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Thank you for joining us!

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Clearing the Air on Transparency Regulations

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Presented by the Regulatory and Legislative Strategy Group

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Agenda

1. Basic Overview Transparency Requirements
2. Machine-Readable Files
3. Prescription Drug Reporting
4. Price Comparison Tool

Overview of Transparency Requirements

Two Sources of Rules

Affordable Care Act

- Publicly Available Machine-Readable Files (discussed later)
- Price Comparison Tool (discussed later)
- Reflected in the final Transparency in Coverage (TiC) regulations issued in November 2020

No Surprises Act

- Prohibition on Gag Clauses
- Health Plan ID Card Enhancements
- Continuity of Care Requirements
- Provider Directory Requirements
- Reporting on Prescription Drug Costs (discussed later)
- Price Comparison Tool (discussed later)
- Advanced EOBs
- Surprise Medical Bills

Compliance Dates

- Prohibition on Gag Clauses – 12/27/20
- Health Plan ID Card Enhancements – PY beginning on or after 1/1/22
- Continuity of Care Requirements – PY beginning on or after 1/1/22
- Provider Directory Requirements – PY beginning on or after 1/1/22
- Surprise Medical Bills – PY beginning on or after 1/1/22
- Publicly Available Machine-Readable Files – 7/1/22
- Reporting on Prescription Drug Costs (discussed later) – 12/27/22
- Price Comparison Tool – PY beginning on or after 1/1/23
- Advanced EOBs – Undetermined

Machine-Readable Files

Publicly Available Machine-Readable Files

Files are for public, not plan participants or employees

- No specific notice requirement for employees or participants

Form and content requirements

- Standardized format
- Three separate machine-readable files:
  1. Negotiated rates between plan and in-network providers
  2. Historical payments to and billed charges from out-of-network providers
  3. ***[Indefinitely delayed]*** In-network negotiated rates and historical net prices for all covered prescription drugs by plan or issued at pharmacy location level

Publicly Available Machine-Readable Files

WHO MUST COMPLY?

Applies to:

- Non-grandfathered Group Health Plans, including:
  - Employer-sponsored plans
  - Multiemployer (Taft-Hartley) plans
  - Multiple Employer plans (MEWAs)
- Individual Insurance (on and off the Marketplace)

Does not apply to:

- Grandfathered health plans
- Group health plans that are excepted benefits:
  - Most dental and vision plans
  - On-site medical clinics, EAPs
- Account-based plans
  - Health FSAs
  - HRAs (including ICHRAs, QSEHRAs)

Publicly Available Machine-Readable Files

WHO MUST COMPLY?

For group health plans, the requirement applies to both group health plan and, if fully insured, insurance issuer, but there are special rules to avoid duplication:

- For **fully insured** plans, the group health plan may satisfy the law's requirements if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement.
  - » If the issuer and plan sponsor enter into written agreement and the issuer fails to comply, the issuer violates the requirement.
- For **self-insured** plans, the group health plan may satisfy the law's requirements by entering into a written agreement under which another party (e.g., the plan's TPA) agrees to make the files available in accordance with the regulations.
  - » Does not shift full responsibility to third-party. If the third party fails to provide the information in compliance with regulations, the plan violates the transparency disclosure requirements.
- No guidance regarding what constitutes a written agreement for this purpose.
- Employers should work with legal counsel to help ensure proper written agreement is in place.

Publicly Available Machine-Readable Files

OTHER ISSUES

If files will be published on the insurance carrier's or TPA's website, is a link required?

- In discussing one of the two machine-readable files, the regulations state: "However, if a plan . . . chooses not to also host the file separately on its own website, it must provide a link on **its own public website** to the location where the file is made publicly available."

Publicly Available Machine-Readable Files

OTHER ISSUES

Additional Guidance on Links

- FAQs About ACA and CAA Part 55 issued 8/15/22
  - **Q/A22:** If a group health plan does not have its own public website, nothing in the TiC Final Rules requires the plan to create its own website for the purposes of providing a link to a location where the machine-readable files are publicly available. The Departments note this guidance applies in instances in which the plan sponsor (for example, the employer) maintains a public website, but the group health plan sponsored by the employer does not.
    Instead, a plan may satisfy the requirements of 26 CFR 54.9815-2715A3(b), 29 CFR 2590.715- 2715A3(b), and 45 CFR 147.212(b) by entering into a written agreement under which a service provider (such as a TPA) posts the machine-readable files on its public website on behalf of the plan.
    To the extent a service provider posts the required information on its public website on behalf of a plan, the plan satisfies the requirements with respect to posting the information on a public website if the service provider makes the information available in the required manner, regardless of whether the group health plan has a public website. In the case of aggregated Allowed Amounts files, however, the plan must post a link to the file hosted by the service provider on the plan's own website, **if the plan maintains a public website,** per the requirements of 26 CFR 54.9815-2715A3(b)(4)(iii), 29 CFR 2590.715-2715A3(b)(4)(iii), and 45 CFR 147.212(b)(4)(iii).

RxDC Reporting

General Overview of Requirements

- Added to ERISA, Internal Revenue Code and PHSA by CAA of 2021
- Interim Final Regulations issued 11/23/21
  - https://www.govinfo.gov/content/pkg/FR-2021-11-23/pdf/2021-25183.pdf
- CMS published filing instructions; most recently updated in June 2022
  - https://regtap.cms.gov/uploads/library/RxDC-Section-204-Reporting-Instructions-06-30-2022.pdf
  - The updated version contains some significant changes, especially to reporting requirements related to wellness programs
- First report due no later than 12/27/22
  - Includes information for 2020 and 2021 “reference years”
  - Reference year = calendar year (even for non-calendar year plans)
  - Future reports due by June 1 of the year following the end of the reference year (e.g., 6/1/23 for 2022 reference year)

General Overview of Requirements

- Applies to fully insured and self-insured group health plans, but:
  - Does not apply to HIPAA excepted benefits (e.g., most dental and vision plans; fixed indemnity plans; disease-specific insurance)
  - Does not apply to account-based plans (e.g., HRAs and health FSAs)
- Applies to plans sponsored by private sector employers, governmental employers, and churches and conventions and associations of churches

General Overview of Requirements

- Using a third party (e.g., insurance carrier, TPA, PBM, etc.)
  - » Regulations allow fully insured group health plans to shift all responsibility to carrier if carrier agrees to perform reporting pursuant to a written agreement
  - » Regulations allow a third party to perform the reporting on behalf of a self-insured group health plan pursuant to a written agreement, but group health plan (and plan sponsor) retains ultimate responsibility if the third party fails to comply
  - » Instructions indicate that multiple reporting entities can submit reports on behalf of a group health plan, but multiple reporting entities should not submit the same data file for a plan (e.g., PBM could submit data files with Rx drug information and TPA could submit data file with medical spending information)
    - – Special rule if vendors change mid-year – Multiple reporting entities can submit the same data file for different portions of the year
  - » Plan sponsor could be a reporting entity if third parties do not agree to submit all data files
    - – Note: Issues may arise in this scenario due to files requiring information related to covered lives, premiums and administrative expenses (D1)

What Information Must Be Reported

Five General Categories of Information

- Plan List – File P2
- Premiums and Life Years (Covered Lives) – File D1
- Medical Spending by Category – File D2
- Rx Cost Information – Files D3-D8
- Narratives

Carriers, TPAs and PBMs that file on behalf of group health plans will generally aggregate data contained in Files D2-D8 by market segment and state.

Plan List

- P2 applies to group health plans
- Must be submitted by any reporting entity that submits a file on behalf of a group health plan
- Includes various pieces of plan identifying information (e.g., plan name, plan number, plan year, plan sponsor name, etc.) and information about issuer, TPA and/or PBM
  - » Plan sponsor may need to provide some of this information to carrier/TPA/PBM if the carrier/TPA/PBM is handling the reporting
- P2 file also indicates which additional files are being included with the reporting entity's submission

Life Years and Premiums

- File D1
- Life years = Average number of members (employees and dependents) throughout the year
  - » Instructions illustrate how to calculate
- Premiums
  - » Earned premium or premium equivalent
  - » ASO and other TPA fees paid (aggregate for plan)
  - » Stop loss premium paid (aggregate for plan)
  - » Average monthly premium paid by members
  - » Average monthly premium paid by employer

- Carrier/TPA/PBM will not have all of this information
- Plan sponsor may need to file D1 or provide information to carrier/TPA/PBM
- Transition Relief:
  “If you have obtained the required information, you must report it. However, the Departments recognize there may be significant challenges to obtain information about employer premium contributions, especially when a contractual relationship began before the passage of the CAA. Accordingly, the Departments will not take enforcement action related to the requirement to report average monthly premium paid by employers versus members for the 2020 and 2021 reference years if those data elements are reported in RxDC report for the 2022 reference year and all future reference years.”

Spending by Category

- File D2
- Report data related to the reference year for claims paid or received through March 31 of the following calendar year
- Categories
  - Hospital
  - Primary care
  - Specialty care
  - Other medical costs and services
  - Medical benefit drugs: Known amounts
  - Medical benefit drugs: Estimated amounts

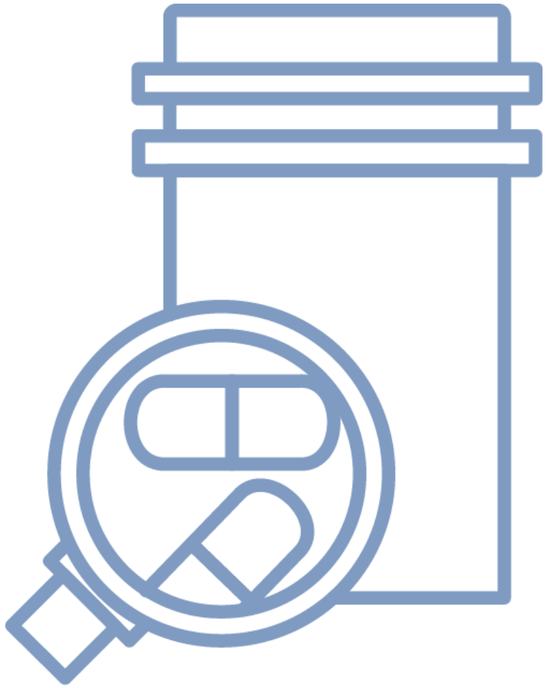
Spending by Category

File D2

- Other medical costs and services includes information regarding wellness spending
- Prior version of instructions appeared to require submission of a broad range of wellness spending by plan sponsor
- Revised instructions narrow scope of this reporting
  - File must include “wellness services billed on a claim”
    - Wellness services are defined as activities primarily designed to implement, promote and improve health
  - Instructions state: “Do not include wellness services that are not covered services under a plan or policy.”
  - Instructions specifically exclude “Wellness services not billed on a claim.”

Prescription Drug Reporting

- Files D3 through D8
  - » Top 50 Brand Drugs, Top 50 Most Costly Drugs, Top 50 Drugs by Spending Increase, Rx Totals, Rx Rebates by Therapeutic Class, Rx Rebates for the Top 25 Drugs
- Does not include Rx drugs covered under a medical benefit (so no coordination needed between PBM and TPA) to complete D3 through D8



Narrative Response

- Seven specific narratives required
  - Employer size for self-funded plans – identify whether size was determined using actual counts or estimates; if estimates, describe estimation method
  - Net payments from federal/state reinsurance or cost-sharing reduction programs
  - Drugs missing from the CMS crosswalk
  - Medical benefit drugs
  - Rx drug rebate descriptions
  - Allocation methods for Rx drug rebates
  - Impact of Rx drug rebates
- Submitted in Word or PDF format

Filing Procedure

- Submit data through the RxDC module in the Health Insurance Oversight System (HIOS)
  - » Instructions for using the RxDC module are in the User Manual
- Process for registering
  - » Must have a HIOS account to file reports
  - » Instructions for creating an account are in the HIOS Portal User Manual
- Instructions contain contact information for additional help

Summary

- Plan sponsors need to determine whether carrier, TPA and/or PBM will be performing reporting on behalf of the plan
  - » If so, enter into a written agreement
- Will all data files be covered by third-party reporting?
  - » If so, determine what information needs to be provided to carrier/TPA/PBM for it to complete the report
  - » If not, plan sponsor needs to create a HIOS account and prepare to file any missing files on its own

Price Comparison Tool

Price Comparison Tool

- Both final TiC regulations under the ACA and the CAA include this requirement
- Final TiC regulations apply to same plans as MRF requirements (e.g., grandfathered plans, excepted benefits and account-based plans are excluded)
- CAA applies more broadly because it applies to grandfathered plans
  - Unclear if CAA requirement will apply to account-based plans
- Agencies addressed interaction between the two in FAQs About ACA and CAA Part 49
  - Intend to propose rulemaking regarding whether compliance with final TiC regulations satisfies the CAA requirements
  - Intend to propose rulemaking requiring that the pricing be provided by telephone upon request (in addition through the online tool or in paper form as required under the final TiC regulations)

Price Comparison Tool

Based on TiC regulations issued under the ACA

- Self-service tools available on Internet website (and by telephone per CAA)
  - Real-time responses as of the date of the request
  - Must be provided in paper form upon request
  - Mobile app alone is insufficient
  - Searchable by:
    - Covered item or service,
    - All in-network providers, or
    - All out-of-network providers.
- Allows participants to compare the amount of cost-sharing that the individual would be responsible for paying under the plan with respect to the receipt of a specific item or service by a particular provider

Price Comparison Tool

- Starting with the first plan year beginning on or after January 1, 2023
  - Must disclose cost-sharing and pricing for 500 specific items and services
  - List available at http://www.cms.gov/healthplan-price-transparency/resources/500-items-services
  - Updated quarterly
- Starting with the first plan year beginning on or after January 1, 2024
  - Must disclose cost-sharing and pricing for all covered items and services
- Rules regarding duplication
  - Plan sponsor can shift responsibility to third party via written agreement
  - Sponsors of self-insured plans retain ultimate responsibility for compliance

Price Comparison Tool

Tool must provide the following information:

1. Estimated cost sharing liability ($) for a covered item or service, including all items and services for which benefits are available under the medical plan (including drugs and durable medical equipment)
2. Participant's accumulated deductible, out-of-pocket maximum and treatment limitation amounts
3. The in-network rate for the requested covered item or services (even if it is not the rate used to calculate cost-sharing liability) and the underlying fee schedule rate to the extent it is different from the negotiated rate
4. The out-of-network allowed amount when the covered item or service is received from an out-of-network provider
5. If the item or service is part of a bundled payment arrangement, a list of the items or services included in the bundled payment arrangement
6. A list of any prerequisites required for plan coverage (e.g., prior authorization, concurrent review, fail-first medical policy or step-therapy drug protocols)
7. Disclosure notice that contains specific information (e.g., the notice must state that the actual charges for a participant's covered item or service may be different from the estimate of cost-sharing liability provided by the self-service tool) – See model notice

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