not able to report data solely for this population, they must notify CHIA in writing (email notification is sufficient) and propose a different member population definition for CHIA approval. Alternative populations may include but are not limited to covered members that are Massachusetts residents, and all covered members. Payers should only include information pertaining to members for which they are the primary payer, and exclude information for members for which they were the secondary or tertiary payer. All Massachusetts resident members for whom a payer provides primary coverage should be included in the member population, regardless of product or funding type.

Member Months: The number of members receiving primary health insurance coverage by a plan over the specified period of time expressed in months of membership. The member months provided in this field should correspond to the patient population identified in Member Population. All members in the defined member population must be counted in the member month value. There is no threshold for reporting based on the total member months in a given member population or insurance category.

Please note that for the Commercial insurance category, payers should only report on those members for whom they have complete pharmacy expenditure and prescription drug rebate information. Any members for which a payer has no pharmacy expenditure or prescription drug rebate data, or partial pharmacy expenditure or prescription drug rebate data, should be excluded from this data reporting. As a result, all member month, pharmacy expenditure, and prescription drug rebate data for excluded members should be excluded from this data filing. See below for definitions of pharmacy expenditures and prescription drug rebates.

Pharmacy Expenditures: The sum of all incurred claim allowed payment amounts to pharmacies for prescription drugs, biological products, or vaccines as defined by the payer’s prescription drug benefit in a given calendar year. This amount shall include member cost sharing amounts. This shall include all incurred claims for individuals included in the member population regardless of where the prescription drugs are dispensed (i.e., includes claims from in-state and out-of-state providers). In addition, this shall include all incurred but not reported claims. To account for such claims, payers should apply incurred but not reported (IBNR) factors to preliminary pharmacy expenditure data. Claims should be attributed to a calendar year based on the date of fill.

Calendar Year: On or after January 1 and on or before December 31 for a given year.

Incurred Claims: All claims for which the date of fill occurs in a given calendar year. This shall include the following: (A) Unpaid claims reserves for a given calendar year, including claims reported in the process of adjustment; (B) Percentage withholds from payments made to contracted providers; (C) Claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity; (D) Changes in other claims-related reserves for claims with dates of fill in a given calendar year; and (E) Claims that are recoverable for anticipated coordination of benefits. For preliminary calendar year data, payers shall allow for a claims run-out period of at least 60 days after December 31 of the prior calendar year.

Allowed Payment Amount: Total payment amounts to a pharmacy including all payer paid amounts, pharmacy benefit manager (PBM) paid amounts, and member cost sharing. This amount shall include direct drug costs and exclude non-claim costs. Importantly, this amount shall not reflect prescription drug rebates in any way (i.e., the amount must not be reduced by prescription drug rebates). In addition, Medicare Part D coverage gap discounts should be treated in the same way as they are treated in payers' TME data. If coverage gap discounts are excluded from TME data, they should be excluded from allowed amounts and pharmacy expenditures. If coverage gap discounts are included in TME data, they should be included in allowed amounts and pharmacy expenditures.

Direct Drug Costs: Include but are not limited to the following:

* Ingredient costs.
* Dispensing fees.
* Taxes.
* Payment adjustments received from or paid to pharmacies after the point-of-sale transaction including but not limited to:
  + Reconciliation amounts that account for differences between the effective rate and the adjudicated rate achieved by the pharmacy at the point-of-sale.
  + Contingent incentive payment adjustments related to generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, or other performance metrics.
* The difference between the amount paid by the plan to the PBM and the amount the PBM pays pharmacies, sometimes referred to as “PBM spread” or "risk premium.”

Non-Claim Costs: Include but are not limited to the following:

* Amounts paid to third party vendors for secondary network savings.
* Amounts paid to third party vendors for any of the following:
  + Network development.
  + Administrative fees.
  + Claims processing.
  + Utilization management.
* Amounts paid, including amounts paid to a pharmacy, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee, such as the following:
  + Medical record copying costs.
  + Attorneys’ fees.
  + Subrogation vendor fees.
  + Bona fide service fees.
  + Compensation to any of the following:
    - Paraprofessionals.
    - Janitors.
    - Quality assurance analysts.
    - Administrative supervisors.
    - Secretaries to medical personnel.
    - Medical record clerks.

Specialty Drug: A drug defined as a specialty drug under the terms of a payer's contract with its PBM. Specialty drug expenditure and rebate amounts should be mutually exclusive from non-specialty brand drug and non-specialty generic drug expenditure and rebate amounts.

Non-Specialty Brand Drug: A drug defined as a non-specialty brand drug under the terms of a payer's contract with its PBM. Non-specialty brand drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty generic drug expenditure and rebate amounts.

Non-Specialty Generic Drug: A drug defined as a non-specialty generic drug under the terms of a payer's contract with its PBM. Non-specialty generic drug expenditure and rebate amounts should be mutually exclusive from specialty drug and non-specialty brand drug expenditure and rebate amounts.

Prescription Drug Rebates: Total rebates, and other price concessions (including concessions from price protection and hold harmless contract clauses) provided by pharmaceutical manufacturers for prescription drugs with specified dates of fill, excluding manufacturer-provided fair market value bona fide service fees. This amount shall include PBM rebate guarantee amounts as well as any additional rebate amounts transferred by the PBM in addition to the rebate guarantee amounts. This amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether they are conferred to the payer directly by the manufacturer, a PBM, or any other entity. In addition, this amount shall include the total amount of prescription drug rebates and price concessions provided by pharmaceutical manufacturers, regardless of whether the they are conferred to the payer through regular aggregate payments, on a claim-by-claim basis at the point-of-sale, as part of retrospective financial reconciliations (including reconciliations that also reflect other contractual arrangements), or by any other method. Payers should apply incurred but not reported (IBNR) factors to preliminary prescription drug rebate data.

Rebates and other price concessions: A reduction in the amount a buyer (i.e., payer or PBM) pays for an item or service based on an arms-length transaction. The terms of the reduction must be fixed and disclosed in writing to the buyer at the time of the initial purchase to which the reduction applies, and the reduction must not be given by the offeror at the time of sale.

For the purposes of this data collection, Medicare Part D coverage gap discounts shall be treated in the same manner as they are treated for pharmacy expenditures. If coverage gap discounts are excluded from pharmacy expenditures, they should be excluded from prescription drug rebates. If coverage gap discounts are included in pharmacy expenditures, they should be included in prescription drug rebates.

Fair market value bona fide service fees: Fees paid by a manufacturer to a third party (e.g., payers, PBMs, payer- or PBM-owned pharmacies), that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement (e.g., data service fees, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs), etc.).

Combined Rebate Identifier: If rebate data is only available to a payer at an aggregated level and cannot be separated to provide unique information for each of the insurance categories for which the payer has business, the payer shall report data at the most granular level available. In such instances, the payer shall report a separate observation with all required data elements for each insurance category. All data provided within each unique insurance category observation should be unique to that insurance category except the following data elements: DR011 - Total Prescription Drug Rebate Amount, DR012 – Prescription Drug Rebate Amount: Specialty Drugs, DR013 – Prescription Drug Rebate Amount: Non-Specialty Brand Drugs, DR014 – Prescription Drug Rebate Amount: Non-Specialty Generic Drugs, and DR016 - Per Member Per Month Prescription Drug Rebate Amount. These data elements should contain the same values for all insurance categories included in the combined rebate data for a given year. To identify combined rebate data, payers should assign common alphabetic identifiers (e.g., A) in the "Combined Rebate Identifier" to observations for which rebate data is combined and the values in data elements DR011, DR012, DR013, DR014, and DR016 are the same. Please see the accompanying "Rebate Submission Examples" document for examples demonstrating how to use the Combined Rebate Identifier field. Example 2 provides specific details on how the rebate identifier should be used.

Comments: Payers may use this field to provide any additional information or describe any data caveats for the Prescription Drug Rebate Data submission.

Data Elements:

| **Element** | **Data Element Name** |
| --- | --- |
| DR001 | Payer Org ID |
| DR002 | Payer Name |
| DR003 | Insurance Category |
| DR004 | Calendar Year |
| DR005 | Member Population |
| DR006 | Member Months |
| DR007 | Total Pharmacy Expenditure Amount |
| DR008 | Pharmacy Expenditure Amount: Specialty Drugs |
| DR009 | Pharmacy Expenditure Amount: Non-Specialty Brand Drugs |
| DR010 | Pharmacy Expenditure Amount: Non-Specialty Generic Drugs |
| DR011 | Total Prescription Drug Rebate Amount |
| DR012 | Prescription Drug Rebate Amount: Specialty Drugs |
| DR013 | Prescription Drug Rebate Amount: Non-Specialty Brand Drugs |
| DR014 | Prescription Drug Rebate Amount: Non-Specialty Generic Drugs |
| DR015 | Per Member Per Month Pharmacy Expenditure Amount |
| DR016 | Per Member Per Month Prescription Drug Rebate Amount |
| DR017 | Combined Rebate Identifier |
| DR018 | Comments |

**PBM Contract Data Specifications**

Payer Org ID: The CHIA-assigned organization ID for the payer or carrier submitting the file.

Payer Name: The name of the payer or carrier submitting the file.

Pharmacy Benefit Manager Name: The name of a pharmacy benefit manager (PBM) that provided any of the following services in a given insurance category and calendar year: claims processing, drug formulary management, or manufacturer drug rebate contracting.

Insurance Category: The insurance category that is being reported. All available insurance categories are listed below. Payers shall report for all insurance categories for which they have business. Payers reporting under the “Other” category will be asked in quality assurance to identify the type of insurance reflected in this category.

| **Insurance Category** |
| --- |
| Commercial |
| Medicare Advantage |
| Standalone Medicare Prescription Drug Plan |
| Medicaid Managed Care (MCO) |
|  |
| Senior Care Options (SCO) |
| One Care |
| Program of All-Inclusive Care for the Elderly (PACE) |
| Other |

Calendar Year: On or after January 1 and on or before December 31 for a given year.

Claims Processing: Payers should identify whether an individual PBM organization performed all, some, or none of the claims processing for its pharmacy benefit within a given insurance category and calendar year. Payers should enter one of three possible responses: All, Some, or None. If multiple PBMs provided claims processing services within a given insurance category and calendar year, payers should include a separate observation for each PBM and enter "Some" for claims processing in each observation.

Drug Formulary Management: Payers should identify whether an individual PBM organization performed all, some, or none of the drug formulary management for its pharmacy benefit within a given insurance category and calendar year. Payers should input one of three possible entries: All, Some, or None. If multiple PBMs provided a drug formulary management services within a given insurance category and calendar year, payers should include a separate observation for each PBM and enter "Some" for drug formulary management in each observation.

Manufacturer Drug Rebate Contracting: Payers should identify whether an individual PBM organization performed all, some, or none of the manufacturer drug rebate contracting for its pharmacy benefit within a given insurance category and calendar year. Payers should input one of three possible entries: All, Some, or None. If multiple PBMs provided contracting services within a given insurance category and calendar year, payers should include a separate observation for each PBM and enter "Some" for manufacturer drug rebate contracting in each observation.

Comments: Payers may use this field to provide any additional information or describe any data caveats for the PBM Contract Data submission.

Data Elements:

| **Element** | **Data Element Name** |
| --- | --- |
| PBM001 | Payer Org ID |
| PBM002 | Payer Name |
| PBM003 | Pharmacy Benefit Manager Name |
| PBM004 | Insurance Category |
| PBM005 | Calendar Year |
| PBM006 | Claims Processing? |
| PBM007 | Drug Formulary Management? |
| PBM008 | Manufacturer Drug Rebate Contracting? |
| PBM009 | Comments |

**Appendix A: File Submission Instructions**

Please see pages following this section.

**Appendix B: Payer Data Verification Statement**

Please see pages following this section.

**Appendix A: File Submission Instructions**

**Data Submission Templates**

Payers can find the rebate data and PBM contract data submission templates available on CHIA’s website at the following location: <http://www.chiamass.gov/prescription-drug-rebate-data-submission>.

**File Submission Naming Conventions**

Prescription drug rebate data submissions should follow the following naming conventions:

**PayerName\_PrescriptionDrugRebates\_Version.fileextension,**

Where Payer Name is the payer name is identified in field DR002.

Version is **optional**, and indicates the submission number.

The file extension must be .xlsx, .xls, or .csv.

**Below are examples of valid file names:**

PayerA\_PrescriptionDrugRebates.xlsx

PayerA\_PrescriptionDrugRebates\_1.csv

**Appendix B: Payer Data Verification Statement**

I, , certify that I am authorized to submit the Prescription Drug Rebate data

on behalf of and that I have examined the data submission and all information necessary and relevant to the data submission, including information from third-parties, for the calendar years 2016, and 2017. I further certify that to the best of my knowledge and belief, the final version Prescription Drug Rebate data submitted by are true, accurate, and complete and prepared in accordance with applicable regulations and instructions from the books and records of , except as noted.

This declaration is based upon all information of which I have knowledge.

|  |  |
| --- | --- |
| Signed: |  |

|  |  |
| --- | --- |
| Printed Name: |  |

|  |  |
| --- | --- |
| Title: |  |

|  |  |
| --- | --- |
| Date: |  |