ALSTON & BIRD

HEALTH & WELFARE PLAN LUNCH GROUP

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Washington Update

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Mental Health Matters Act, HR 7780, as passed by the House

- Passed the House on Sept. 29; vote 220-205
- Authorizes DOL to impose civil monetary penalties on plan sponsors, plan administrators, and health insurers for MHPAEA violations
- Plan participants, beneficiaries, fiduciaries and DOL can sue to require re-adjudication and payment of benefits to remedy violations of title I of ERISA, notwithstanding any other available relief
- Provides generally that arbitration clauses, class action waivers, and discretionary clauses regarding plan interpretation are unenforceable and impermissible
  - Limited exceptions for collectively bargained arrangements (arbitration clauses) and multiemployer plans (discretionary clauses)
- Authorizes $275 million (over 10 years) for DOL for parity enforcement
- Next steps?

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Ways and Means Committee Provisions

(collection of bills approved on a bi-partisan basis on Sept. 21, 0222)

- **Required coverage of forensic medical exams with no cost sharing**
- "Forensic medical exams" must be covered without cost-sharing and regardless of whether the provider is in-network.
- Applies surprise billing requirements to OON providers as if the services were emergency services.
- A "forensic medical exam" is: (1) an examination for physical trauma; (2) a determination of penetration or force; (3) an interview; and (4) the collection and evaluation of evidence.
- The coverage requirements do not apply if the State in which the exam was furnished is responsible for full out-of-pocket costs with respect to the exam. If a plan denies a claim on the ground that the State will pay for the exam, it must notify the individual that they may seek reimbursement from the State and, if authorized by the individual, notify the appropriate State agency of the claim.
- Effective for plan years beginning on or after Jan. 1, 2025.

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Ways and Means Committee

(provisions relating to provider directories)

- **Information on accepting new patients**
  - Amends the provider directory requirements added by the CAA to include information provided as to whether new patients are being accepted and, if so, whether in-person or telehealth (or both) are available for new patients. This information is to be updated at least annually.
  - Providers/facilities are required to provide such information to plans and to update this information at least annually.
  - Effective for plan years beginning on or after Jan. 1, 2025.
- **Machine readable files; providing information to the federal government; posting on a public governmental website**
  - Group health plans are required to provide provider directory information annually to the federal gov't (HHS/DOL/IRS) in a machine readable file. This information will be made available on a public federal website.
  - Effective for plan years beginning on or after Jan. 1, 2025. The federal government is to make the files publicly available starting no later than July 1, 2025.

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Ways and Means Committee Provisions (cont.)

- **Definition of mental health and substance use disorder (MH/SUD) benefits by reference to nationally recognized standard**
  - For purposes of the parity rules, "mental health conditions" and "substance use disorder" plans must include at least the conditions that fall into any of the diagnostic categories listed in the mental and behavioral disorders chapter of the most recent edition of the World Health Organization's International Statistical Classification of Diseases and Related Health Problems, or in the most recent version of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.
  - Effective for plan years beginning on or after the date that is 6 months after the date of enactment.
- **Agency report and outreach**
  - HHS, DOL, and Treasury are required to submit a report to Congress not later than Jan. 1, 2024 regarding coverage of MH/SUD crisis services under group health plans.
  - The tri-agencies are also directed to initiate a public outreach campaign to inform individuals with insurance coverage required the federal requirements for MH/SUD crisis services.

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Ways and Means – Disclosure

- **Disclosure of percentage of in-network providers of behavioral health and substance use disorder treatment**
  - Group health plans must disclosure along with the SBC and on a public website information regarding the number and percentage of in-network providers for MH/SUD benefits in the service area of the plan.
  - HHS/DOL/Treasury are to develop a system for qualitatively reflecting the breadth of such networks (e.g., high/medium/low or a star rating) that correspond to ranges of percentages.
  - Not later than June 30, 2025, HHS/DOL/Treasury are to post on a public website a list of all MH/SUD providers in the country, the location of such providers, and provider specialty (if any). Providers/facilities are to annually provide to HHS the information needed for the posting of provider information.
  - Not later than Dec. 31, 2026, the tri-agencies are to submit a report to Congress on MH/SUD provider networks.
- **Improved access to Summary of Benefits and Coverage (SBC)**
  - Beginning not later than Jan. 1, 2024, group health plans are required to provide SBCs in machine readable format to HHS/DOL/Treasury annually. The tri-agencies are to make the SBCs available on a public federal government website.
  - Not later than Jan 1, 2024, the tri-agencies are to submit a report to Congress regarding SBCs, including recommendations for improvement.

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Overall Legislative Outlook

- Bi-partisan, bi-cameral interest in mental health and substance abuse disorders continues
- "Must do" federal government funding bill may be a vehicle for a number of provisions
- Funding runs out on December 16

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Request for Information on Advanced EOBs

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Request for Information on Advanced EOBs

- On September 16th, the Departments of Labor, Treasury and Health and Human Services (Agencies) and the Office of Personnel and Management issued a request for information (RFI) regarding the Advanced Explanation of Benefits and Good Faith Estimate requirements of the No Surprises Act.
  - Very technical RFI primarily concerning data transfer.
- The No Surprises Act requires providers and facilities to transmit estimates of costs to patients in either of two ways:
  - Directly to the patient through a Good Faith Estimate (GFE) for the uninsured.
  - Or, by providing the GFE to a plan or insurer who then provides the patient/covered individual with an Advanced Explanation of Benefits (AEOB).
- Original effective date was January 1, 2022, but pursuant to FAQs issued by the Agencies in April 2021 enforcement was delayed until rulemaking was complete.

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Request for Information on Advanced EOBs

- AEOBs are especially complicated due to timing and coordination between the provider/facility and insurer/plan.
  - If the patient schedules the service three to nine business days before the intended service date, the plan/insurer must issue the AEOB within one business day after receiving the GFE from the provider or facility.
  - For scheduled appointments that are 10 days or more from the intended date of the service, the plan/insurer must issue the AEOB within three business days of receiving the GFE from the provider or facility.
  - AEOB must also be provided upon request from the covered individual

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Request for Information on Advanced EOBs

- There is currently no standard on how the data will be transmitted from the provider/facility to the plan/insurer.
- Agencies had suggested some possible standards in December 2021.
  - Information is outside what is required of the HIPAA transaction standards.
- The RFI requests comments on data transmission including:
  - What issues the Agencies should consider in the transmittal of data.
  - How HIPAA privacy concerns factor into that data transmission.
  - Effect on small and rural providers/facilities as well as plans/insurers.
  - Making sure that accurate information is transferred about No Surprises Act protections against balance billing including any permissible waiver of those protections.
  - Possible coordination with the Transparency in Coverage (TiC) self-service tool
- Comments are due by November 15th.
- Enforcement still delayed pending rulemaking.

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Braidwood Management v. Becerra

Preventive Services under the ACA

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Braidwood Management v. Becerra

- On September 7th a federal judge in the Northern District of Texas issued a decision in *Braidwood Management v. Becerra*.
- The decision calls into question the constitutionality of some aspects of the Affordable Care Act's (ACA's) preventive services mandate.
- The decision has received the most attention because the Court ruled that the requirement to offer certain HIV preventive drugs violates the Religious Freedom Restoration Act (RFRA) for a Christian, for-profit corporation whose owner said the coverage violated his religious beliefs.
- The decision, however, has broader implications with regard to ACA preventive services in general.
- The district court judge, Reed O'Connor has history of decisions with regard to the constitutionality of the ACA as well as enforcement of the ACAs provisions in Section 1557 regarding gender identity discrimination.

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Braidwood Management v. Becerra

- ACA (for non-grandfathered plans) requires coverage of a list of preventive vaccines, screenings , drugs and other services (preventive services) without any cost sharing.
  - Currently there are 22 categories of preventive for adults, an additional 27 for women, and 29 for children.
- Preventives services can get on the list in one of four ways:
  - First preventive services that get an "A" or "B" recommendation from the U.S. Preventive Services Task Force (USPSTF) must be covered. These include colonoscopies, mammograms, cancer screenings etc.
  - Second the Advisory Committee on Immunization Practices (ACIP) recommends certain immunizations.
  - Third, the Health Resources and Services Administration (HRSA) issues "comprehensive guidelines" with respect to infants, children, and adolescents for preventive care and screenings.
  - Fourth, HRSA issues guidelines with respect to women for "such additional preventive care and screenings" not covered above.

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Braidwood Management v. Becerra

- Judge O'Connor's ruling concerns those services designated by the USPSTF which is a non-governmental body of volunteers "with appropriate expertise" to make healthcare recommendations.
  - A sub-agency of the Department of Health and Human Services "convenes" the USPSTF.
  - By statute, USPSTF and its members "shall be independent and, to the extent practicable, not subject to political pressure."
- Judge O'Connor ruled that the members of the USPSTF are principal "Officers of the United States" and must be appointed pursuant to the Constitution's "Appointments' Clause" which requires appointment by the President and confirmation by the Senate. So, Judge O'Connor ruled that USPSTF members were not properly appointed.
- Unlike the USPSTF, the recommendations of ACIP and HRSA are subject to approval by the HHS secretary, who is properly appointed, So, Judge O'Connor held that preventive services designated by those organizations are valid.

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Braidwood Management v. Becerra

- Judge O'Connor did not immediately issue an order blocking enforcement of the USPSTF preventive coverage requirements.
  - He did not specify what will be the scope of any order– will it be nationwide, just the Northern District of Texas, just the parties to the case etc.
  - He requested further briefing on appropriate relief.
- Very likely that that any final order will be appealed to the Fifth Circuit. Also, once there is a final order it might be stayed pending appeal.
- Unlikely, at this time, that any insurer or group health plan will drop coverage without cost sharing for preventive services designated by the USPSTF. But certain changes, especially for expensive preventive drugs, might take place if the ruling stands.

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Data Marketing Partnership v. Department of Labor

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Data Marketing Partnership v. Department of Labor

- On August 17, 2022, Fifth Circuit Court of Appeals largely upheld another decision by District Court Judge Reed O'Connor out of the Northern District of Texas.
- The case has a long history including a Department of Labor advisory opinion.
- The case involves what constitutes a self-funded single employer plan under ERISA and therefore not subject to state law (because of ERISA preemption) or some of the ACA requirements for insured small or individual group market plans such as essential health benefits, guaranteed issue and community rating.
- Data Marketing Partnership (DMP) offered limited partnership interests to individuals who installed tracking software on their phones and computers (basically allowing their internet activity to be tracked) and DMP would then sell the data.

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Data Marketing Partnership v. Department of Labor

- The limited partners were then offered self-funded group health coverage through DMP where the limited partners paid 100% of the cost of the coverage.
- DMP claimed that these individuals were working owners and therefore could be participants in a single employer self-funded ERISA plan. DMP sought an advisory opinion from DOL. (The advisory opinion was actually sought by L.P. Management Services the general partner of DMP).
- After being sued by DMP, DOL then issued an opinion letter stating that the limited partners were not participants because they were not DMP's employees under ERISA.
- Judge O'Connor set aside DOL's opinion letter and enjoined DOL from refusing to acknowledge that the limited partners were plan participants.
- On appeal, the Fifth Circuit agreed that DOL's opinion letter was arbitrary because DOL did not consider or discuss past guidance on working owners. Finding some issues with the standards that Judge O'Connor employed, however, the case was remanded back to the district court.

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Data Marketing Partnership v. Department of Labor

- We are still awaiting a further decision for Judge O'Connor and then likely another appeal to the Fifth Circuit.
- Then National Association of Insurance Commissioners and others filed amicus briefs expressing concern that this would allow similar passive arrangements where such plans could target younger healthier workers with what they viewed as unregulated individual insurance. Neither ACA nor state law protections would be in place.
- Concerns were expressed that the decision could have a similar effect to what happened with insolvent self-funded multiple employer welfare associations (MEWAs) in the 1980s that caused Congress to amend ERISA to allow state regulation of MEWAs.
- We will continue to monitor this case and also see if "copycat" arrangements are marketed.

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RX Reporting

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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
  - Only applicable to group health plans that are subject to ACA's health insurance reforms (including grandfathered plans) other than HRAs
  - Not applicable to:
    - Excepted benefits such as dental, vision, health FSA
    - Not applicable to stand alone retiree health plans

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Rx Reporting

- 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 fully insured plans can rely on insurance carriers and shift responsibility/liability with a written agreement with carrier
- Plan sponsors of self-insured plans can rely on TPAs or PBMs or both 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
  - **Coordination required among plan sponsor, TPAs and PBMs**

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Rx Reporting

- P2 File for Plan Specific Information (e.g. plan name, number and year)
- The reporting templates include eight data files for:
  - Premium spending and life years (D1)
  - Spending by category (D2)
  - Top 50 most frequently used brand drugs (D3)
  - Top 50 most costly drugs (D4)
  - Top 50 drugs by spending increase (D5)
  - Rx spending/Total Rebates/Fees/Other Remuneration (D6)
  - Rx rebates by therapeutic class (D7)
  - Top 25 drugs with highest rebates (D8)

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Rx Reporting

- Plan can file all plan and data files
- Plan can file some and vendor can file some
- Vendor(s) can file all files
  - Some information will still be required from the plan sponsor (e.g. information required for D1 file will likely need to come from the plan sponsor)
- Challenges presented when plans have multiple vendors and/or benefit package options
  - Claims administrator different from PBM
  - Plan with different benefit package options administered by different claims administrators
  - Medical benefit or PBM benefit has carve out vendors
    - Medical claims administrator different from behavioral health vendor
    - PBM and special drug PBM are different
  - Changing vendors during the reference year

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Rx Reporting

- If Vendor files, can be plan by plan or in the "aggregate"
  - Special aggregation rules apply
    - Data reported by state and market segment (e.g. fully insured large group market, self funded large group, etc.)
    - D1 and D3-D8 cannot be reported at a less granular level than D2
      - If D2 (the medical plan files) are reported on plan level, D1 and D3-8 must also be reported at a plan level
      - If D2 reported in the aggregate, then D1 and D3-8 may be reported at plan and/or aggregate level.
    - CMS originally said that each plan could have only 1 data file; recent guidance has provided relief that allows multiple vendors to submit a data file for a plan so long as information is reported in the P2 file a certain way so that CMS can determine that multiple files are for 1 plan

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RX Reporting—Example 1

- Plan A has a medical plan claims administrator (TPA A), a behavioral health vendor (TPA B), and a PBM

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Rx Reporting-Example 1

- TPA A's P2 File

Group Health Plan Name		Plan Year Beginning Date	Plan Year End Date		TPA Name		Included in D-1?	Included in D2?		Included in D8
Plan A	..	01/01/2020	12/31/20	..	TPA A TPA B	..	1	1		0

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Rx Reporting-Example 1

- TPA B's P2 file

Group Health Plan Name		Plan Year Beginning Date	Plan Year End Date		TPA Name		Included in D-1?	Included in D2?		Included in D8
Plan B	..	01/01/2020	12/31/20	..	TPA A TPA B	..	1	1		0

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Rx Reporting-Example 2

- Plan A, number 501, has multiple benefit package options, each administered by a different claims administrator (TPA 1 and 2), and 1 PBM for all options

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Rx Reporting-Example 2

- TPA 1's P2 File

Group Health Plan Name	Group Health Plan Number				TPA Name			Included in D2?		Included in D8
Plan A	501-1	..	..	..	TPA 1	..	..	1	..	0

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Rx Reporting-Example 2

- TPA 2's P2 File

Group Health Plan Name	Group Health Plan Number				TPA Name			Included in D2?		Included in D8
Plan A	501-2	..	..	..	TPA 2	..	..	1	..	0

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Rx Reporting-Example 2

- PBM's P2 File

Group Health Plan Name1	Group Health Plan Number				TPA Name			Included in D2?		Included in D8
Plan A	501-1	..	..	..	TPA 1	..	..	0	..	1
Plan A	501-2				TPA 2			0		1
Plan B	501-2				TPA 3			0		1

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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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Grab Bag

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Disaster Relief Filing Extensions

- Those in FEMA-designated areas with valid extension to file their 2021 Form 5500 due to run out on October 17, 2022, will now have until February 15, 2023:
  - IR 2022-168: Hurricane Ian/Florida
    - Sept 23, 2022-Feb 15, 2023
  - IR 2022-164: Storms and Flooding/Alaska
    - Sept 15, 2022-Feb 15, 2023
  - IR 2022-161: Hurricane Fiona/Puerto Rico
    - Sept 17, 2022-Feb 15, 2023
- The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area.
- Visit https://www.irs.gov/newsroom/tax-relief-in-disaster-situations for more information.

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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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Key Highlights of FAQs Part 55 on No Surprises Act (NSA) and Transparency in Coverage (TiC)

- NSA requires group health plans to disclose its balanced billing protections as follows:
  - Post on group health plan's/insurer's website.
  - Include with affected EOBs.
  - May use model notice from DOL.
- 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.
  - Available even if the plan sponsor 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.

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FAQs Part 55 on TiC

- The Consolidated Appropriations Act of 2021 and Transparency in Coverage rule (TiC) require group health plans and insurers to publish machine readable disclosures of rates for in-network, out of network and Rx allowed amounts ("Public Disclosure").
- Plans that do not have a website may satisfy the Public Disclosure obligation for posting 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.
  - Original 1/1/22 Deadline for providing machine readable IN rates extended to 7/1/22 for plan years starting 1/1/22 – 6/30/22
  - Original 1/1/22 Deadline for providing machine readable OON allowed amounts and billed charges extended to 7/1/22 for plan years starting 1/1/22 – 6/30/22.
  - Original 1/1/22 Deadline for providing machine readable negotiated rated and historical net prices for prescription drugs extended indefinitely pending updated regulations.

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FAQs Part 55 on NSA and TiC

- 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.

Thanks!

- Questions?