Health Cost Transparency Guide for Employers

A practical guide to understanding health cost transparency rules

Updated April 2023

Table of Contents

OVERVIEW

Background

The Consolidated Appropriations Act (CAA), No Surprises Act (NSA), and the Transparency in Coverage Final Rule (TiC Final Rule) impose several new requirements on employer sponsored group health plans. A list of the various rules is included Section 1. This guide will focus on the portion of the new rules that we will refer to as the "Transparency Requirements."

The goal of the Transparency Requirements is to make it easier to understand, and have access to, what medical services cost, and what health plans pay for those services. Historically, it has been very difficult, if not impossible, to find out what most health care services will cost in advance. As the various Transparency Requirements begin to come into force over the next few years, access to much more detailed information regarding health care costs will help consumers and businesses become better buyers of health care services.

While the Transparency Requirements may seem overwhelming at times, employers will find that in most cases they will be relying on their insurance carriers, administrators, and other vendors to do most of the heavy lifting. This guide is designed to help employers understand their role and navigate their compliance responsibilities. The guide will be regularly updated as additional regulations and guidance is issued.

What Plans are Subject to the Transparency Requirements?

The Transparency Requirements apply to health insurance issuers ("issuer" is how the regulatory agencies refer to health insurance carriers, we will use the term "carrier" in this guide) and most group health plans, including non-federal governmental plans (e.g., cities, public schools, etc.), multiemployer plans (i.e., Taft Hartley plans) and multiple employer plans. The requirements do not apply to account-based plans such as an HRA, nor to excepted benefits (e.g., stand-alone dental and vision plans, EAPs, etc.).

The TiC Final Rule carves out an exception for grandfathered health plans, but the CAA does not. Due to overlap between the TiC Final Rule and the CAA, it appears that all Transparency Requirements may apply to grandfathered plans other than the requirement to post machine-readable files.

Employer Compliance Roadmap

Section 1 – Understand the effective dates and compliance deadlines of the various requirements

Section 2 – Understand who is responsible for compliance with each of the rules

Section 3 – Prepare for the health plan cost machine readable file requirement going into effect beginning July 1, 2022

Section 4 – Prepare for the prescription drug cost reporting requirement beginning December 27, 2022

Section 5 – Begin to prepare for making the pricing tool available to participants beginning January 2023

Section 6 – Understand other requirements that will go into effect later depending on new guidance

A Note about the Hospital Cost Data Files

While not part of this guide, it is interesting to note that the first stage of health cost transparency effort began January 1, 2021, when hospitals were required to publicly post data on what they charge different payers for various medical services. Compliance with this requirement has been mixed, with some hospitals still not making the required information available. However, as more hospitals come into compliance, the industry is already learning much more about how hospitals price their services than has been known before.

Section 1 - Summary of Requirements & Timeline of Effective Dates

2021 — **2022** — **2023** — **2024**

January 2021
Hospital Cost Reporting

January 2022
No Surprises Act
No Gag Clauses in Contracts
Continuity of Care
ID Cards
Provider Directory Accuracy

July 2022
Carriers & Plan Release
Health Plan Cost Data
Machine Readable Files

December 2022
Rx & Health Care Spending
Reporting (Dec. 27, 2022)

January 2023
Price Transparency Tools - 500
Items & Services

January 2024
Price Transparency Tools - All
Items & Services

> **Delayed Until Additional Guidance Is Released**
>
> Prescription Cost Data
> Machine Readable File
>
> Provider treatment cost estimate and Advanced EOB

2021
- **Hospital Cost Data -** Effective January 1, 2021, hospitals were required to make publicly available data containing charges for all items and services provided by the hospital. Hospitals must also publish a consumer-friendly list for the hospital's 300 most "shoppable services."

2022
- **No Surprises Act** – Effective for plan years beginning January 1, 2022, balance billing protection for claims related to out-of-network emergency services, out-of-network providers in an in-network facility, and air ambulance claims.
-
- **Continuity of Care** - Effective January 1, 2022, certain participants can request 90 days of in-network coverage when a provider leaves the network.
- **ID Card Requirements** - Effective January 1, 2022, ID cards must include additional information, including deductible and copay details.
- **Health Plan Machine Readable Data Files** - Effective July 1, 2022, for plan year data beginning January 1, 2022, carriers and health plans are required to publicly disclose machine-readable files detailing reimbursement rates for in-network providers and allowed amounts for out-of-network covered items and services. An additional requirement to post prescription drug reimbursement data is delayed pending additional guidance.
- **Prescription Drug Cost Reporting** - Effective December 27, 2022, carriers and health plans are required to annually report prescription drug costs and other plan information. Submission grace period extended to January 31, 2023.

2023 - 2024
- **Advanced Cost Estimate "Price Comparison Tools"** - Carriers and health plans are required to develop and make available an internet-based, self-service tool for comparing the prices of items and services. The information must also be available in paper form upon request, as well as via telephone.
  - 500 items and services for plan years effective January 2023
  - All covered items and services for plan years effective January 2024
- **Gag Clauses Prohibited** – Effective starting in 2023, carriers and health plans must submit an annual attestation each December 31st indicating compliance with the prohibition on gag clauses in provider reimbursement contracts that took effect in 2020.

Delayed Pending Additional Guidance

- **Advanced Explanation of Benefits (EOB)** - Health care providers will be required to provide an advance good faith estimate to a carrier or health plan when a patient seeks care. The carrier or health plan will then need to provide an advanced EOB to the individual.
- **Air Ambulance Reporting** – Carriers and health plans are required to report claims data and other information related to air ambulance services. The reporting is required for two years and will begin 90 days after the first calendar year following final rules from the agencies.

Section 2 - Who is Responsible for Compliance?

Multiple Stakeholders Will Be Involved

Many of the requirements discussed in this guide involve data and information not readily available to the typical employer/plan sponsor. For example, the health plan cost data machine-readable files must include reimbursement data specific to the provider agreements between the carrier or network and a particular medical provider. This information is contained in the provider agreements between the carrier or network and the provider that, until now, have been confidential. So obviously, employers will need to rely on their carriers and vendors to do much of what is required by the various rules. However, just because the employer will need to rely on its vendors does not mean they can simply ignore the Transparency Requirements. Actual responsibility for compliance in most cases will depend on whether the employer's plan is fully-insured or self-insured.

Compliance Responsibility Based on Plan Type

Compliance responsibility is addressed in more detail in each section, but at a high-level, employers should think of it this way:

<u>Fully-Insured Plans</u>

In most cases, employers who sponsor fully-insured plans will be able to rely on the carrier for compliance. In fact, most of the rules discussed in this guide specifically make the carrier responsible for compliance. Some of the Transparency Requirements may require that the employer enter into a "written agreement" with the carrier, but the exact form of that written agreement is not defined. Most carriers have taken the position that existing language in the group contract that clarifies that the carrier is responsible for complying with all applicable laws and regulations, along with communications they have sent to their clients in the form of emails and FAQs, is enough. At a minimum, fully-insured employers should have a discussion with their carrier regarding compliance with these rules.

<u>Self-Insured Plans</u>

The issue is more complicated for employers who sponsor self-insured (or level-funded) plans. In this case, technically, the employer is usually the entity that is liable for the compliance of their plan. This is even the case when, from a practical perspective, most of the responsibility will fall on the shoulders of the administrator or other vendor.

Employers who sponsor self-insured plans will need to ensure that their vendors are fulfilling their obligations so that the employer's plan is in compliance with the rules. For this purpose:

- Employers/Plan Sponsors should reach out to their vendors to discuss their plans for compliance and ask for written assurances.

- Service agreements and contracts should be reviewed and amended as necessary to ensure that the administrator or other vendor is taking the necessary steps to comply with the applicable rules.

- Employers should ask vendors if there will be any additional costs related to compliance with these rules.

- Indemnification language in existing contracts should be reviewed and updated, if necessary, to protect the employer in cases where a vendor is not able to comply with a rule or regulation. There are various transparency requirements discussed herein where the employer has to rely heavily on the vendor. It would be best to have contractual language specifically addressing such requirements and providing for indemnification if the vendor fails to comply. Many contracts already have language more broadly promising to comply with applicable laws and regulations. While this might be enough, we encourage employers to ask for more specific contract language to be added, or to obtain something further in writing (e.g., mailing or email) clarifying the vendor's intention to comply with the different transparency requirements.

A Note about Vendor Compliance

Many of the Transparency Requirements require vendors to implement very significant technical and administrative changes, and not all vendors will get everything exactly right from the beginning. Even the regulatory agencies recognize this in comments made in the preambles to various regulations. While employers need to hold their vendors accountable, at the same time they should recognize that this is a process that may take some time to work itself out. It is expected that the regulatory agencies' approach to enforcement in the beginning will be to try to help the industry implement these rules rather than penalizing those who are making a good faith attempt to comply.

Section 3 - Health Plan Cost Disclosure: The "Machine Readable Files"

Updated to reflect new guidance issued August 19, 2022

Background

Under the TiC Final Rule, effective July 1, 2022, health plans (which include employer sponsored health plans) and carriers must publicly post pricing data known as the "machine-readable files" or "MRFs." The point of releasing these cost data files has nothing to do with communication to employees or plan participants. Instead, in the name of health cost transparency, this rule requires insurance companies and self-insured plans to publicize what they pay providers for medical services and make that information available to the public. One of the primary goals with this requirement is that the information can then be gathered broadly, and data analytics can be run to provide more cost transparency across the industry.

As long as there is a written agreement in place, employers may generally rely on their carrier or claims administrator to handle this requirement on behalf of the plan

Effective Date

The applicable files should be available July 1, 2022, for any plan years beginning January 1, 2022 through July 1, 2022. For plan years beginning after July 1, 2022, the files should be made available during the first month of the plan year. For example, a plan with a plan year start date of September 1, 2022, should make the files available no later than September 30, 2022.

Posting Requirements

Carriers and plans are required to publicly disclose in a machine-readable file the following reimbursement rate:
- In-network provider rates for covered items and services; and
- Out-of-network allowed amounts for covered items and services.

The TiC Final Rule requires the machine-readable files to be accessible free of charge, without having to establish a user account, password, or other credentials, and without having to submit any personal identifying information such as a name or email address (see Treas. Reg. §54.9815-2715A3(b)(2)).

The machine-readable files must be updated monthly (and clearly indicate the date the filed was last updated) and must be available in a form and manner specified in any guidance issued by applicable regulatory agencies.

Compliance Responsibility

One of the requirements of particular interest to employers is that the data must be posted on a publicly available website. Carriers and administrators have interpreted this requirement differently, creating some confusion among employers. On August 19, 2022, the Departments released guidance in the form of frequently asked questions (FAQs) that clarified employers are not required to post a link to the data files on their organization's website as long as there is a written agreement in place that ensures that the carrier or administrator will make the relevant files publicly available in compliance with the requirements.

- **Fully-Insured Plans**: Employers sponsoring fully-insured medical plan options can rely on the carrier to satisfy this requirement. The TiC Final Rule specifically states that if the employer has a "written agreement" with the carrier indicating that the carrier is posting the information, then the employer does not need to take further action. In this case, the FAQs clarify that the carrier is liable when the files are not made available according to the requirements.

- **Self-Insured Plans**: The FAQs also make it clear that self-insured employers can also rely on their administrator to make the necessary files publicly available, again as long as there is a written agreement in place. However, in the case of a self-insured plan, if the employer's vendor does not post the files in accordance with the regulations, **the employer/plan sponsor is liable**.

Section 4 - Prescription Drug Cost Reporting

Background

In accordance with the Consolidated Appropriations Act of 2021 (CAA), beginning in December 2022, health plans, including grandfathered plans, and health insurance carriers are required to submit certain information about prescription drug and health care spending to the agencies annually. The agencies plan to use this information to issue public reports on prescription drug pricing costs and trends beginning in 2023. CMS calls the reporting requirement the "RxDC Report" ("Rx" stands for "Prescription Drug" and the "DC" stands for "Data Collection").

Plans and carriers must annually submit certain information on prescription drug and other health care spending, including:

- General information regarding the plan or coverage;
- Enrollment and premium information, including premiums paid by employees versus employers;
- Total health care spending, broken down by type of cost (hospital care; primary care; specialty care; prescription drugs; and other medical costs), including prescription drug spending by enrollees versus employers and carriers;
- The 50 most frequently dispensed brand prescription drugs;
- The 50 costliest prescription drugs by total annual spending;
- The 50 prescription drugs with the greatest increase in plan expenditures from the previous year;
- Prescription drug rebates, fees, and other remuneration paid by drug manufacturers to the plan or carrier in each therapeutic class of drugs, as well as for the 25 drugs that yielded the highest amount of rebates; and
- The impact of prescription drug rebates, fees, and other remuneration on premiums and out-of-pocket costs.

Most employer-sponsored health plans will need to rely heavily on their vendors such as their Third-Party Administrator (TPA) and/or Pharmacy Benefit Manager (PBM) to provide the data necessary, or to submit the plan's data to CMS. Any organization submitting data to CMS is referred to as a "reporting entity." There may be multiple reporting entities involved in compiling and submitting data for any particular employer plan.

CMS published updated reporting instructions, including templates for the various data files that are required to be submitted. For reporting that is submitted by vendors (e.g., TPAs and PBMs) on behalf of employer plan clients, the IFC and the CMS instructions encourage reporting entities to submit aggregated data to CMS on behalf of all of their employer plan clients. This is the approach that is used by most vendors. However, choose instead to provide the necessary data to the employer/plan sponsor with the expectation that the plan sponsor will submit their own data to CMS.

Detailed reporting instructions and other important information can be found on the CMS RxDC website at https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection.

Effective Date

The CAA requires plans and carriers to submit the required information for the first time by December 27, 2021, and then by June 1 of each year thereafter. The agencies originally delayed enforcement as long as the required information for 2020 and 2021 was submitted by December 27, 2022. Then on December 23, 2022 the agencies released new guidance and provided an additional grace period for submission of 2020 and 2021 data until January 31, 2023.

Compliance Responsibility

Employers with fully-insured group health plans, where all prescription drug coverage is provided through the group health plan, can rely on their carrier to submit the necessary data to CMS, except that the carrier will likely ask the employer to provide information about the employer and employee contributions toward the monthly premium (average monthly premiums). However, if a fully-insured employer covers some prescription drug costs through separate arrangements, such as a specialty drug carve-out or a separate mail order drug benefit, other reporting may be necessary.

For employers who sponsor self-insured plans, CMS recognizes that employers will need to rely on their vendors to provide the required data to the employer for submission to CMS, or to submit the data on behalf of the employer's plan. However, CMS also makes it very clear that it is the employer/plan sponsor's responsibility to work with their vendors to ensure reporting is completed. CMS also recognizes that it is possible that no single entity will have all the information necessary, so some coordination will need to occur between stakeholders, such as the plan sponsor and their vendors.

The Reporting Process

Filles to be Submitted to CMS

Data is provided to CMS by submission of a series of files. There are 9 separate files, plus a narrative file, that are required for employer-sponsored group health plans.

Plan Lists

There is one plan list file applicable to employer-sponsored plans (Note - there are other plan lists for student health plans and the Federal Employee Health Benefit Plan):

P2. Group health plan list

Data Files

There are 8 separate data files that need to be submitted for employer-sponsored group health plans:

D1. Premium and Life-Years

D2. Spending by Category

- Hospital
- Primary care
- Specialty care
- Other medical costs and services
- Medical benefit drugs: known amounts
- Medical benefit drugs: estimated amounts

D3. Top 50 Most Frequent Brand Drugs

D4. Top 50 Most Costly Drugs

D5. Top 50 Drugs by Spending Increase

D6. Rx Totals

D7. Rx Rebates by Therapeutic Class

D8. Rx Rebates for the Top 25 Drugs

The Narrative File

Every submission should include a narrative response file to address a number of topics. Most of the topics included in the narrative response will need to be addressed by the carrier, PBM, or TPA. They include:
- Net payments from federal or state reinsurance or cost-sharing reduction programs
- Drugs missing from the CMS crosswalk
- Medical benefit drugs
- Prescription drug rebate descriptions
- Allocation methods for prescription drug rebates

- Impact of prescription drug rebates
- Employer size for self-insured plans (Employer would need to submit this only if they are filing files themselves.

<u>Submission Tips (or Clarifications)</u>

✓ A P2 plan list file must accompany any data file that is submitted. A P2 file could be submitted on its own, but a data file or narrative file cannot be submitted without an accompanying P2 file.

✓ In some cases, separate vendors may include the employer's data in the same file type (e.g., a PBM and a separate specialty drug vendor both must report their drug data for the year in files D3-D8, or separate TPA/PBMs within the same plan year submit files D1-D2). CMS guidance indicates that multiple vendors can submit the same data files for a particular plan (e.g., 2 each of files D3-D8). It is also acceptable to submit multiple narrative files. This relieves the employer from having to collect and consolidate the information from separate vendors into a single data file.

<u>Using The CMS Health Insurance Oversight System (HIOS).</u>

Data is submitted through the RxDC module in the Health Insurance Oversight System (HIOS). HIOS is an application within the CMS Enterprise Portal at https://portal.cms.gov/portal/. Employers do not need to set up an account in HIOS if their vendors will be submitting all the required data on their behalf. However, depending on how the employer's vendors approach the requirement, some employers may need to submit at least some of the files themselves and therefore set up an account.

For Rx reporting submitting in the first round of reporting for 2020 and 2021 data, if the employer was submitting only the plan list (P2 file), premium and life-years data (D1 file), and any narrative response, it may submit the files by email to RxDCsubmissions@cms.hhs.gov instead of submitting it through the HIOS system. However, for Rx reporting submitted for 2022 data and later years, any submissions will likely be required to be submitted via HIOS.

Instructions for creating a CMS Enterprise Portal and HIOS account can be found at https://regtap.cms.gov/uploads/library/HIOS-Portal-User_Manual-07-11-2022.pdf . CMS has also set up a help desk to assist with this process which can be reached at 1-855-267-1515 or CMS_FEPS@cms.hhs.gov.

NOTE: Additional information regarding the HIOS submission process, including a step-by-step guide and associated tips for registering and accessing the portal, may be found in **Appendix B** of this document.

<u>Who Has the Data? – Who Will Submit it?</u>

As mentioned above, for a fully-insured plan with all prescription drug claims paid by the carrier, employers can rely on their carriers to handle all of the reporting other than the employer and employee portion of the average monthly premiums.

For employers who sponsor self-insured plans, the employer may have to play a role in the reporting. For such employers, one of the most difficult things about the reporting process is that in many cases, no single entity will have all of the required data. Chart A identifies which organization is most likely to have the data necessary to submit each particular file.

Chart A

Data File	Who Has the Data?
P2. Group health plan list	Employer/TPA/PBM
D1. Premium and Life-Years	Employer/TPA
D2. Spending by Category	TPA
D3. Top 50 Most Frequent Brand Drugs	PBM
D4. Top 50 Most Costly Drugs	
D5. Top 50 Drugs by Spending Increase	
D6. Rx Totals	
D7. Rx Rebates by Therapeutic Class	
D8. Rx Rebates for the Top 25 Drugs	

Here is a link to a data collection spreadsheet the Benefit Comply created to assist employers with collecting information from their vendors. The spreadsheet shows exactly which data elements are required for each file. Download Data Collection Spreadsheet here: https://benefitcomply.com/wp-content/uploads/2022/08/Rx-Data-File-Responsibility.xlsx.

We are also aware that there are employee benefit consultants and other consulting organizations that will provide services to assist the employer in working with their vendors and coordinating the employer plan's data submission.

Administrative Challenges

- Some vendors have communicated that they plan to submit aggregated data for all of their clients and will not provide plan-specific data to the employer. Other vendors are planning to simply provide the data to the employer and assume the employer will take responsibility for the submission to CMS. Without a uniform industry process, it may be difficult for employers with multiple vendors to ensure that their plan data is correctly submitted.
- Employers who have a relatively complex set of vendors who cover or administer Rx related payments (e.g., PBM carve-out, separate specialty drug benefit, stand-alone mail order Rx benefit, etc.) will struggle to coordinate with the various vendors to determine if all of the plan's Rx costs have been reported.
- The guidance indicates the reporting applies to group health plans, but not account-based plans such as HRAs or excepted benefits (e.g., limited-scope dental or vision, health FSAs, onsite clinics, and some EAPs). For group health plans that do not qualify as excepted benefits, such as telemedicine/telehealth, reporting appears to be required. However, we recognize that employers may struggle to get the necessary data to report for such plans. It seems unlikely that an employer who attempts to obtain such information, but who is unable to coordinate with the vendor to actually include it in the report, will be penalized.

Summary and Employer Next Steps

Employers and vendors face many challenges to complete the required Rx reporting, and CMS understands that the data will not be perfect. Vendors will also likely coalesce around more common processes as the industry gains experience with the CMS reporting system and additional guidance is issued. At this point, employers should be actively working with their vendors to determine how much of the reporting will be done by the vendor, and what, if anything, the employer will need to do to complete the process. We anticipate that as long as an employer is making a good faith attempt to comply, the regulatory agencies will be trying to assist employers and vendors in completing the reporting rather than taking enforcement actions, at least for the first couple of years of the requirement.

Section 5 – Pricing Tools

Background

The next phase of the Transparency Requirements will be the requirements for carriers and plans to develop an Internet-based price comparison tool. The tool will allow an individual to receive an estimate of their cost-sharing responsibility for a specific item or service from a specific provider or providers. The information must also be made available by phone or on paper upon request from participant.

Many carriers already offer some kind of online health cost estimator. However, most existing tools will need significant modifications to meet the new price comparison requirements.

Effective Date

This information must be available for plan years beginning on or after January 1, 2023, with respect to the 500 items and services identified by the agencies in Table 1 in the preamble to the TiC Final Rule, and with respect to all covered items and services for plan or policy years beginning on or after January 1, 2024.

Compliance Responsibility

As with many of the requirements described in this guide, employers will need to rely on their carriers and administrators to develop and implement these cost comparison tools.

Section 6 – Gag Clause Prohibition Compliance Attestation

Background

The Consolidated Appropriations Act, 2021 (CAA) prohibits group health plans and health insurance issuers from entering into contracts that restrict specific data and information that a plan can make available to another party. Plans must annually submit an attestation that they have not entered into any prohibited contractual restrictions.

Effective Date

While the prohibition against gag clauses has been effective since December 27, 2020, the first CAA Gag Clause Prohibition Compliance Attestation (GCPCA) is due by December 31, 2023. Subsequent attestations will be due by December 31 of each year thereafter.

Compliance Responsibility

Employers typically rely on their carrier, TPA or PBM to contract with medical providers to provide services to participants in the health plans offered to employees. The agencies recognize this and provided guidance indicating that if specific requirements are met, employers can rely on their carrier or TPA to submit the attestation on behalf of their employer-sponsored plans similar to other CAA requirements.

The GCPCA instructions note that a self-insured plan can enter into a written agreement to have their TPA, PBM or another third party submit the attestation on their behalf, but the legal responsibility to submit a timely attestation remains with the self-insured plan sponsor.

For a fully-insured plan, the carrier is jointly liable with the employer plan sponsor to submit the attestation, so the employer can likely rely on the carrier to submit the attestation, but we recommend that employers sponsoring fully-insured plans seek assurance from their carrier that the attestation is being submitted.

Employers with direct contracts with providers may need to take responsibility for submitting the Attestation on behalf of those plans and the Attestation requirement not apply to "excepted benefits," such as most dental, vision, health FSA and EAP plans. The Tri-Agency FAQs (Q/A-8) also confirms that the requirement also will not be enforced against HRAs (including ICHRAs) and other account-based group health plans because such arrangements will likely be integrated with other coverage that are required to complete the attestation.

Attestation Process

For plan sponsors that must submit their own attestation, the Departments have created a website through the Centers for Medicare and Medicaid Services for health plans and issuers to submit their gag clause compliance attestations, available here - https://hios.cms.gov/HIOS-GCPCA-UI.

The process is relatively straightforward, especially compared to the RxDC Reporting. To access the user interface, users must first obtain an authentication code from the website by entering an email address. With the code, the user is able to log in using just their email address and code.

More information, including links to the guidance, submission instructions for entities required to submit the attestation, and more, can be found at https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/gag-clause-prohibition-compliance.

Summary and Employer Next Steps

- Plan sponsors should confirm that no prohibited provisions remain in their agreements.

- Self-insured plan sponsors should request in writing from their TPA, PBM or another third party that they will submit the attestation on their behalf.
- Employers sponsoring fully-insured plans should seek confirmation from their carrier that the attestation will be submitted on behalf of their plan.

Section 6 – Other Pending Requirements

Rx Cost Data Machine Readable File Delayed

After the agencies finalized the TiC Final Rule, Congress enacted the CAA, which imposes the new prescription drug reporting requirements described in Section 4 of this guide. The agencies recognized that there is significant overlap in what needs to be reported in the CAA reporting rule effective December 27, 2022, and what would be included in the prescription drug cost data machine-readable file. Consequently, the agencies have decided to delay enforcement of the TiC Final Rule's prescription drug cost data machine-readable file requirement until further guidance is issued.

Air Ambulance Reporting

Background

In accordance with the No Surprises Act in the CAA, for plan years beginning in 2022, group health plans must cover air ambulance services provided by non-participating providers (out-of-network) as if they were in-network. Participants can only be subject to cost-sharing as if the services were provided in-network, and the plan must pay the difference of whatever gets negotiated with the provider (e.g., in accordance with the independent dispute resolution (IDR) process).

In addition, group health plans are required to report certain information about air ambulance services claims data. This reporting will be required for only two years. HHS and the Department of Transportation will then use this information to issue public reports to assist in better understanding what drives the high costs of these services.

Details

For two separate calendar years, group health plans must report data for air ambulance services provided during the year, and services for which payment was made during the year. The report will be due 90 days after the end of each calendar year. The reporting requires claims-level data rather than aggregate information. The proposed rules suggest the following information must be included in the report for each calendar year:

> (1) Identifying information for any group health plan, plan sponsor, or issuer, and any entity reporting on behalf of the plan or issuer, as applicable.

> (2) Market type for the plan or coverage (individual, large group, small group, self-insured plans offered by small employers, self-insured plans offered by large employers, and Federal Employees Health Benefits).

> (3) Date of service.

> (4) Billing NPI information.

> (5) Current Procedural Terminology (CPT) code or Healthcare Common Procedure Coding System (HCPCS) code information.

> (6) Transport information (including aircraft type, loaded miles, pick-up (origin zip code) and drop-off (destination zip code) locations, whether the transport was emergent or non-emergent, whether the transport was an inter-facility transport, and, to the extent this information is available to the plan or issuer, the service delivery model of the provider (such as government-sponsored (Federal, State, county, city/township, other municipal), public-private partnership, tribally-operated program in Alaska, hospital-owned or sponsored program, hospital independent partnership (hybrid) program, independent).

> (7) Whether the provider had a contract with the group health plan or issuer of group or individual health insurance coverage, as applicable, to furnish air ambulance services under the plan or coverage, respectively.

> (8) Claim adjudication information, including whether the claim was paid, denied, appealed; denial reason; and appeal outcome.

> (9) Claim payment information, including submitted charges, amounts paid by each payor, and cost sharing amount, if applicable.

For fully-insured plans, the carrier is expected to handle this reporting requirement on behalf of the plan. For self-insured plans, the TPA is probably in a better position to provide the data for the reporting, but employers should coordinate with their TPAs to understand who will submit the report to HHS.

<u>Effective Date</u>

The reporting is required 90 days after the first full calendar year following release of final rules by the agencies. Since we do not have final rules yet, the earliest the reporting would be required is in March of 2024 (assuming final rules are released before the end of 2022).

Provider Good Faith Cost Estimates and Advanced EOBs

<u>Background</u>

The last initiative of the Transparency Requirements requires providers to provide a good faith estimate of the cost of medical services to a patient. Subsequently, the plan or carrier will be required to provide a participant with an "Advanced Explanation of Benefits (EOB)" estimating the participant's out-of-pocket cost for those services.

<u>Details</u>

The CAA requires providers and facilities to inquire whether the individual is enrolled in a health plan or health insurance coverage and to provide a good faith estimate of the expected charges. If the individual is enrolled in a health plan or other coverage, the provider must provide this notification to the individual's plan.

Upon receiving a "good faith estimate" from the provider, the plan or carrier must provide an Advanced EOB notification in clear and understandable language. The notification must include:

1. The network status of the provider or facility;

2. The contracted rate for the item or service, or if the provider or facility is not a participating provider or facility, a description of how the individual can obtain information on providers and facilities that are participating;

3. The good faith estimate received from the provider;

4. A good faith estimate of the amount the plan or coverage is responsible for paying, and the amount of any cost-sharing for which the individual would be responsible for paying with respect to the good faith estimate received from the provider; and

5. Disclaimers indicating whether coverage is subject to any medical management techniques.

The EOB also must indicate that the information provided is only an estimate based on the items and services reasonably expected to be provided at the time of scheduling (or requesting) the item or service and is subject to change.

<u>Effective Date and Delayed Enforcement</u>

These provisions were originally scheduled to go into effect for plan years beginning on or after January 1, 2022. However, the agencies received feedback from the industry about the challenges of developing the technical infrastructure necessary for medical providers to transmit the necessary information to plans and carriers. The agencies released a Request for Information (as proposed regulations) in an effort to better determine and establish appropriate data transfer standards, amongst other things. Until the agencies release additional rules and guidance, the agencies will continue to delay enforcement of the requirement that plans and carriers must provide an Advanced EOB.

Appendix A – Additional Resources

Transparency in Coverage Final Rule - https://www.govinfo.gov/app/details/FR-2020-11-12/2020-24591

CMS Transparency in Coverage Website - https://www.cms.gov/healthplan-price-transparency

Agency FAQs Part 49 Clarifying and Delaying Transparency Requirements - https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf

Prescription Drug Reporting Interim Final Rule (IFC) - https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending

CMS Rx Reporting Website - https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

CMS Machine-Readable Files FAQ - https://www.cms.gov/sites/default/files/2022-04/FAQ-Affordable-Care-Act-Implementation-Part-53.pdf

Air Ambulance Reporting – Proposed Rule - https://www.federalregister.gov/documents/2021/09/16/2021-19797/requirements-related-to-air-ambulance-services-agent-and-broker-disclosures-and-provider-enforcement

Request for Information: Advanced EOBs - https://www.federalregister.gov/documents/2022/09/16/2022-19798/request-for-information-advanced-explanation-of-benefits-and-good-faith-estimate-for-covered

Gag Clause Attestation Website - https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/gag-clause-prohibition-compliance

Appendix B – Registration & Access to CMS Enterprise Portal and HIOS

Added September 2022

The CMS Enterprise Portal is used to access CMS systems. The Health Insurance Oversight System (HIOS) is an application found within the CMS Enterprise Portal and is a federal system of record and provides a centralized, multi-user interface for several different purposes, including the RxDC reporting.

> **TIP:** *Employers do not need to set up an account in HIOS if their vendors will be submitting all the required data on their behalf. However, employers that sponsor a self-insured health plan that intend to submit any data directly to CMS should apply for a HIOS account as soon as possible.*

There are several registration and approval steps that need to be completed for a new user to gain access to the HIOS system to upload RxDC files. In addition to the full HIOS Portal User Manual (HIOS Portal User Manual (cms.gov), CMS has provided a Quick Reference Guide outlining the steps for new users to register for a CMS EIDM account and request access to HIOS. HIOS Portal Quick Guide (cms.gov).

> **TIP:** *CMS has set up a help desk to assist with this process which can be reached at 1-855-267-1515 or CMS_FEPS@cms.hhs.gov .*

EIDM is the acronym for CMS' Enterprise Identity Management system which includes Identity Management, Access Management, Authorization Assistance Workflow Tools, and Identity Lifecycle Management functions (i.e., Password Reset, Forgot User ID, etc.). EIDM handles the identity verification of users trying to request access to CMS systems. New users are required to complete the Remote Identity Proofing (RIDP) process as well as set-up Multi-Factor Authentication (MFA) before access to HIOS will be granted.

> **TIP:** *If you prefer more detailed, step-by-step instructions, the HIOS Portal User Manual, HIOS Portal User Manual (cms.gov), may be used in place of or alongside the Quick Reference Guide.*

1. **Register for a CMS IDM Account. See** page 1 of the **Quick Reference Guide.**
    - Users will create a User ID, Password & set Challenge Questions
    - After completing the registration process, users will also receive an email acknowledging successful registration and the email will include the EIDM user ID.

2. **Sign into the CMS Enterprise Portal and Request Access to the HIOS System. See page 2 of the Quick Reference Guide.**
    - Navigate to the CMS Enterprise Portal (https://portal.cms.gov) and enter your User ID and Password and answer the Challenge Questions from Step 1 above.
        - ✓ On the My Portal Page, Select **Add Application**
        - ✓ Application is **HIOS**
        - ✓ Role is **HIOS User**

3. **Register an MFA Device. See Page 3 of the Quick Reference Guide.**
    - Users must associate a security code with their Phone, Computer, or E-mail. The registered device will be used to send a code each time a user signs in.

4. **Login to CMS Portal and HIOS using MFA. See bottom of page 3 of the Quick Reference Guide.**
    - On the landing page, select Access HIOS.

- After users have logged into the CMS Enterprise Portal, they must select HIOS from the My Portal page and then the Overview link.

> **TIP:** *The HIOS Portal User Manual,* HIOS Portal User Manual (cms.gov), has several examples and screen shots that may be helpful for this next section.

5. **Register an Organization in HIOS (for New Users). See pages 4 - 6 of the** Quick Reference Guide, **and/or Page 43 (3.3) of the** HIOS Portal User Manual (cms.gov) **.**
   - New users will not have any organizational associations or role permissions. The Manage Organizations functionality allows new users to create an organization before requesting a user role(s).

> **TIP:**
> - *You will need a Federal EIN/TIN to determine if the organization currently exists in HIOS, or for organization type "Other Organization" that may not have a FEIN/TIN, search using the organization name.*
> - *Employers will generally not add Issuers to an Organization as a "Company" is the only organization type that have issuers associated to it (Company is typically an insurance company that is a legal entity licensed to sell health insurance products and plans.).*
> - *A description of the Frequently Requested Roles can be found on page 8 of the Quick Reference Guide. "Organization Role Approver" will be the most common role for an employer.*
> -

6. **Request HIOS Module Roles. See bottom of page 7 of the** Quick Reference Guide, **and/or Page 93 (3.8) of the** HIOS Portal User Manual (cms.gov).
   - Note, you must have an organization registered in HIOS to request access to a module.
   - The HIOS home page will display a Request a Role link from the drop-down menu under the "Welcome, Jane Doe" link (top right).
     - ✓ Select HIOS Portal – click next
     - ✓ Select a role
     - ✓ Add association (find the organization you registered earlier)
     - ✓ Confirm request

7. **After HIOS Role request is approved, log back into HIOS and again, under Request a Role, and select "Prescription Drug Data Collection (RxDC) under HIOS Modules.**
     - ✓ Role will be RxDC Submitter
     - ✓ Add association (find the organization you registered earlier)
     - ✓ Confirm request

8. **After "Prescription Drug Data Collection (RxDC) role is approved, login to the Prescription Drug Collection (RxDC) Platform to upload files.** https://idm.cms.gov/

Resources:

CMS Enterprise Portal and HIOS Quick Reference Guide: *9/22*

- [HIOS Portal Prod Quick Guide (cms.gov)](#)

HIOS Portal User Manual: *7/22*

- [HIOS Portal User Manual (cms.gov)](#)

Prescription Drug Data Collection (RxDC) User Manual *10/22*

- [HIOS RxDC User Manual (cms.gov)](#)

Prescription Drug Data Collection (RxDC) Reporting Form Instructions: *6/22*

- [Prescription Drug Data Collection - RxDC - Reporting Instructions (cms.gov)](#)

> ***TIP:*** *CMS has set up a help desk to assist with this process which can be reached at 1-855-267-1515 or CMS_FEPS@cms.hhs.gov .*