Consolidated Appropriations Act Prescription Drug Reporting

Warner Pacific – November 30, 2022

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Your Host

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Today's Speaker

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Agenda

- Prescription Drug Data Collection (RxDC) Reporting
  - Background and Overview
  - Deadlines
  - Applicability
  - Content and Process

- Highlights: Important Updates & Answers to Your Questions
  - Federal
  - California

Prescription Drug Data Collection (RxDC) Reporting

December 27 Deadline!

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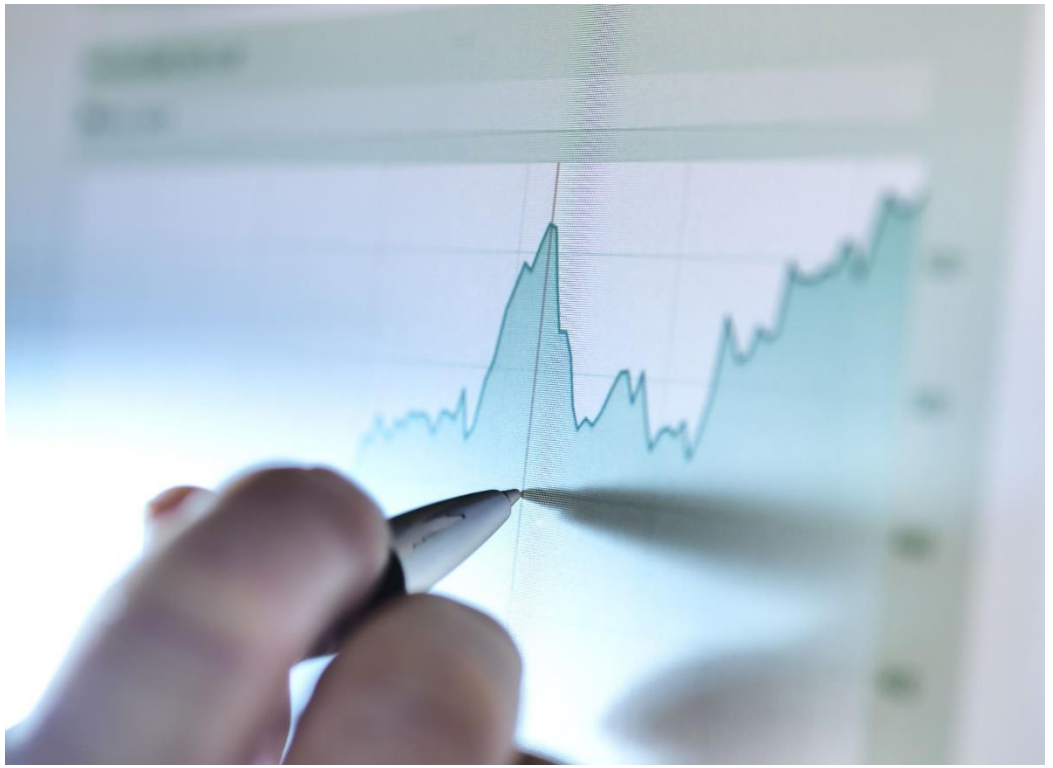
Background

- **The Law:** On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was enacted. Section 204 of Title II of Division BB of the CAA added parallel provisions to the Internal Revenue Code (the Code), the Employee Retirement Income Security Act (ERISA), and the Public Health Service Act (PHS Act)
  - The law requires group health plans and health insurance issuers offering group or individual health insurance coverage to annually submit to the Departments certain information about prescription drug and health care spending
- **The Regulations:** Prescription Drug and Health Care Spending Interim Final Rules with Request for Comment (Nov. 23, 2021) (IFR); additional resources have been issued (more later)
  - **Enforcement**: Depts. of Labor (EBSA), Treasury (IRS), and Health & Human Services (CMS)
- **The Results:** Reports are submitted to CMS, and CMS will then publish findings about prescription drug pricing trends and the impact of prescription drug rebates on patient out-of-pocket costs

Goal

The data collection required by the IFR will provide valuable information about competition and market concentration in the pharmaceutical and health care industries. Policymakers can use the prescription drug and health care spending data to make informed decisions, including identifying any excessive pricing of prescription drugs driven by industry concentration and monopolistic behaviors, promoting the use of lower-cost generic drugs, and addressing the impact of pharmaceutical manufacturer rebates, fees, and other remuneration on prescription drug prices and on plan, issuer, and consumer costs.



Deadlines

- **Original deadline:** "Not later than 1 year after the date of enactment of the Consolidated Appropriations Act, 2021, and not later than June 1 of each year thereafter . . . ." Through ACA FAQs, Part 49, additional time was granted

- **New Deadlines:**
  - Must report for 2020 and 2021 calendar years ("reference years") by **December 27, 2022**
  - Must report for 2022 calendar year by **June 1, 2023**
  - Must report for each calendar year ("reference year") thereafter by following **June 1**

- **Producer:** What is the role of the producer?

Applicability

Required to Submit

- **Health insurance issuers** (insurers/HMOs) offering **group** coverage
- **Fully-insured and self-funded employer-based group health plans**, including:
  - Non-federal governmental plans, such as plans sponsored by state and local government
  - Church plans that are subject to the Internal Revenue Code
  - Federal Employees Health Benefits (FEHB) plans
- Health insurance issuers offering individual market coverage, including:
  - Student health plans
  - Plans sold through the Exchanges
  - Plans sold outside of the Exchanges
  - Individual coverage issued through an association

Not Required to Submit

- Account-based plans, such as health reimbursement arrangements
- Excepted benefits including but not limited to:
  - Limited-scope dental and vision
  - Short-term limited-duration insurance
  - Hospital or other fixed indemnity insurance
  - Disease-specific insurance
- Medicare Advantage and Part D plans
- Medicaid plans
- State children's health insurance program plans
- Basic Health Program plans

What Do Group Health Plans and Issuers Have to File?

1 P2 Group Health Plan List

- ❑ Group health plan name
- ❑ Group health plan number
- ❑ Market segment
- ❑ Plan year beginning date
- ❑ Plan year end date
- ❑ Members as of 12/31 of the reference year
- ❑ Issuer name and EIN
- ❑ TPA name and EIN
- ❑ PBM name and EIN
- ❑ Included in D1 – D8

2 D1-D8 Data Files

- ❑ D1 - Premium and Life-Years
- ❑ D2 - Spending by Category
- ❑ 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

3 Narrative Response

- ❑ Employer size for self-funded plans
- ❑ 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
- ❑ Other relevant information

What Data Is Reported?

- For **fully insured employers**, group health plan data will typically be reported by the issuer (as the "**reporting entity**")—but the issuer may need "**plan-level**" and other data to complete report (more later)—issuer will file:
  - P2 - Plan List: Issuer lists all group policyholders, broken down by market segment and state
  - D1 – D8 Data Files: Issuer aggregates Rx drug, health, and premium costs for all of its policyholders, but broken down by market segment and state
  - Narrative Response
- For **self-funded employers**, group health plan data will typically be reported by one or more third party vendors (such as TPA, PBM, ASO)—but these "**reporting entities**" will typically need certain "**plan-level**" data from the employer—employer must coordinate and may also have to submit some of the files—TPA/PBM will typically file:
  - P2 - Plan List: TPA/PBM lists all group clients, broken down by market segment and state
  - D1 – D8 Data Files: TPA/PBM aggregates Rx drug, health, and premium costs for all of its policyholders, but broken down by market segment and state
  - Narrative Response

What Data Is Reported? Examples

- **Fully Insured Example**: Alpha Corp., located in CA, offers employees a fully insured small group health plan
  - Typically, Alpha's group health plan issuer will file a P2 file listing all its policyholders, D1 – D8 files with aggregated data for all its policyholders, and a Narrative Response

- **Self-Funded Example**: Beta Corp., located in TX, has a self-funded large group health plan (Form 5500: "Beta Corp. Employee Welfare Benefit Plan," Plan 501); administered by a TPA and PBM
  - Beta must coordinate with PBM and TPA to specify who will file which files; both will file a P2 file listing all their clients; PBM will typically file certain D files (such as D3-D8) and TPA will file other D files (such as D1 and D2) with aggregated data for all their clients (but broken down by market segment and state); both may file Narrative Response; Beta files any data not provided by vendors

What Data May Employers Have to Furnish to the Reporting Entities?

- **Plan-Level Data—To Complete the P2 Data File, Employers May Be Asked to Provide:**
  - Identifying information such as plan name; plan number(s); plan sponsor; plan sponsor EIN; and issuer, TPA, and PBM names and EINs;
  - Beginning and end dates of the plan year that ended on/before the last day of the reference year;
  - Number of participants and beneficiaries ("**members**") covered on the **last day of reference year**; and
  - Each state in which the plan or coverage is offered
- **To Complete the D1 Data File, Employers May Also Be Asked to Provide:**
  - **Premium amounts, including—**
    - Average monthly premium amount paid by employers and other plan sponsors on behalf of participants and beneficiaries;
    - Average monthly premium amount paid by participants and beneficiaries; and
    - Total annual premium amount and the total number of **life-years**. (See over.)
  - **Life-Years:** The total number of members covered on a given day of each month of the reference year, divided by 12
  - **Note:** For premium data, enforcement relief offered for 2020 and 2021 reference years

What Aggregated Data Is Reported? Information for Each State and Market Segment

The 50 brand prescription drugs most frequently dispensed by pharmacies. (D3) (The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.)	**Total annual spending on health care services** by the plan or coverage and by participants and beneficiaries, broken down by the type of costs **(D2),** including— i. Hospital costs; ii. Health care provider and clinical service costs, for primary care and specialty care separately; iii. Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and iv. Other medical costs, including wellness services.
The 50 most costly prescription drugs. **(D4)** (The most costly drugs must be determined according to total annual spending on each drug.)	**Prescription drug spending and utilization (D6), including—** i. Total annual spending by the plan or coverage; ii. Total annual spending by the participants and beneficiaries enrolled in the plan or coverage; iii. The number of participants and beneficiaries, as applicable, with a paid prescription drug claim; iv. Total dosage units dispensed; and v. The number of paid claims.
The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year. **(D5)**	**Premium amounts (D1), including—** i. Average monthly premium amount paid by employers and other plan sponsors on behalf of participants and beneficiaries; ii. Average monthly premium amount paid by participants and beneficiaries; and iii. Total annual premium amount and the total number of **life-years**.

What Data Is Reported?
Information for Each State and Market Segment

Prescription drug rebates, fees, and other remuneration, including–

i. Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

ii. Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants and beneficiaries, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer—

   A. For each therapeutic class **(D7)**; and

   B. For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year **(D8).**

The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts. (Narrative)

The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable. (Narrative)

Aggregation Process

- **Aggregation:** Entities reporting on behalf of multiple plans—issuers or TPAs or PBMs—will aggregate data and report by market segment and state (D1-D8)
  - State for a fully insured plan is the place where the policy was issued
  - State for a self-funded plan is the employer's principal place of business
- **Seven Market Segments**:

Individual Market	Student Market
Fully-insured small group market (50 and under)	Fully-insured large group market (over 50)
Self-funded plans offered by small employers (50 and under)	Self-funded plans offered by large employers (over 50)
Federal Employees Health Benefits (FEHB) line of business	

Register with HIOS Now!

Filing Process

- **Filing:** Data is submitted to **CMS** through its Health Insurance and Oversight System (**HIOS**)
  - If all the data is filed by third parties, employer does not have to register; if employer has to file some of the data, employer must register; registration takes time—up to 2 weeks!
- **Resources:**
  - CMS has issued, "Prescription Drug Data Collection (RxDC) Reporting Instructions," templates for each data file, "RxDC Data Dictionary for the 2020 and 2021 Reference Years," "Health Insurance Oversight System (HIOS) Prescription Drug Data Collection (RxDC) User Manual," and FAQs
  - CMS provides resources, FAQs, and other educational tools through the Registration and Technical Assistance Portal (REGTAP—registration required)—will training be offered for Rx reporting?
  - There is also a phone number and email address to submit questions
  - Website: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/Prescription-Drug-Data-Collection

Plan Lists and Data Files

Subject	Plan Lists	Data Files
File Names	**P stands for Plan**: • P1 Individual and student market plan list • **P2 Group health plan list** • P3 FEHB plan list	**D stands for Data**: • D1 Premium and Life-Years • D2 Spending by Category • 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
Purpose	**The plan lists identify the plans in a submission**. The plan lists also collect **plan-level information** required by statute, such as the beginning and end dates of the plan year, the number of members, and the states in which the plan or coverage is offered.	The data files collect premium and spending information at an **aggregate level**.
Requirement	• P1 is required for plans in the individual or student market • **P2** is required for **employer-based** health plans (not FEHB plans) • P3 is required for FEHB plans	**All 8 data files are required**
File Format	Comma Separated Values (CSV)	Comma Separated Values (CSV)

What Else Do We Have to Submit? Narrative Response

- **Narrative Response:** In addition to the plan and data files (P and D), a narrative response is required. In it, describe the impact of prescription drug rebates on premium and cost sharing, and address other topics that may be described in places throughout the Instructions
  - The narrative response file format must be Portable Document Format (.pdf) or Microsoft Word (.doc or .docx)
  - You can—but do not have to—submit additional information about your submission using PDF or Word documents
  - "It's not a problem if multiple reporting entities upload different narrative responses on behalf of the same plan, issuer, or carrier."
- **Include, at a minimum, the following**: Employer size for self-funded plans, 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**, and **impact of prescription drug rebates**. The narrative response is also used to describe certain methodologies chosen (for examples, see Instructions)

Action Item: Written Agreement Requirement

- **Fully Insured Plan:** If your plan is fully insured, the plan may satisfy the reporting mandate if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement
  - Then, if the issuer fails to provide the information, the issuer, but not the employer's plan, violates the reporting requirement
- **Self-Funded Plan:** If your plan is self-funded, the plan may satisfy the reporting requirement if the plan enters into a written agreement under which another party (such as a TPA, ASO, or PBM) will report the information
  - But, if the third party fails to provide the information, the employer's plan violates the reporting requirement
- **Form of Written Agreement:** Not defined
- **Liability Protection:** Particularly for self-funded plans, review the full agreement to ensure it provides the protections the plan and employer need

Action Items

- **Action Items for Employers:**
  - **All Plans:** Calendar compliance dates—initial (**December 27, 2022**) and annual (**June 1**)
  - **Fully Insured**: Enter into a written agreement with issuer; timely provide any plan-level or other data required by issuer
  - **Self-Funded**: Self-funded plans must either comply or outsource to a TPA, ASO, or PBM; if outsource, enter into a written agreement and specify who will submit each required file; timely provide any plan-level or other data required by third party; employer-sponsored plan may have to register with HIOS and file some data on your own
    - Even with a written agreement, the "plan" remains responsible, so ensure that the written agreement provides appropriate protections for plan and employer

- **Note:** Written agreement requirement also applies to TiC Final Rule (both MRF and on-line self-service tool mandates) and the CAA air ambulance reporting requirement (awaiting final rule)

Highlights: Important Updates & Answers to Your Questions

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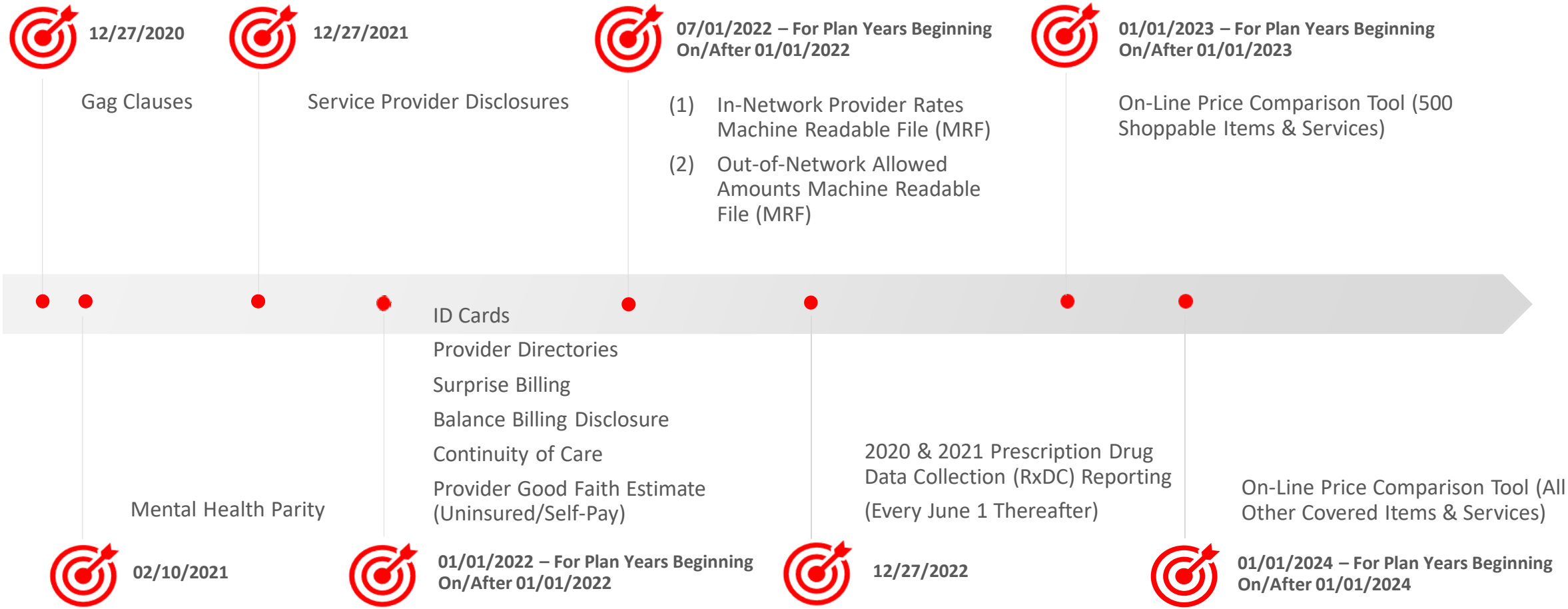
TiC Final Rule/CAA Deadlines

Delayed:
- Gag Clause Attestation
- Prescription Drug MRF
- Provider Good Faith Estimate (Insured)
- Advanced Explanation of Benefits
- Air Ambulance Reporting



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TiC Final Rule: Status

MRFs

- **Machine Readable File (MRF) of In-Network Provider Rates**
- **Machine Readable File (MRF) of Out-of-Network Allowed Amounts**
- July 1, 2022—For Plan Years Beginning On/After January 1, 2022
- Action Items: Written agreement; posting?

Price Comparison Tool

- **On-Line Price Comparison Tool – 500 Shoppable Items & Services**
- January 1, 2023—For Plan Years Beginning On/After January 1, 2023
- Action Items: Written agreement

Price Comparison Tool

- **On-Line Price Comparison Tool – For All Other Covered Items & Services**
- January 1, 2024—For Plan Years Beginning On/After January 1, 2024
- Action Items: Written agreement

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TiC Final Rule & CAA Updates: Written Agreement Requirement

- Machine-Readable Files (MRFs) (TiC)
- On-Line Price Comparison Tool (TiC)
- Prescription Drug Data Collection (RxDC) Reporting (CAA)
- Air Ambulance Reporting (CAA)

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TiC Final Rule & CAA: Updates & Reminders

- **Service Provider Disclosures**: This is an on-going requirement
- **Balance Billing Disclosure**: There is an updated form to be used going forward
- **Mental Health Parity**: Mental health is a priority of the DOL—both in the workplace and in connection with group health plans
  - The Mental Health Parity and Addiction Equity Act (MHPAEA) requires parity between mental health/substance use disorder benefits and medical/surgical benefits—including "non-quantitative treatment limitations" (NQTLs). The CAA requires plans and issuers to prepare comparative analyses of the NQTLs in their plans; these will be asked for as part of a DOL audit
  - U.S. Department of Labor, *2022 MHPAEA Report to Congress*
  - U.S. Surgeon General, *Workplace Mental Health & Well-Being*
  - What can employers do now?

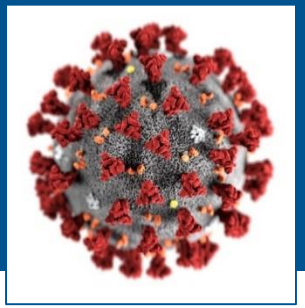
The Family Glitch

- **Affordability of Employer Coverage for Family Members of Employees Final Rule:** The final rule adopts an affordability test for employer-sponsored minimum essential coverage for purposes of the premium tax credit that takes into consideration the cost of covering an employee's family members in addition to that of the employee—does not change affordability calculations for 4980H purposes
  - **Effective:** December 12, 2022. **Application:** Tax years beginning **January 1, 2023**
- **IRS Notice 2022-41: Additional Permitted Election Changes for Health Coverage under Section 125 Cafeteria Plans:** This notice expands the application of the permitted change-in-status rules for health coverage (not health FSAs) under a cafeteria plan. The notice addresses the situation in which, during a plan year, a cafeteria plan participant may wish to revoke the employee's election for other-than-self-only (family) coverage under a group health plan in order to allow one or more family members to enroll in a Qualified Health Plan (QHP) through a Health Insurance Exchange (Exchange) in the individual market.
  - **Effective:** For plan amendments allowing elections on/after **January 1, 2023**

OTC Hearing Aids

- Due to a new rule issued by the federal Food and Drug Administration (FDA), as of **October 17**, hearing aids are now available over-the-counter—without a prescription, medical exam, or a fitting by an audiologist. A new category of hearing aids was created: **OTC hearing aids**
  - The FDA advises those under 18 and with severe hearing loss obtain a prescription hearing aid
  - "People with normal hearing can identify sounds less than 25 decibels (dB). Mild to moderate hearing loss is in the 26 dB to 55 dB range. A person with mild hearing loss may hear certain speech sounds, but find softer sounds hard to hear. Someone with moderate hearing loss may have difficulty hearing speech when another person talks at a normal level." (*Should you get an over-the-counter hearing aid?*, Harvard Health Publishing)
  - FDA: https://www.fda.gov/medical-devices/consumer-products/hearing-aids
  - National Institute on Deafness & Other Communication Disorders: https://www.nidcd.nih.gov/health/over-counter-hearing-aids
  - Harvard Health Publishing: https://www.health.harvard.edu/blog/should-you-get-an-over-the-counter-hearing-aid-202211162852
  - Johns Hopkins: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/hearing-aids/over-the-counter-hearing-aids-faq

COVID-19 Emergency Declarations: Still in Effect



- **Department of Health and Human Services (HHS) Public Health Emergency (PHE)**: The Secretary of HHS originally declared a Public Health Emergency (PHE) due to COVID-19. The PHE was most recently extended on October 13, 2022, for another 90 days, and therefore will run until **January 11, 2023** (at which time it may be extended again—we will be given 60 days notice if HHS does not intend to renew)
  - The PHE applies to the obligation of plans to cover testing for COVID-19 without cost-sharing, including over-the-counter tests
- **The President's National Emergency (National Emergency)**: President Trump declared a National Emergency concerning the Novel Coronavirus Disease (COVID-19) Outbreak (National Emergency), effective March 1, 2020. National Emergency has been extended twice—for one-year increments—it will now expire on **February 28, 2023**, unless ended earlier or extended
  - The timeframe extensions are tied to this National Emergency declaration
- **California:** State of Emergency will end **February 28, 2023**

More Developments:

- **Telehealth**: Telehealth Beyond COVID-19 Act of 2021 (H.R. 4040): Would extend through December 31, 2024, critical telehealth policies implemented during the pandemic to make it easier for seniors on Medicare to access remote care and other emerging health care technologies; passed the House
  - **Note**: The relief (CARES Act/CAA) which allowed plans to reimburse telehealth benefits below the HDHP deductible—without risking HSA eligibility—expires December 31, 2022
- **Contraceptive Coverage**: New guidance has been issued on contraceptives; FDA-approved contraceptives are covered as preventive care services if the plan is non-grandfathered; OTC contraceptives may be reimbursed by a health FSA or HRA.
  - New preventive care guidelines—for plan years beginning in 2023—on care for women and colorectal cancer screening

California

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Agent Licensing: S.B. 1242

- **Producer Emails**: Effective **January 1, 2023**, S.B. 1242 adds emails to the list of documents that must include the producer's license number. The bill also specifies that the font size of the license number shall be no smaller than the largest of any street address, email address, or telephone number of the licensee, and the license number must be adjacent to or on the line below the individual's name or title. If the producer is working for a licensed agency, both the individual's and the agency's license numbers must be included. CDI issued a bulletin explaining the new mandate.
- **Producer Education**: On/after **March 1, 2023**, the three-hour CE ethics course requirement shall include one hour of study on insurance fraud.
- **Mandatory Fraud Reporting**: A producer who, before submitting an application to an insurer, "reasonably suspects or knows that a fraudulent application is being made," shall, within 60 days, submit to the CDI's Fraud Division an electronic form reporting the potential fraud. The form cannot be submitted anonymously. If fraud is reasonably suspected or is known after the application has been submitted to the insurer, the agent or broker shall report the matter to the insurer's special investigative unit. The agent or broker must also cooperate with the CDI or the insurer and produce requested records and other information.

Individual Plans & Parents: A.B. 570

- **Dependent Coverage:** **Individual** health policies and HMO contracts issued, amended, or renewed on/after **January 1, 2023**, that provide dependent coverage must make that coverage available to a qualified dependent parent or stepparent
  - Parent/stepparent must meet the definition of a "qualifying relative" under section 152(d) of the Internal Revenue Code and live or reside within the HMO/insurer's service area
- **Notices:** If an applicant is seeking to add a dependent parent/stepparent who is eligible for or enrolled in Medicare, at the time of solicitation and on the application:
  - The insurer/HMO (or Covered CA) must provide an applicant seeking to add a dependent parent/stepparent with written notice about the Health Insurance Counseling and Advocacy Program (HICAP), which provides health insurance counseling to senior California residents free of charge
  - The **solicitor/agent** shall provide the name, address, and telephone number of the local HICAP program and the statewide HICAP telephone number (1-800-434-0222)
  - HICAP offices listed by county: https://cahealthadvocates.org/hicap/

CalSavers

California Secure Choice Retirement Savings Trust Act: CalSavers

S.B. 1126 (Ch. 192): Expands CalSavers

- Employers with 5 or more employees (not govt.) will be required to *either* provide a qualified retirement plan for their workers *or* register for CalSavers
- Employers register with CalSavers, pay no fees, and submit employee data and contributions; a CalSavers account is currently a Roth IRA; 5% of gross pay
- Qualified retirement plans include qualified pension or profit-sharing plans under 401(a), 401(k) plans, 403(a) plans, 403(b) plans, SEP plans, SIMPLE plans, and payroll deduction IRAs with automatic enrollment

Size of Business	Deadline
Over 100 employees	Sept. 30, 2020
Over 50 employees	June 30, 2021
5 or more employees	June 30, 2022
1 or more employees	**December 31, 2025**

Questions?

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The information provided during this program does not constitute legal advice. In addition, this program only provides a summary of certain complex and always evolving laws and regulations. Attendees should consult their legal counsel for guidance on the application and implementation of the many federal and state laws that impact employee benefit plans and the workplace, including the topics discussed during this program.

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