

APPENDIX 4:

Prescription Drug Machine-Readable File Data Elements

The Departments of the Treasury, Labor, and Health and Human Services (the Departments) have issued the Transparency in Coverage final rules (85 FR 72158), which require non-grandfathered group health plans and health insurance issuers in the individual and group markets (plans and issuers) to disclose certain pricing information. Under the final rules at 26 CFR 54.9815-2715A3(b), 29 CFR 2590.715-2715A3(b), and 45 CFR 147.212(b), a plan or issuer must disclose in-network drug prices through a machine-readable file posted on an internet website. In-network drug prices include both “negotiated rates” and “historical net prices” as defined at 26 CFR 54.9815-2715A1, 29 CFR 2590.715-2715A1, and 45 CFR 147.210. The table below identifies data elements that a plan or issuer is required to include in each machine-readable Prescription Drug File.¹

DATA ELEMENT	DESCRIPTION
General Information	
Name of Reporting Entity ²	The legal name of the entity publishing the machine-readable file.
Type of Entity	The type of entity that is publishing the machine-readable file (a group of health plan, health insurance issuer, or a third party with which the plan or issuer has contracted to provide the required information, such as a third-party administrator, a health care claims clearinghouse, or a health insurance issuer that has contracted with a group health plan sponsor).

¹ For more technical implementation guidance for this machine-readable file, please see the GitHub website space established by the Departments. GitHub is a website and cloud-based service that helps developers store and manage their code, as well as to track and control changes to their code. The GitHub space offers the Departments the opportunity to collaborate with industry, including regulated entities, and third-party developers to ensure the file format is adapted for reporting of the required public disclosure data for various plan and contracting models. The GitHub space is available at: <https://github.com/CMSgov/price-transparency-guide>.

² A plan or issuer may contract with a third party (such as a third-party administrator, a health care claims clearinghouse, or a health insurance issuer that has contracted with a group health plan sponsor) to satisfy the disclosure requirements, subject to the requirements in the final rules.

DATA ELEMENT	DESCRIPTION
Date of Last File Update	The date the machine-readable file was last updated.
Identification of Plan or Coverage	
Plan or Coverage Name	The plan name and name of plan sponsor and/or insurance company (for example, “Maximum Health Plan: Alpha Insurance Group”).
Plan Identifier	The 10-digit Health Insurance Oversight System (HIOS) identifier, or, if the 10-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN), for each coverage option offered by a plan or issuer.
Type of Plan Identifier	EIN or HIOS IDs, as applicable.
Type of Plan Market	The type of market in which the plan is offered (individual or group market coverage).
Identification of Providers, Pharmacies, and Place of Service	
Individual Provider Identifier	<i>The National Provider Identifier (NPI) Type 1³</i> - The unique 10-digit identification number issued to a provider by the Centers for Medicare & Medicaid Services (CMS) to identify individual health care providers.

³ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/NPI-What-You-Need-To-Know.pdf>

DATA ELEMENT	DESCRIPTION
<p>Provider Group and Pharmacy Identifier (<i>Required if the in-network provider is a group organization or pharmacy</i>)</p>	<p><i>The NPI Type 2</i>⁴ - The unique 10-digit identification number issued to a provider by CMS for an organization of health care providers, such as a medical group or pharmacy.</p>
<p>Pharmacy Identifier (<i>Plans and issuers have the option to include these elements in addition to the NPI Type 2</i>)</p>	<p><i>The National Council for Prescription Drug Programs (NCPDP) ID</i>⁵ - The unique 7-digit number assigned by the NCPDP to every licensed pharmacy and non-Pharmacy Dispensing Site (NPDS) in the United States and its territories. This number represents a unique pharmacy entity or line of business and is used to identify licensed pharmacies and NPDSs to insurance companies, health care providers, and other entities.</p> <p><i>The NCPDP Chain Code</i>⁶ - The ID number provided by the NCPDP that represents a group of pharmacies under the same ownership.</p> <p>If the plan or issuer includes the NCPDP Chain Code, it must also include the NCPDP IDs for each pharmacy that is represented in the group of pharmacies that are identified by the NCPDP Chain Code.</p>
<p>Type of Pharmacy Identifier</p>	<p>Allowed values: “NCPDP ID,” “NCPDP Chain Code,” or “NPI.”</p> <p>“NPI” must be selected to indicate NPI-type 2 pharmacy identifiers.</p> <p>“NCPDP ID” must be selected to indicate NCPDP ID pharmacy identifiers.</p> <p>“NCPDP Chain Code” must be selected to indicate NCPDP chain code pharmacy identifiers.</p>

⁴ Ibid.

⁵ <https://www.resdac.org/cms-data/variables/ncpdp-pharmacy-identifier-pharmacy-characteristics>

⁶ <https://accessonline.ncpdp.org/Resources/Help/NCPDP%20Part%202%20Training%20Guide%20v1.04.pdf>

DATA ELEMENT	DESCRIPTION
Tax Identification Number (TIN)	The unique identification number issued either by the Social Security Administration or by the Internal Revenue Service (IRS).
Plan of Service Code ⁷	The CMS-maintained two-digit code that is placed on a professional claim, to indicate the setting in which a service was provided.
Drug Pricing Information	
Drug Name/ Plain Language Description	The proprietary and nonproprietary name assigned to the National Drug Code (NDC) by the Food and Drug Administration (FDA).
Type of Drug	“Branded,” “Generic,” or “Biosimilar.”
National Drug Code (NDC)	<p>A unique 10-digit or 11-digit, 3-segment number assigned by the FDA, which provides a universal product identifier for drugs in the United States.</p> <p>Data reporting will be on the first 8 digits of the full 10-digit or 11-digit NDCs. The last 2 digits of the full 10-digit or 11-digit NDC specify quantity and do not have an impact on the negotiated rate or historic net price.</p>
Historical Net Price	The retrospective average amount paid, reflected as a dollar amount, by a plan or issuer to an in-network provider for the 90-day period beginning 180 days before the file publication date, including any in-network pharmacy or other prescription drug dispenser, for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or

⁷ “Place of Service Code Set.” CMS. Available at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.

DATA ELEMENT	DESCRIPTION
Historical Net Price	<p>issuer with respect to the prescription drug or prescription drug service.</p> <p>The historic net price must be reported at the billing unit level as defined by the NCPDP. The standard contains three units: Each “EA,” Milliliter “ML,” or Gram “GM.”⁸</p> <p><i>Notes on reasonable allocation of rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer:</i></p> <ul style="list-style-type: none"> • If the total amount of the price concession is known to the plan or issuer on the file publication date, then rebates, discounts, chargebacks, fees, and other price concessions must be reasonably allocated by total known dollar amount. • If the total amount of the price concession is not known to the plan or issuer on the file publication date, then rebates, discounts, chargebacks, fees, and other price concessions should be reasonably allocated using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period.
Historical Net Price Allocation Reporting Period	<p>If the historical net price concessions are not known to the plan or issuer on the last publication date on the file, then the time period prior to the current reporting period used for reporting purposes must be displayed.</p>
Negotiated Rate for each Covered Prescription Drug	<p>The amount, reflected as a dollar amount, that a plan or issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, whether directly or indirectly, including through a third-party administrator</p>

⁸ NCPDP Billing Unit Standard Fact Sheet found here: https://www.ncdp.org/NCPDP/media/pdf/BUS_fact_sheet.pdf.

DATA ELEMENT	DESCRIPTION
Negotiated Rate for each Covered Prescription Drug	<p>or pharmacy benefit manager, for prescription drugs. The negotiated rate must be reported at the billing unit level as defined by NCPDP. The standard contains three units: “EA,” “ML,” or “GM.”</p> <p>Fees that are assessed at the point of sale must be reflected separately as a dollar amount (see Dispensing Fee, Administrative Fee, and Transaction Fee data elements).</p>
Dispensing Fee	The fee, reflected as a dollar amount, for dispensing a prescription applied at the point of sale. The fee must be reflected separately only for the negotiated rate data element.
Administrative Fee	The fee, reflected as a dollar amount, charged by the Pharmacy Benefit Manager to the plan or issuer for administrating each prescription. This fee must be reflected separately only for the negotiated rate data element.
Transaction Fee	Any fees, reflected as a dollar amount, assessed when processing a prescription that is not associated with the administrative or dispensing fee. This fee must be reflected separately only for the negotiated rate data element.

Paperwork Reduction Act Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. The Departments are seeking OMB approval for the model as part of the approval for a new OMB control number 0938-1372. The time required to complete this information collection is estimated to average 1,031 hours per respondent, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.