This Webinar Will Start Momentarily.
Thank you for joining us!

Transparency Update

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Presented by the Regulatory and Legislative Strategy Group

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Agenda

1. Price Comparison Tool
2. Prescription Drug Reporting
3. Gag Clause Attestations

Price Comparison Tool

Price Comparison Tool

- 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
- Self-service tool 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.

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

Price Comparison Tool

- More to come?
- Both final TiC regulations under the ACA and the CAA include this requirement
- Agencies addressed interaction between the two in FAQs About ACA and CAA Part 49
  - Intend to propose rules regarding whether compliance with final TiC regulations satisfies the CAA requirements
  - Intend to propose rules requiring that the pricing be provided by telephone upon request (in addition to being provided through the online tool or in paper form as required under the final TiC regulations)
  - Issued in August 2021 but nothing since then

RxDC Reporting

General Overview of Requirements

- Added to ERISA, Internal Revenue Code and PHSA by CAA of 2021
- Generally due by June 1st of the year following the applicable reporting year (i.e., immediately preceding calendar year)
- 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)
  - » Does not apply to retiree plans
- Applies to plans sponsored by private sector employers, governmental employers, and churches and conventions and associations of churches
- Applies regardless of employer's size

General Overview of Requirements

Penalties

- Regulatory agencies have provided no guidance regarding enforcement or potential penalties

- RxDC reporting requirement added as Section 9825 of the Internal Revenue Code
  - Section 9825 is part of Chapter 100
  - Section 4980D imposes an excise tax on any failure of a group health plan to meet the requirements of Chapter 100
  - Excise tax amount is $100 for each day in the noncompliance period with respect to each individual to whom such failure relates
  - Unclear to what individuals a failure to comply with RxDC reporting would relate to, so not clear how IRS would calculate excise tax

General Overview of Requirements

Guidance Issued to Date

- 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 March 2023
  - » https://regtap.cms.gov/reg_librarye.php?i=3860
- Agencies released FAQs on 12/23/22 (shortly before the first filing due date)
  - » FAQ About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 56
  - » Provided a filing grace period until 1/31/23
  - » Provided relief for plans that used a good faith, reasonable interpretation of the regulations and instructions in making their submission
    - – No enforcement action will be taken by regulatory agencies

What Information Must Be Reported

Five General Categories of Information

1. Group Health Plan List – File P2
2. Premiums and Life Years (Covered Lives) – File D1
3. Medical Spending by Category – File D2
4. Rx Cost Information – Files D3-D8
5. 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

D1: Life Years and Premiums

Six Data Elements

1. Life Years = Average number of members (employees and dependents) throughout the year
   - First, calculate total member months
     - » Count the number of members covered on a given day of each month of the year
     - » Add the count for each month together
   - Then divide total member months by 12
2. Earned Premium (FI) or Premium Equivalent (SI)
   - Earned Premium = All money paid to carrier
   - Premium Equivalent = Total cost of providing and maintaining coverage, including claims costs, administrative costs, Administrative Services Only (ASO) and other TPA fees and stop loss premiums
3. Admin fees paid (aggregate for plan)
4. Stop loss premium paid (aggregate for plan)
5. Average monthly premium paid by members
   - Total premiums paid/contributions made by members/total member months
6. Average monthly premium paid by employer
   - Total premiums paid/contributions made by employer/total member months
   - For SI, employer contributions would typically be the difference between the premium equivalent and total member contributions

Data Files (D2 – D8)

D2

- Medical spending by category (hospital, primary care, specialty care, other medical costs and services, and medical benefit drugs (known amounts and estimated amounts)

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

Filing Procedure

Submit Data Through the RxDC Module in the Health Insurance Oversight System (HIOS)

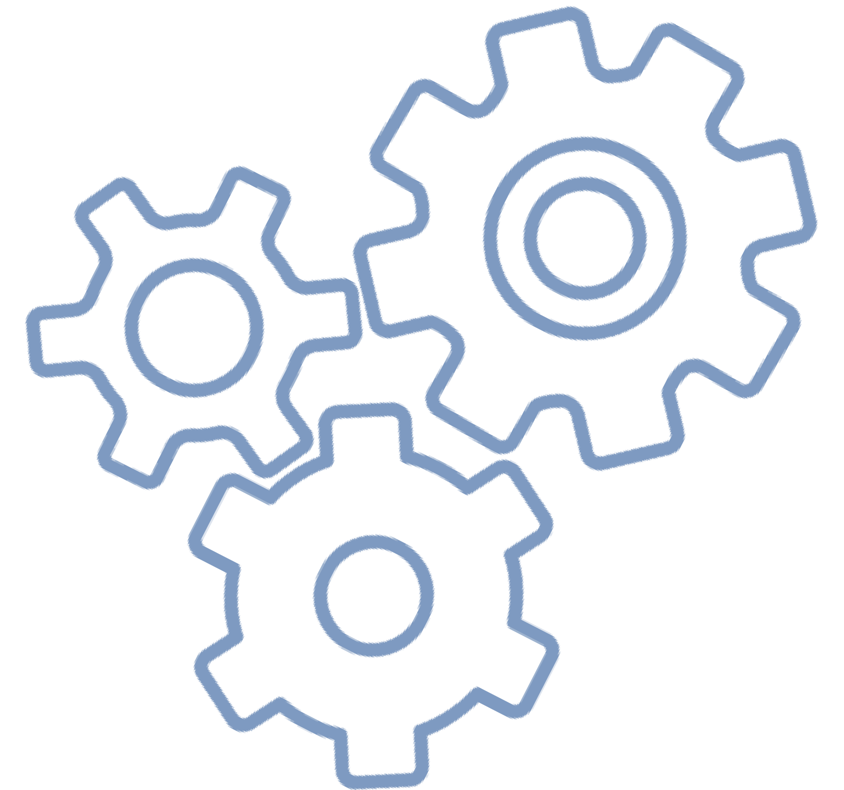
- Instructions for using the RxDC module are in the User Manual

- Exception: FAQ 56 indicates that, for applicable calendar year 2020 and 2021 filing, premium and life years data (i.e., D1 data) could be submitted by email if that is the only information a plan or reporting entity was submitting

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



Who Files?

- 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
  - » Plan sponsor could be a reporting entity if third parties do not agree to submit all data files
- Carrier/TPA/PBM will not have all this information (especially premium information)
  - » For initial filing, carriers/TPAs/PBMs could omit average monthly premium paid by employers versus members from initial filing pursuant to relief issued by regulatory agencies
  - » Plan sponsor may need to file D1 or provide information to carrier/TPA/PBM
  - » Carriers/TPAs/PBMs generally impose deadlines for providing information
    - – What if employer misses deadline? Depends on specific circumstances

Who Files?

Rules regarding multiple files

- Original 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
  - **Example:** PBM could submit data files with Rx drug information and TPA could submit data file with medical spending information, but TPA and plan sponsor both cannot submit D1 file for plan
  - Special rule if vendors change mid-year – Multiple reporting entities can submit the same data file for different portions of the year
- FAQ 56 indicated that, for initial filing, more than one entity may submit the same data file on behalf of the same plan
  - Allowed two vendors to submit D1 files for plan
  - Allowed employer to submit a D1 file even if carrier/TPA/PBM also submitted a D1 file

Updates for 2023

- Updated instructions issued in March
- Key changes/clarifications include:
  - » Multiple data files of same type – "if entities are unwilling or unable to work together, more than one reporting entity may submit the same type of data file on behalf of the same plan, issuer, or carrier"
    - **Example:** TPA submits D1 with some fields completed, employer submits D1 with other fields completed
- Confirmation that RxDC requirements do not apply to retiree-only plans
- No extension of relief to omit average monthly premiums paid by members and employer
- Revision to P2 File – HIOS Plan ID column replaced to collect information about carve-out benefits
- Data files revised to replace Issuer or TPA Name and Issuer or TPA EIN with Company Name and Company EIN so that information can be reported at the plan sponsor level
- Clarified some premium reporting
  - All admin fees reported, not only ASO/TPA fees
  - Omit prescription drug rebates from premium equivalent and total spending, even if expected but not yet received
  - Omit stop loss reimbursement from premium equivalent but not from total spending

Gag Clause Attestations

General Overview of Requirements

- Prohibition on gag clauses was effective December 27, 2020
- Applies to fully insured and self-insured group health plans, including plans subject to ERISA, non-Federal governmental plans and church plans
  - Does not apply to plans providing excepted benefits and account-based plans
- A plan may not enter into an agreement regarding a provider network that would directly or indirectly restrict the plan from:
  - Providing provider-specific cost or quality of care information or data to referring providers, the plan sponsor, enrollees, or individuals eligible to become enrollees of the plan or coverage;
  - Electronically accessing de-identified claims and encounter information or data for each enrollee in the plan, upon request and consistent with applicable federal law; and
  - Sharing information or data described above, or directing that such data be shared, with a HIPAA business associate.

Recent Regulatory Guidance

FAQ About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 57

- Issued February 23, 2023

- Provides examples of prohibited gag clauses
  - A provision in a contract between a TPA and group health plan indicating that the plan may not share information regarding the rates the TPA pays to providers with participants and beneficiaries
  - A provision in a contract between a TPA and group health plan providing that the plan sponsor's access to provider-specific cost and qualify of care information is at the discretion of the TPA

Attestations

- A group health plan must annually submit to the DOL an attestation that it is complying with these requirements
- FAQ 57 indicates first attestation due by December 31, 2023
  - » Covers the period of 12/27/20 through date of attestation
  - » For future years, attestation due by 12/31
- Attestations submitted via a website (https://hios.cms.gov/HIOS-GCPCA-UI)
- Departments have issued instructions, a system user manual and a Reporting Entity Excel Template
  - » Available at: https://www.cms.gov/cciio/programs-and-initiatives/other-insuranceprotections/gag-clause-prohibition-compliance
- Third party can submit on behalf of group health plan
  - » **Fully Insured** – Submission by carrier constitutes compliance by plan
  - » **Self-Insured** – Written agreement; plan retains ultimate responsibility to ensure compliance

Surprise Billing

Ongoing Developments For IDR Process

Background

- Payment from plan to provide for claims coverage by surprise billing rules determined by negotiation or IDR process
- Prior regulations had addressed how IDR determines payment amount (e.g., what factors are considered, what presumptions are made, etc.)
- IDR process has been subject to much litigation
- Federal court had vacated final IDR regulations, causing a pause to IDR determinations

New Regulatory Guidance

- Generally, applies to determinations made on or after February 6, 2023, for items/services furnished on or after October 25, 2022
- Adjusts process to reflect the court's determination that the final regulations favored the qualifying payment amount (QPA) determined by the plan by requiring the IDR entity to consider the QPA before considering other factors and by limiting the situations in which non-QPA factors could be considered
- IDR entities must now consider both the QPA and other information submitted by a party (unless it is a prohibited factor)

COVID Related Rules

Generally: FFCRA and CARES Act

BENEFIT PLAN MANDATES FOR COVID-RELATED CARE AND POST-PHE

Current Rules until the end of the Public Health Emergency (PHE) (different than NE/OP):

- No cost-sharing for diagnostic/testing items and services (including OTC tests)
- No cost-sharing for preventive services including COVID immunizations (both in-network (IN) and out-of-network (OON))

End of Public Health Emergency: 5/11/23

- Cost-sharing for diagnostic/testing items and services (including OTC tests)
- No in-network cost-sharing for preventive services including COVID immunizations (only applies to IN services)

Notice 2020-15 and HDHPs

HDHP COVERAGE AND COVID CARE

Current Rules until the end of the Public Health Emergency (different than NE/OP):

- HDHPs may provide first dollar coverage for COVID testing without jeopardizing HDHP status and without affecting HSA eligibility
- COVID immunizations are considered a preventive care service, so it must be provided without any cost-sharing and does not impact HSA eligibility pursuant to IRS rules

End of Public Health Emergency: 5/11/23

- HDHPs may provide first dollar coverage for COVID testing without jeopardizing HDHP status and without affecting HSA eligibility for a limited time
  - » FFCRA FAQs 58 - An individual covered by an HDHP that provides medical care services and items purchased related to testing for and treatment of COVID-19 prior to the satisfaction of the applicable minimum deductible may continue to contribute to an HSA until further guidance is issued. Any future modifications to the guidance previously provided in Notice 2020-15 will not generally require HDHPs to make changes in the middle of a plan year in order for covered individuals to remain eligible to contribute to an HSA. (March 30, 2023)
- COVID immunizations: Continue to be a PCS, so it must be provided without any cost-sharing and does not impact HSA eligibility pursuant to IRS rules

FFCRA and CARES Act

BENEFIT PLAN MANDATES FOR COVID-RELATED CARE

Carriers/TPAs and Plan Amendments

Carriers and TPAs

- Some carriers and TPAs will provide options for employers to either continue with PHE level coverage despite end of the PHE, or require that cost-sharing apply to COVID diagnostic/testing services and OON immunizations
  - » **Caution**: Retaining PHE level coverage could impact the following items:
    - – Mental Health Parity and Addiction Equity Act (MHPAEA) and other laws
    - – HDHPs cannot provide coverage until the IRS minimum deductible is met

Plan Amendments

- Employers/Plan sponsors should review plan documents/SPDs to make sure those documents accurately reflect the post-PHE benefits/plan features the employer chooses to adopt
  - » Material Reduction – If there is an associated cost when there previously was not, this could be a material reduction in benefits – 60 days notice after amendment is made
  - » Material Modification in SBC – If there is an aspect of the SBC that needs to be modified due to a change in COVID policy under the plan, it would require 60-day advanced notice of effective date, if not made coincident with renewal

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