



Regulatory Affairs and Action Update

TO: Our Valued Clients and Brokers
FROM: Health Plans, Inc.
DATE: September 9, 2022
RE: Regulatory Affairs and Action Update

Over the past year, Health Plans, Inc. (HPI) has issued Compliance Alerts and eBlasts advising our clients about the regulatory requirements of the Transparency in Coverage Final Rule (TiC) and HPI's solutions to meet those requirements. The Alerts/eBlasts can be [found here](#). This new Regulatory Affairs and Action Update provides a high level summary of the TiC and HPI's success in meeting compliance with the Machine Readable File requirements, as well as updates on our ongoing work and solutions for meeting the Transparency Tool requirements. In addition, this Update provides information about the upcoming Consolidated Appropriations Act of 2021 Prescription Drug Data Collection Reporting requirements and HPI's solution to assist clients with compliance.

Consolidated Appropriations Act of 2021 Prescription Drug Data Collection (RxDC) Reporting

- Rule Effective December 27, 2022, then June 1 each year and must contain data for the previous calendar year.
 - The Consolidated Appropriations Act of 2021 (CAA) included transparency requirements for reporting on pharmacy and drug costs, known as Prescription Drug Data Collection (RxDC Reporting). These new requirements were effective on December 27, 2021, but the Departments delayed enforcement until December 27, 2022 to allow health plans and sponsors more time to comply with the requirements.
 - The new reporting requirements include information which is intended to identify the major drivers of increases in prescription drug and healthcare costs to allow for increased understanding of how prescription drug rebates impact premiums and out-of-pocket costs and to increase the transparency of prescription drug pricing.
 - » At a high level, the new reporting requirements require group health plans to report the following to the Centers for Medicare & Medicaid Services (CMS):
 - The date the plan year begins and ends
 - The number of plan enrollees

Regulatory Affairs and Action Update

- The states in which the plan or coverage is offered
 - The top fifty (50) most frequently dispensed brand prescription drugs and total of paid claims for each drug
 - The top fifty (50) costliest prescription drugs by total annual spending and the annual amount spent for each drug
 - The top fifty (50) prescription drugs with the greatest increase in expenditure compared to the previous year and the change in amount spent on each drug
 - Total spending on health care services broken down by:
 - Type of costs including hospital costs, health care provider and clinical service costs for primary and specialty care separately, prescription drug costs and other medical costs including wellness services
 - Spending on prescription drugs by health plan or coverage and enrollees
 - The average monthly premium paid by:
 - Employers on behalf of enrollees
 - Enrollees
 - The impact on premiums of any rebates, fees, and other remuneration for prescription drugs paid by drug manufacturers to the plan or its providers for prescription drugs prescribed to enrollees including:
 - Amounts paid for each therapeutic class
 - Amounts paid for the twenty five (25) drugs which generated the greatest amount of rebates or other remunerations
 - Any reductions in premiums or out-of-pocket costs associated with rebates, fees and other remunerations mentioned above
- Required Data Files: The following data files are required to meet the reporting obligations:
- » P2 Plan List
 - » D1 Premium and Life Years Data
 - » D2 Spending by Category Data
 - » D3 – D8 PBM Rx Data (consists of 6 separate Rx Data files)
- How Data Will be Submitted: The reporting and submission of the required data files will be a joint effort between the client, the client’s pharmacy benefit manager (PBM) and HPI.
- » Clients’ PBMs will complete and provide the D3 –D8 *PBM Rx Data* files to either the client or directly to CMS.
 - » HPI will complete and submit the D2 *Spending by Category Data* file **aggregated by our book of business** directly to CMS on our clients’ behalf. This will allow clients’ PBMs to submit their D3 through D8 files on an aggregated basis to CMS, if the PBM chooses to do so.
 - » HPI will also complete and submit the P2 *Plan List* file **for our book of business** directly to CMS; however, we will need some information from clients to populate the P2 files. Please see the below **Action Required** section regarding the attached **P2 Plan List Data Survey**.

Regulatory Affairs and Action Update

- » Clients will still need to submit their D1 (*Premium and Life Years*) file directly to CMS since the information is client based which HPI does not have. Clients will also need to submit their P2 (*Plan List*) files for their own plan information.
- HPI will provide updates on our progress in completing and submitting the D2 and P2 files to CMS prior to the December 27, 2022 reporting deadline.

Action Required: As indicated above, HPI will need some information to complete our P2 Plan List File. We have created the attached **P2 Plan List Data Survey** which clients need to complete and submit to us at RegulatoryReporting@healthplansinc.com **no later than September 23, 2022** in order to allow us sufficient time to complete the File. Since each client's information HPI includes in our P2 File for our book of business must match what each client individually includes in their own P2 file, the fields included in the Survey reflect what is included in the P2 template. As such, clients need to ensure the data provided in the Survey will match with what they will submit for their Plan information.

The Transparency in Coverage Final Rule (TiC):

Machine Readable Files (MRFs)

- Pursuant to the Department of Health and Human Services (HHS), the Department of Labor, and the Department of the Treasury (the Departments) August 20, 2021 FAQ, enforcement was deferred until July 1, 2022 (previously had been effective January 1, 2022).
 - Two separate MRFs must be made available to the public via a website and updated monthly:
 - » Negotiated rates for all covered items and services for in-network providers; and
 - » Historical payments to, and billed charges from, out-of-network providers.
 - Enforcement of a third MRF for in-network negotiated rates and historical net prices for all covered prescription drugs at the pharmacy location level has been deferred to a to be determined future date pursuant to the Departments' August 20, 2021 FAQ.

Note: A Machine Readable File means data formatted in such a way that it can be read by a computer, e.g. comma-separated value (CSV), JavaScript Object Notation (JSON) or Extensible Markup Language (XML).

Regulatory Affairs and Action Update

- HPI Solution: HPI has partnered with Healthcare Bluebook to assist us with meeting the MRF requirements on our clients' behalf. On 7/1/2022, in collaboration with Healthcare Bluebook, HPI successfully posted the required machine-readable files (MRF) to the HPI MRF public website. The HPI MRF website can be accessed [here](#), or by visiting hpitpa.com and clicking the "Transparency in Coverage – Machine Readable Files" link located under "Privacy Policy" at the bottom of the homepage.



MACHINE READABLE FILES

Transparency in Coverage – Machine Readable Files

Transparency in Coverage – Machine Readable Files

As part of the Transparency in Coverage Final Rule issued by the U.S. Department of the Treasury, the U.S. Department of Labor, and the U.S. Department of Health and Human Services, health insurers and self-funded health benefit plans must post machine-readable files (MRFs) on a public internet website that includes:

- Negotiated rates for all covered items with in-network providers, and
- Historical payments to and billed charges from out-of-network providers.

These files will permit the public access to health plan payment information to help understand pricing and costs for health care services. The MRFs are accessible free of charge, without establishing a user account, password, or other credentials, and without submitting identifying information such as a name, email address, or telephone number.

[Download machine-readable files \(MRFs\) here](#)

- » Once on the HPI page, please read the disclaimer and simply click the link at the bottom on of the page titled "Download machine-readable files (MRFs) here", and then follow the instructions on the corresponding page. Please note that some of these files are very large, so plan accordingly for download time and space requirements on your computer.
- Our MRF website is operational, accessible free of charge without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information, and updated in accordance with TiC.
- CMS has confirmed it is the self-funded account's (client's) responsibility to post a link to the MRFs on their own public website. Fortunately, CMS has also confirmed that the client can link to the MRFs that are on their plan administrator's site. This means that HPI clients can simply copy the provided HPI URL for the MRFs (<https://hpitpa.com/transparency-in-coverage-machine-readable-files/>) and paste it on their company website at a location compliant with the accessibility requirements (being free of charge, without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information).
- The MRFs will be updated monthly as required by the TiC.

Transparency Tool

- Rule Effective January 1, 2023 and January 1, 2024
 - Internet-based self-service tool to obtain personalized out-of-pocket cost information and the underlying negotiated rates for all covered health care items and services, including prescription drugs.
 - » For plan years that begin on or after January 1, 2023: An initial list of 500 shoppable services must be available
 - » For plan years that begin on or after January 1, 2024: The remainder of all items and services must be available
 - HPI Solution: HPI is working with Healthcare Bluebook to create and implement the self-service Transparency Tool on our clients' behalf for January 1, 2023 and January 1, 2024. HPI Member Services, along with Healthcare Bluebook, will be prepared to help members access Healthcare Bluebook's branded "Bluebook Comply" self-service tool to search for detailed price information as well as a list of in-network medical facilities located in the member's area. This information is intended to help members shop for the best price before scheduling medical procedures. Additional information including links to the Bluebook Comply as well as Member Service phone lines will be provided in future communications as we approach the January 1, 2023 due date.

Thank you for your patience with HPI as we work and move forward with understanding, implementing, and communicating the impacts of the new regulations. If you have any questions, please feel free to reach out to your HPI Account Services Team.

The information in this Compliance Alert is intended to provide a summary of our understanding of recent regulatory developments which may affect our clients' plans. It should not be construed as specific legal advice or legal opinion.