July 23, 2021

Office of Personnel Management
Department of Health and Human Services
Department of Labor
Department of the Treasury

Greetings,

Thank you for the opportunity to respond to **CMS-9905-NC**, Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs

FDB (First Databank) is the leading provider of drug knowledge that helps healthcare professionals make precise decisions. We empower our information system developer partners serving the majority of hospitals, physician practices, pharmacies, payers (including health plans and pharmacy benefit managers), and all other healthcare industry segments to deliver valuable solutions used by millions of clinicians, business associates, and patients every day. For more than four decades our drug knowledge has been used to help improve patient safety, operational efficiency, and healthcare outcomes.

FDB has been the drug knowledge provider of choice for a variety of government entities including the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, Department of Defense, the Department of Veterans Affairs (Veterans Health Administration), the Indian Health Service, many state and county health plans and departments of health, and the majority of state Medicaid agencies.

Please review FDB responses (in blue) to specific questions posed within this RFI.

Sincerely,

Julie Suko, Pharm D
Vice President, Editorial Content
FDB (First Databank, Inc.)
jsuko@fdbhealth.com

B. Definitions

B2. What considerations should the Departments and OPM take into account in defining the term ‘‘pharmacy’’? Are there different considerations for retail pharmacies versus mail order or specialty pharmacies? Are there different considerations for prescription drugs dispensed in an inpatient, outpatient, office, home, or other setting?

Products/drugs that are considered specialty will be dispensed and monitored differently than products that are dispensed within a retail or mail order setting. Similarly, drugs are packaged for dispensing in an inpatient environment could have a higher price than those packaged for dispensing in a retail setting. Using the 11-digit National Drug Code (NDC) will identify the level of packaging that was dispensed, and the related price associated to this level of packaging.

B3. What considerations should the Departments and OPM take into account in defining the term ‘‘prescription drug’’? Should prescription drugs be identified by National Drug Codes (NDCs)? Are there other prescription drug classification systems that should be considered, such as the first nine digits of the NDC, the RxNorm Concept Unique Identifier (RxCUI), or the United States Pharmacopeia Drug Classification (USP–DC)?

Using the NDC11 would provide information on the name of the manufacturer and the exact packaged product that was dispensed. The RxCUI provides a general category of an ingredient, strength, dosage form and route, but will not identify manufacturer specific entities or package level price differences. FDB provides our proprietary clinical formulation structures to the National Library of Medicine for mapping to their RxCUIs.

How does the choice of prescription drug classification influence plan and issuer operational costs?

B4. Should there be different definitions of ‘‘prescription drug’’ for different elements of the PHS Act section 2799A–10, ERISA section 725, and Code section 9825 data collection, such as the 9-digit NDC for identifying the 25 drugs with the highest rebates and the RxCUI for identifying the 50 most costly drugs?

Reporting at the RxCUI level will provide a higher group view of the drug(s) with the highest rebate. In situations where the RxCUI represents multiple manufactures of a product, the data will not differentiate if there are rebate and non-rebate manufactures. Using the NDC 9-digit will identify the manufacturer, ingredient, strength, and dosage form.

B5. What considerations should the Departments and OPM take into account in defining the term ‘‘therapeutic class’’? How do plans and issuers currently classify prescription drugs by therapeutic class? Does the classification method rely on proprietary software, and how would the choice of therapeutic classification method influence plan and issuer operational costs?

FDB provides their own proprietary therapeutic classification schema, Enhanced Therapeutic Classification (ETC). Within FDB content, mappings are available to other therapeutic classification schemas.

D. Information Required to be Reported

D1. What considerations are important for plans and issuers in determining the 50 brand prescription drugs that are most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each drug?

FDB recommends the following common NDC attributes to best describe a product dispensed.

- NDC11 – drug identifier used in billing transactions, dispense identification and patient charting. The NDC contains the FDA issued manufacturer/distributor identifier, the ingredient and strength of the product and the package size of the drug. By utilizing the NDC11, the following attributes can be derived
    - Label name as printed on the container of the drug product
    - Manufacturer/distributor name represented in the NDC11
    - Package size of the container
- Fill quantity of the prescription dispensed to patient
- Day supply of the prescription
- Dispense as Written (DAW) – indicates if the physician did not want the pharmacy to substitute if a therapeutic equivalent was available

D2. What considerations are important for plans and issuers in determining the 50 prescription drugs with the greatest increase in plan expenditures?

1. NDC11 – drug identifier used in billing transactions, dispense identification and patient charting. The NDC contains the FDA issued manufacturer/distributor identifier, the ingredient and strength of the product and the package size of the drug. By utilizing the NDC11, the following attributes can be derived
    a. Label name as printed on the container of the drug product

   b. Manufacturer/distributor name represented in the NDC11
   c. Package size of the container
2. Price Type – see attached FDB Drug Pricing Policy
3. Average prior cost per unit
4. Average new cost per unit
5. Average out of pocket cost per unit

D3. If the top prescription drugs are identified by RxCUI (or any classification other than NDC), is it feasible for plans and issuers to report the required information separately by NDC for each NDC associated with the given RxCUI?

Yes, this is possible. Reporting information at the NDC11 will provide manufacturer name, ingredient, strength, and package size. These NDCs can then be rolled up to the RxCUI to summarize the information at the ingredient/strength level and will not specify manufacturer level information.

D4. Which data elements can be directly tied to a specific prescription drug or class of prescription drugs, and which data elements must be allocated among prescription drugs or prescription drug classes? If an amount must be allocated, what allocation method(s) are preferable, and why?

Using the NDC11 product identifier and using a compendial source such as FDB, the user will be able to identify the manufacturer, ingredient and strength and package size that was dispensed. In addition, NDC11 product attributes such as FDA approval, FDA Marketing Category, FDA OBC therapeutic equivalence, DEA schedule and state-controlled substance information can also be identified at the NDC11 identification. In addition, this information can be associated to FDB therapeutic drug classifications, RXNORM concepts, American Hospital Formulary Service (AHFS), and Anatomic, Therapeutic, Clinical Classification Codes (WHO-ATC) classes.

D5. What considerations are important for plans and issuers in determining the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year?

- NDC11 – drug identifier used in billing transactions, dispense identification and patient charting. The NDC contains the FDA issued manufacturer/distributor identifier, the ingredient and strength of the product and the package size of the drug. By utilizing the NDC11, the following attributes can be derived
  - Label name as printed on the container of the drug product
  - Manufacturer/distributor name represented in the NDC11

- Package size of the container
- Price Type – see attached FDB Drug Pricing Policy
  - Average price per unit
- Average price per prescription
- Average out of pocket cost per unit
- Average days supplies and quantity dispensed
- Average rebate amount
- Most common indications (ICD10)

Should rebates and other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price?
Recommend capturing estimated total dollar value of rebate.

Should rebates and other remuneration be measured in comparison to another measure, such as total spending on a drug or a unit price?

Drug price is reported by entities such as CMS as per unit. CMS reports the NADAC price per unit.

If a price measure is used, which price measure should be used and why?

FDB is committed to serving our customers and the healthcare industry by publishing the best available drug and drug pricing information.

In addition to clinical drug information, FDB publishes several drug pricing data fields, including:

- Average Acquisition Cost (AAC)
- Wholesale Acquisition Cost (WAC)
- Direct Price
- Suggested Wholesale Price (SWP)
- Federal Financing Participation Upper Limits (FFPUL)
- Medicare Part B Pricing
- National Average Drug Acquisition Cost (NADAC)
  - CMS National Average Drug Acquisition Cost (NADAC) is published for Brand and Generic drugs. This file provides purchase prices of all covered outpatient drugs by retail community pharmacies.

FDB discontinued the publication of Blue Book Average Wholesale Price (AWP) on September 28, 2011. FDB does not recommend the use of Average Wholesale Price (AWP). For many years it has been demonstrated that Average Wholesale Price (AWP) is not a viable benchmark for or a true representation of a drug product's price. The United States General Accounting Office (GAO), the Department of Health and Human Services' Office of Inspector General (OIG), the National Health Policy Forum and numerous investigations, litigation, and legislative proposals surrounding the AWP have all questioned its appropriateness as a mechanism for prescription drug reimbursement.

Wholesale Acquisition Cost (WAC) as published by FDB represents the manufacturer's (for purposes of this Drug Pricing Policy, the term "manufacturer" includes manufacturers, repackagers, private labelers and other suppliers) published catalog or list price for a drug product to wholesalers as reported to FDB by the manufacturer. WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price. FDB does not perform any independent investigation or analysis of actual transaction prices for purposes of reporting WAC. FDB relies on manufacturers to report or otherwise make available the values for the WAC data field.

Direct Price (DP) as published by FDB represents the manufacturer's published catalog or list price for a drug product to non-wholesalers as reported to FDB by the manufacturer. Direct Price does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions. FDB does not perform any independent investigation or analysis of actual transaction prices for purposes of reporting Direct Price. FDB relies on manufacturers to report or otherwise make available the values for the Direct Price data field.

Suggested Wholesale Price (SWP) as published by FDB represents the manufacturer's suggested price for a drug product from wholesalers to their customers (i.e., retailers, hospitals, physicians and other buying entities) as reported to FDB by the manufacturer. SWP is a suggested price and does not represent actual transaction prices. FDB relies on manufacturers to report or otherwise make available the values for the SWP data field.

Average Acquisition Cost (AAC) as published by FDB reports the average acquisition cost at which pharmacies within a state purchase a drug, as defined, calculated and reported by the relevant state Medicaid program. Since not all states report an AAC, FDB publishes AACs for each state where it is available.

Federal Upper Limit (FUL), which was previously referred to as Federal Financing Participation Upper Limits (FFPUL) and first published by HCFA (now CMS) in their State Medicaid Manual on July 31, 1987, limits the amount Medicaid can reimburse for multi-source drugs, and is established for products if there are three or more versions of the product rated therapeutically equivalent. The Centers for Medicare & Medicaid Services (CMS) maintains and publishes the FUL prices.

The Affordable Care Act of 2010 redefined the methodology for calculating FULs as "no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis." Use of this revised methodology commenced in late March 2016, when CMS began publishing final Affordable Care Act FUL prices and the accompanying Weighted Average of Average Manufacturer prices (WAAMP) with an effective date of April 1, 2016. FDB added these new price types to MedKnowledge and will continue to publish both the ACA FUL and WAAMP as reported by CMS.

National Average Drug Acquisition Cost (NADAC) as reported by the Centers for Medicare & Medicaid Services (CMS) is described in the **CMS Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs**. FDB publishes brand (NADACB) and generic (NADACG) prices, as reported by CMS.

FDB relies on manufacturers and other third parties to report or otherwise make available the values for the above referenced drug price data fields and, as a result, such data fields are subject to the availability of the relevant information.

Emerging Price Types

FDB remains actively engaged with the public and private sector in efforts to gather and publish additional drug pricing data elements, as available, and to facilitate the establishment of sustainable drug reimbursement benchmarks.

FDB constantly monitors new price types and evaluates the opportunity to publish these in our databases. FDB plans to publish other data as they become available, and at that time this Pricing Policy will be modified to reflect these and any other new price types.