# Supporting Statement B for Pharmacy Benefit Manager Transparency for Qualified Health Plans
# (CMS-10725/OMB control number: 0938-1394)

## B. Background

Implementation of section 1150A of the Social Security Act, as added by section 6005 of the Patient Protection and Affordable Care Act (ACA), requires, among other entities, Qualified Health Plans (QHPs) and pharmacy benefit managers (PBMs) that serve QHP issuers to report information on prescription drug benefits to the U.S. Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. CMS finalized regulations for this reporting at 45 CFR 156.295 and 184.50.

Under these requirements a QHP issuer is required to report issuer and plan level prescription drug data to CMS only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Because Stand-alone Dental Plans (SADPs), which are a subset of QHPs, do not generally include a prescription drug benefit or contract with PBMs, we are not seeking data from them at this time.

Section 1150A(a)(1) of the Social Security Act authorizes CMS to collect the same prescription drug and rebate information from Prescription Drug Plan sponsors of a prescription drug plan and Medicare Advantage organizations offering a Medicare Advantage Prescription Drug Plan under part D of title XVIII. Since 2012, CMS has collected this data from Part D sponsors as part of the Medicare Part D Direct and Indirect Remuneration (DIR) reporting requirement, and detailed drug information for each National Drug Code (NDC) from the Prescription Drug Event (PDE) data that plans are required to submit.[1]

## B.1. Respondent Universe and Sampling Methods

CMS collects drug data from QHP issuers that do not contract with a PBM and PBMs (hereinafter referred to as "submitters") for each QHP at two levels of detail. The first set of data is aggregated prescription drug data at the QHP issuer level and is submitted via web form. The second set of data is detailed prescription drug data broken down by a drug's NDC. The NDC is a unique three-segment number that is a universal product identifier for human drugs assigned by the Food and Drug Administration under section 510 of the Federal Food, Drug and Cosmetic Act.

We collect this data at these two levels of detail to balance meaningful transparency efforts with the imposition of reasonable burden. The collection of ten of the data elements described by section 1150A of the Social Security Act aggregated at a higher level of detail at the plan level allows for issuer-to-issuer and PBM-to-PBM analysis.

[1] See 77 FR 22094.

However, collection of all of the data described by section 1150A of the Social Security Act aggregated at the plan level would produce insufficient information to ensure comprehensive transparency, as it does not provide insight to the treatment of individual drugs. To this end, we collect four of the data elements described by section 1150A of the Social Security Act at the NDC level for each QHP. These four data elements (Total Number Prescriptions Dispensed, Total Number Prescriptions Dispensed at Retail Pharmacies, Total Number Prescriptions Dispensed at Mail Order Pharmacies, and Total Rebate Dollars), when broken down by NDC level, allows CMS to compare PBM and issuer treatment of individual drugs. Additionally, in collecting some of this data at the NDC-level of detail, we are interpreting section 1150A of the Social Security Act in a manner consistent with previous rulemaking by CMS.[2]

There are an estimated 8 Pharmacy Benefit Managers (PBMs) that administer prescription drug programs on behalf of QHP issuers and 15 QHP issuers that do not contract with a PBM to administer their prescription drug benefit that are subject to the Pharmacy Benefit Manager Transparency data collection.

## B.2. Procedures for Collection of Information

This collection focuses on collecting prescription drug data related to how prescriptions are dispensed, the generic and brand dispense rate, rebates, discounts, and spread pricing. PBMs submit this data to CMS via the Health Insurance Oversight System (HIOS), which is an existing federal system for collecting QHP data and market wide data.

To ensure data quality, the data collection system in HIOS includes automated data validations at the point of data submission. It is expected that the submitted data will have some inherent limitations. Prior to the data collection, submitters did not report prescription drug dispensing, pricing, and rebate data to CMS. Therefore, the first few data collection years will serve as a baseline and help establish trends in the data in future years.

Given that this continues to be a relatively new data collection, we will continue to conduct technical assistance with PBMs prior to the start of the data collection. Technical assistance will focus on how PBMs gain access to HIOS and submit data, along with technical requirements. We will hold training sessions via webinar and conduct more tailored one-on-one assistance as needed.

## B.3. Methods to Maximize Response Rates and Deal with Nonresponse

[2] See "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule" at 77 FR 22094. In that final rule, CMS interpreted section 1150A of the of the Social Security Act to impose no additional reporting requirements for entities subject to direct and indirect remuneration (DIR) reporting, except for PBM spread amount aggregated to the plan benefit package level. The existing DIR reporting required data reporting at the NDC. As such, CMS has previously interpreted that section 1150A of the Social Security Act authorizes collection at an NDC level of reporting. For consistency with previous rulemaking by CMS and to reduce the burden of creating different CMS, collection requirements, we will collect some of this data at the NDC level. We recognize that the DIR reporting requirements under Part D are partly based on statutory authority that is not applicable to this collection, and we do not claim to rely on any authority other than section 1150A of the Social Security Act as the basis for this collection. We do, however, rely on that final rule as far as CMS strives to interpret the same statute consistently.

In addition to pre-submission outreach and training, CMS will continue to cross-check submitter data with QHP issuer IDs and plan IDs to identify missing QHP issuer and plan data. CMS will conduct outreach to PBMs and/or QHP issuers that do not report or are missing data.

**B.4. Test Procedures for Methods to be Undertaken**

CMS has conducted User Acceptance Testing (UAT) to ensure that the data collection system is designed to reflect submitter data reporting requirements and to help ensure the integrity, reliability, and validity of the prescription drug data being submitted. In addition, we will continue to work with submitters prior to the data collection to ensure that they can access and use the system.

Analysis of submitted prescription drug dispensing, pricing, and rebate data serve several additional purposes.
There are three categories of analysis that we conduct:

1. assessment of drug utilization, based on the number of prescriptions filled for each type of drug,
2. a financial analysis of the payments to drug manufacturers and to pharmacies, as well as total amounts of other rebates, and
3. a cluster analysis along groups of related NDC drug categories.

The drug utilization analyses focus on the number and types of prescriptions that are most commonly dispensed across plans, PBMs, and issuers. The analyses highlights mean and outlier values across issuers, regions, and metal level and type (HMO/PPO) of plan.

Additionally, we analyze aggregated data by PBM and issuer. For example, this analysis focuses on NDCs within drug categories that were reviewed for potential discriminatory benefit designs during QHP certification to help identify plans that may be using plan design features or marketing practices that discourage consumers with related health conditions from enrolling. The financial analyses focus on overall financial variables provided by submitters in order to understand the payments to, and rebates from, submitters for prescription drugs. These analyses will highlight the mean and outlier values across issuers, regions, and metal level and type (HMO/PPO) of plan. Cluster analysis is used as an exploratory method to identify patterns in cost and utilization among submitters (or QHPs, or any other aggregated unit of interest), and how various characteristics of submitters or QHPs are related to these patterns. The results of these analyses can potentially identify patterns of submitter behavior that are not readily observable using more basic descriptive methods. Ultimately, we use these analyses to gain insight into the drug industry and drug pricing so that we may potentially use the data to inform future policymaking.

**B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The data will be collected by the Marketplace Plan Management Group in the Center for Consumer Information and Insurance Oversight (CCIIO) in CMS and analyzed in collaboration with their contractors.

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