ALSTON & BIRD

HEALTH & WELFARE PLAN LUNCH GROUP

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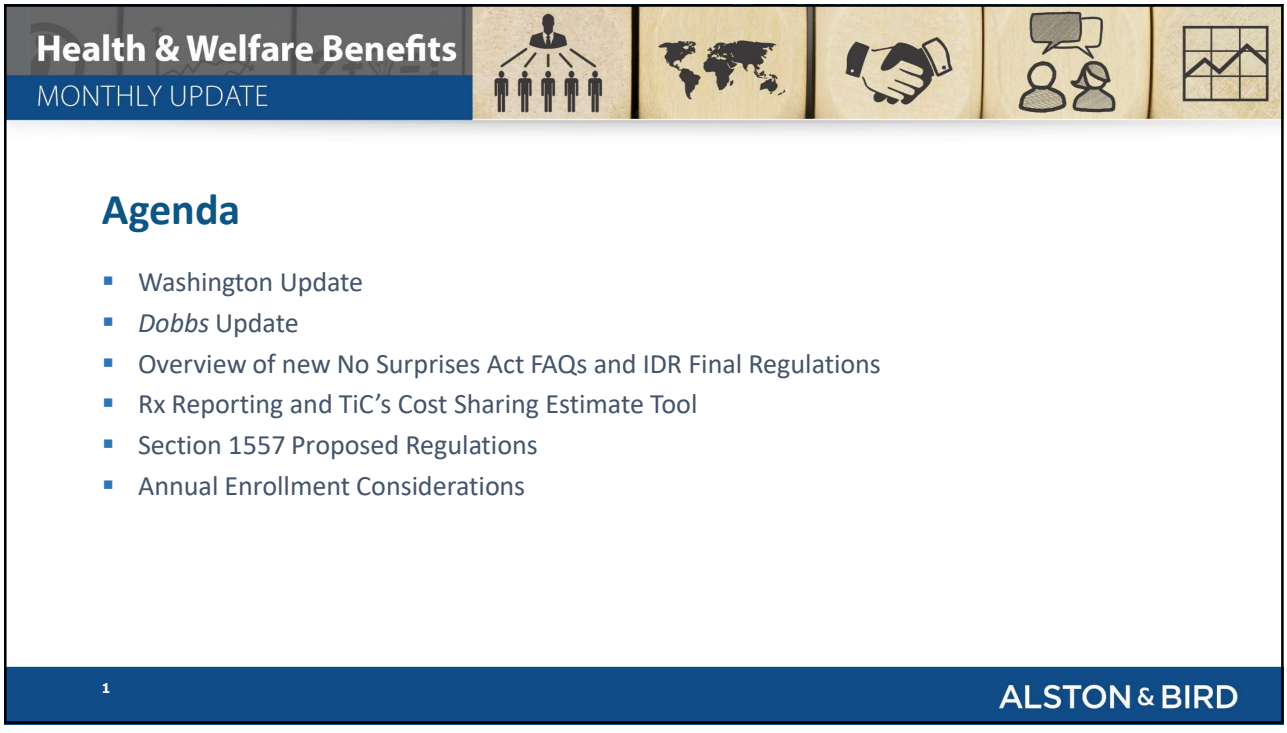

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Washington UPDATE:

- Inflation Reduction Act
- Regulatory Guidance

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Inflation Reduction Act (HR 5376, DOE Aug. 16, 2022)

- What's NOT included
- What IS included -- Statutory "safe harbor" permits HDHPs to cover insulin before the deductible is met
  - Applies to "any dosage form" (e.g., vial, pump or inhaler) of "any different type" (e.g., rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed)
  - Effective for plan years beginning after Dec. 31, 2022
  - Compare to IRS Notice 2019-45

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Regulatory Update – No Surprises Act

- Final Rule on the IDR process, 87 FR 52618 (Aug. 26, 2022)
  - Very limited. Addresses payment determination under the IDR process (eliminating the presumption that the QPA is the correct OON amount), disclosure of information regarding the QPA (including downcoding).
  - Other NSA issues to be addressed in subsequent rules
- Status update on the federal IDR process
  - https://www.cms.gov/files/document/federal-idr-process-status-update-august-2022.pdf
- CMS updated notice on the IDR process
  - https://www.cms.gov/nosurprises/help-resolve-payment-disputes/payment-disputes-between-providers-and-health-plans
  - This includes technical guidance for IDR entities https://www.cms.gov/files/document/TA-certified-independent-dispute-resolution-entities-August-2022.pdf
  - Also, common mistakes and helpful tips https://www.cms.gov/nosurprises/help-resolve-payment-disputes/Tips-for-Disputing-Parties
- FAQS on No Surprises Act and TiC Rules (Part 55, Aug. 19, 2022)
  - https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-55.pdf

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Regulatory Update -- Other New Guidance

- ACA Section 1557 proposed rule (87 FR 47824, Aug. 4, 2022)
  - In general, reverses Trump Administration rules. Addresses scope of section 1557, notices and tag lines, among other issues.
- FAQs on Preventive Care Services (Part 54, July 28, 2022)
  - https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf
- IRS 2023 Adjustment to Employer Responsibility Affordability Percentage
  - Rev. Proc. 2022-34
  - For plan years beginning in 2023 the affordability percentage is lowered to 9.12% (down from 9.5%) https://www.irs.gov/pub/irs-drop/rp-22-34.pdf

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What's coming….

- Expected any day now --
  - Advanced EOB requirements – proposed rule cleared OMB on Aug. 15, 2022
- Under review at OMB:
  - ACA preventive services requirements
    - Described as a proposed amendment to the rules regarding religious and moral exemptions and accommodations
    - Has been under review since July 8, 2022
- EBSA proposed amendment and restatement of voluntary fiduciary correction program under review at OMB (since Aug. 23, 2022)
- Still anxiously awaiting – MHPAEA and comparative analysis proposed rules
- Other…

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Dobbs Update

- State court activity regarding trigger laws and other state-based litigation
- Title VII claim against Dick's Sporting Goods and its travel/lodging reimbursement program
- Recap of Texas' efforts to impede travel and lodging programs
- Practical considerations for travel and lodging programs

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FAQs on the No Surprises Act and Consolidated Appropriations Act, 2021

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FAQs Part 55 on NSA and CAA

- Issued on August 19, 2022
- 23 FAQs over 28 pages on No Surprises Act (NSA) and Consolidated Appropriations Act of 2021 and Transparency in Coverage rule (TiC).
- Main subjects
  - Applicability of NSA to No-Network Plans (e.g., reference-based price plans) and Closed Network Plans
  - Applicability of NSA to Air Ambulance
  - Applicability of NSA to Behavioral Health Crisis Centers
  - Disclosure of Protections Against Balance Billing
  - Calculating the Qualifying Payment Amount (QPA)
  - Independent Dispute Resolution Process
  - TiC Machine Readable Files

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FAQs Part 55 on NSA and CAA

- No-Network Plans-- NSA ***is applicable*** to no-network plans for emergency services and air ambulance.
  - No network plans are sometimes referred to as reference-based price plans (RBP plans). For example, where there are no networks and pricing for all services is based on a percentage of Medicare.
  - Balance billing prohibitions are applicable to RBP plans for emergency and air ambulance services.
  - QPA for determining cost-sharing (e.g., deductible and co-insurance) is applicable to RBP plans for emergency and air ambulance. Since there are no networks to determine median network contracted rate, QPA is ***determined using a database*** unless there is an All- Payer Model Agreement or a specified state law.
  - Amount payable to the provider for emergency services governed by the independent dispute resolution (IDR) process if there is no All-Payer Model Agreement or specified state law.
  - Cost sharing must count toward maximum out of pocket (MOOP) for ACA purposes including post-stabilization services that are part of the NSA definition of emergency services.
- For No-Network Plans, NSA and QPA ***are not applicable*** to non-participating provider in a participating facility since there are no participating facilities in a RBP plan.

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FAQs Part 55 on NSA and CAA

- No Out of Network Coverage-- Plan has a network but does not provide ***any*** out-of-network coverage.
  - NSA generally fully applicable.
  - Must provide coverage for non-participating provider in a participating facility even if the plan would not otherwise provide any coverage for that out-of-network provider.
- Air Ambulance
  - Can limit coverage to emergency only.
  - NSA applies even if point of pick up is outside the US if air ambulance is properly licensed by a state.
    - Complexity over "geographic region" for QPA purposes.
- Behavioral Health Crisis Centers
  - Generally covered to the extent the service meets the definition of emergency services and the center is licensed under state law to provide emergency services and geographically separate from the hospital (classifies as an Independent Freestanding Emergency Department).

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FAQs Part 55 on NSA and CAA

- Disclosures on Protections against Balance Billing.
  - Group health plan may contract with insurers or TPA/ASO to post disclosures on the insurer's/TPA's/ASO's website on behalf of a plan.
    - Can also apply in instances where the employer maintains a website but the group health plan does not.
  - Disclosure of all state laws is not required-- only state balance billing laws applicable to participants/beneficiaries/enrollees in the coverage.
  - Multiple versions of the model disclosure forms have been developed by the agencies and use of earlier versions will be compliant for plan years beginning after January 1, 2022 and before January 1, 2023. Only the newest version can be used for plan years beginning on or after January 1, 2023.
- Calculation of QPA.
  - Specific guidance on whether separate QPA is required for specialists where contracted rates vary by service code due to market conditions and as part of the contracting process as opposed to the specialty itself.
    - Need only establish separate QPA if contracted rates for a service code are "materially different between providers of different specialties." Materiality depends on "all the relevant facts and circumstances."
  - If a plan uses different TPAs for different benefit options, then different QPAs can be calculated for each TPA.

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FAQs Part 55 on NSA and CAA

- IDR
  - Reiterates that plans must provide initial payment or denial to the provider within 30 calendar days of a "clean claim" and advises providers to contact the NSA help desk if they are having issues with a plan's timeliness.
  - Payment should be the amount the plan reasonably intends to pay in full.
  - Payment does not have to be QPA, but plan must disclose QPA with the payment along with a certification that QPA has been calculated in accordance with the Interim Final Rules as well as other required information.
  - If plan fails to meet the disclosure obligation but still issues a payment or denial, provider can initiate open negotiations within the 30 business days or request an extension from CMS.
  - Providers cannot initiate IDR before receiving an initial payment or denial. This is true even if the plan misses the 30 calendar day deadline.
  - Plans can develop a portal for providers to initiate the open negotiation period and encourage use of the portal but cannot limit providers to only using this portal.

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FAQs Part 55 on NSA and CAA

- TiC
  - Plans that do not have a website may satisfy the obligation to post machine readable files on a public website by using a service provider (e.g., a TPA) to post the files on behalf of the plan.
- Takeaways—
  - Insurers will have primary responsibility for fully insured plans.
  - Self-funded plans will need to rely on TPAs/ASOs but the plan remains responsible.
    - Need to review service provider agreements so that TPAs/ASOs are contractually responsible.
  - Need to review plan SPDs to make sure NSA protections against balance billing are properly disclosed.
  - RBP plans need to make sure they comply with the new FAQs with respect to emergency services and air ambulance.

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Rx Reporting and TiC's Cost Share Estimate Tool

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Rx Reporting

- CAA requires group health plans and health insurers to report to CMS certain information related to medical and Rx spending
- There is both an initial report and annual report
  - Initial report was originally due December 27, 2021 for 2020 calendar year data; however, it was extended by the agencies until December 27, 2022 (for 2020 and 2021 calendar year data).
  - The first annual report was due June 1, 2022 (for 2021 Calendar year data) but not it is June 1, 2023 (for 2022 calendar year data) and then every June 1 thereafter (for the prior calendar year).
- Plan sponsors of self-insured plans can rely on TPAs to report some or all of the information on their behalf but remain responsible for reporting failures
  - Should have written agreement between the parties regarding the filing responsibilities/obligations
  - Some coordination may be required between medical administrator and PBM

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Rx Reporting

- The reporting templates include eight data files for:
  - Premium and life years (D1)
  - Spending by category (D2)
  - Top 50 most frequently used brand drugs (D3)
  - 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
- Additional data file includes plan identifying information

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Rx Reporting

- Recent guidance to assist with reporting:
  - Interim Final Rule
    - https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending
  - CMS Reporting Instructions
    - https://regtap.cms.gov/uploads/library/RxDC-Section-204-Reporting-Instructions-06-30-2022.pdf
  - CMS Reporting Templates
    - https://regtap.cms.gov/reg_librarye.php?i=3863

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Cost Share Estimate Tool

- Part of final transparency regulations that included the public machine readable files
- Only applicable to non-grandfathered health plans
- Plan years beginning on or after January 1, 2023
  - Must make an internet-based tool available to *participants and beneficiaries* that provides a cost estimate of the 500 HHS-enumerated services covered by the plan
  - Unlike its predecessor, the tool is not publicly available
  - Real-time
- Plan years beginning on or after January 1, 2024
  - Includes ALL services covered by the plan
- Self insured plans may rely on TPA to provide
  - Is a link from plan's website to TPA's required?
  - Should have written agreement that outlines responsibilities but plan still liable for failures

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2022 Proposed Rule for Section 1557: Nondiscrimination in Health Programs and Activities

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2022 Proposed Rule for Section 1557: Nondiscrimination in Health Programs and Activities

On July 25, 2022 HHS issued the proposed rule *Nondiscrimination in Health Programs and Activities*. Section 1557 of the ACA incorporates protections from existing civil rights laws:

- Title VI of the Civil Rights Act of 1964 (race, color, and national origin)
- Title IX of the Education Amendments of 1972 (sex)
- Age Discrimination Act of 1975
- Section 504 of the Rehabilitation Act of 1973 (disability).

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Section 1557 Regulations—brief history

- 2016 Final Rule provided express protection against discrimination on the basis of gender identity, sex stereotyping, and termination of pregnancy (among other things) and faced several court challenges.
- 2020 Final Rule repealed and revised several parts of the 2016 Final Rule, including parts that protected gender identity and sex stereotyping, and removed notice and tagline requirements. This 2020 Final Rule also faced court challenges.
- The 2020 Bostock Supreme Court opinion, which held that discrimination based on sex for Title VII purposes encompasses discrimination based on sexual orientation and gender identity, was issued before the 2020 Final Rule took effect. Bostock complicated the effect of court challenges to both the 2016 and 2020 final rules.
- 2022 Proposed Rule proposes to reinstate/revise parts of the 2016 Final Rule and add several new provisions. Aligns regulatory requirements with Federal court opinions to prohibit discrimination on the basis of sex, including sexual orientation and gender identity, and adds discrimination on the basis of pregnancy or related conditions, including "pregnancy termination."

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Application of Section 1557: 2020 Final Rule

- Under the current 2020 Final Rule, Section 1557 generally applies to:
  - any "health program or activity," any part of which is receiving federal financial assistance (including credits, subsidies, or contracts of insurance) provided by HHS;
    - Note: "health program or activity" encompasses all of the operations of entities "principally engaged in the business of providing healthcare," but an entity principally engaged in the business of providing health insurance is not considered principally engaged in the business of providing health care.
  - any program or activity administered by HHS under Title I of the ACA; or
  - any program or activity administered by any entity established under Title I of the ACA

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Application of Section 1557: 2022 Proposed Rule

- ***Broadens Application Generally***--Under the 2022 Proposed Rule, applicability is restored of 1557 to Medicaid and Medicare, ACA's state and federal marketplaces and plans sold through them, and other commercial health plans if the insurer receives federal financial assistance, directly or indirectly, from HHS.
- ***Refines Application to GHPs.*** Under the 2016 Final Rule, GHPs were included as entities that were categorically covered. The 2022 Proposed Rule does not explicitly include GHPs as covered entities because many GHPs are not recipients of federal financial assistance, even if the employer, plan sponsor or TPA administering the GHP are recipients. Complaints against GHPs will be evaluated case-by-case to determine if the GHP is covered.
- ***Medicare Part B as federal financial assistance.*** HHS is proposing to reverse its position and treat Medicare Part B funds as "federal financial assistance to the providers and suppliers subsidized by those funds."

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2022 Proposed Rule: Notices

- New notice requirements, including Notice of Nondiscrimination and Notice of Availability
- Both must be provided to participants, beneficiaries, enrollees, applicants and members of the public
- Both must be provided annually; on request; placed at a conspicuous location on the covered entity's health program or activity website; and in "clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice."

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2022 Proposed Rule: Notice of Nondiscrimination

- Must state:
  - that the entity does not discriminate;
  - The entity provides reasonable modifications for disabilities and appropriate auxiliary aids and how to obtain these;
  - The entity provides language assistance services and how to obtain these;
  - Contact information for Section 1557 coordinator
  - The availability of grievance procedure
  - How to file a complaint
  - How to access entity's website

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2022 Proposed Rule: Notice of Availability/"Taglines"

- Notice must at a minimum state: covered entity, in its health programs or activities, provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with Section 1557, to participants, beneficiaries, enrollees, and applicants of its health program or activities, and members of the public.
- Must be provided in English and at least the 15 languages most commonly spoken by LEP individuals of the relevant state or states and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.
- Unlike prior 2016 Final Rule, the 2022 Proposed Rule offer the option for people to "opt out" of receiving the notice, or to provide communication to people in their primary language instead of the notice and provides a list of communications in which the notice must be included.

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2022 Proposed Rule: Notice of Availability/"Taglines"

Notice must be included on the following forms:

- Notice of nondiscrimination
- Notice of Privacy Practices
- Application and intake forms
- Notice of denial, EOBs, notice of appeal and grievance rights
- Communications related to the program/activity that require/request response from participant, beneficiary, enrollee or applicant
- Communications related to PHE
- Consent forms, instruction related to medical procedures, medical PoA, living will
- Discharge papers
- Complaint forms
- Patient and member handbooks

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2022 Proposed Rule: Other Changes

- Implements grievance procedure.
- Mandates staff training on the provision of language assistance services for people with limited English proficiency (LEP), and effective communication and reasonable modifications to policies and procedures for people with disabilities.
- Prohibits discrimination in the use of clinical algorithms to support decision-making in covered health programs and activities.
- Clarifies that nondiscrimination requirements applicable to health programs and activities include those services offered via telehealth, which must be accessible to LEP individuals and individuals with disabilities

2022 Proposed Rule: Enforcement and Religious Freedom

- The enforcement mechanisms available under the following apply to 1557:
  - Title VI of the Civil Rights Act of 1964,
  - Title IX of the Education Amendments of 1972
  - Section 504 of the Rehabilitation Act of 1973
  - Age Discrimination Act of 1975
- Federal Conscious and Religious Freedom laws:
  - Recipients can notify OCR of their view that it is exempt under federal conscious or religious freedom laws
  - OCR will consider, investigate, and make a determination
  - A determination in favor of exemption for one provision does not limit the application of other provisions of 1557

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Annual Enrollment Considerations

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Medicare Creditable Coverage

- Medicare Part D notices (either creditable or non-creditable coverage) are due prior to October 15 (October 14th).
- Online disclosure to CMS is due no later than 60 days after the beginning date of the plan year (contract year, renewal year, etc.) and upon change of the plan's creditable coverage status.
- NOTE: prescription drug cost reductions for Medicare enrollees in the Inflation Reduction Act may impact analysis of whether employer sponsored prescription drug coverage is creditable

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Things to Remember

- Annual Enrollment Notices
- Telehealth exception in Section 307 of CAA 2022 ends December 31, 2022
  - Issue for CY plans that included telehealth in January-March 31st
    - No issue for FY April 2021 (or later) plans, but issue for months after December 2022.
  - Individual Accountholder Risk varies based on whether full contribution made and/or eligible on December 1st
    - That quirky last month rule
    - Employer obligations if sponsor HDHP and allow pre-tax HSA contributions
      - Reasonable belief excludable at time contribution made?
  - Outbreak Period still in place for certain plan related time frames, COBRA notices, claims and appeal deadlines, etc.

Thanks!

- Questions?