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Employee Benefits & Executive Compensation ADVISORY ■

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Year-End Health Benefits Roundup 2023

The year 2023 was another active one for health and welfare plans. It started with the big announcement of the end of the COVID-19 national emergency and public health emergency and peaked over the summer with the release of the long-anticipated proposed rules for non-quantitative treatment limitations under the Mental Health Parity and Addiction Equity Act (MHPAEA). Regulators also issued several sets of proposed rules, including proposed rules for fixed indemnity excepted benefits coverage and short-term, limited-duration insurance; privacy of reproductive health information; and investment fiduciaries. Although there is still no final resolution to the independent dispute resolution (IDR) process, a new proposed regulation was issued this fall after several court opinions disrupted the federal IDR process. The IRS quietly released a chief counsel memorandum confirming that the substantiation rules for account-based plans really do mean what they say they mean. While litigation over state legislation of pharmacy benefit managers (PBMs) continues to wind through the courts, Congress introduced several bills this year aimed at regulating PBMs.

We revisit some of the most pressing issues for employers, plan sponsors, plan administrators and service providers, and health insurers, and we provide some practice pointers heading into 2024.

COVID-19: The End Is Here (National Emergencies and Outbreak Period Expire)

On January 30, 2023, the White House announced that the national and public health emergencies would officially end on May 11, 2023. For group health plans, this meant an end to several temporary changes that plan sponsors and group health plans were either required or permitted to make in response to the COVID-19 pandemic and the beginning of a transition back to pre-pandemic benefits and administration. The chart below provides a high-level summary of the status of mandated or permitted benefits and relief granted in response to the COVID-19 national and public health emergencies.

BENEFIT/RELIEF	STATUS AFTER MAY 11, 2023
COVID-19 tests (prescribed and OTC)	No coverage is required; plans that continue coverage can impose cost-sharing and medical management techniques such as pre-authorization and can disregard the safe harbor requirements for OTC COVID-19 tests (e.g., must cover up to eight tests per month per family member) if they continue to cover those tests.
COVID-19 vaccine	*In-network:* Coverage is required without cost-sharing under the Affordable Care Act (ACA) preventive services requirements. *Out-of-network:* No coverage is required.

Personal protective equipment (PPE)	The IRS continues to recognize PPE as a qualified medical expense, so health flexible spending accounts (FSAs) and health reimbursement arrangements (HRAs) that allow reimbursement for all qualifying §213(d) medical expenses must continue to reimburse claims for PPE.
Stand-alone telehealth for employees not eligible for employer's major medical group health plan	Relief for these stand-alone plans from most ACA mandates continues until the end of the plan year that begins on or before May 11, 2023 (December 31, 2023 for calendar year plans) unless extended by future legislation or guidance (no such guidance has been issued as of the publication of this advisory).
Relief for "excepted benefit" status of employee assistance programs (EAPs) providing COVID-19 diagnosing, testing, and vaccines	There is no clear guidance on whether EAPs can continue to provide these benefits and maintain status as an excepted benefit after May 11, 2023. Without further guidance, plan sponsors will need to weigh the risk of noncompliance with continuing to provide this benefit through the EAP until the end of the plan year.
Health savings accounts (HSAs)/high-deductible health plans (HDHPs): COVID-19 testing	IRS Notice 2020-15 allows HDHPs to cover COVID-19 testing before the deductible without disqualifying HSA eligibility, and as provided by IRS Notice 2023-37, this relief remains in effect for plan years ending on or before December 31, 2024. This relief will not be available for subsequent plan years.
HSAs/HDHPs: telehealth	The Coronavirus Aid, Relief, and Economic Security Act permitted HDHPs to cover pre-deductible telehealth and other remote services offered through the HDHP without disqualifying a person from HSA participation. Original relief expired on December 31, 2022, regardless of plan year; the Consolidated Appropriations Act (CAA), 2023 extended the relief, but only for *plan years* starting on or after January 1, 2023 and before January 1, 2025. The original relief for non-calendar year plans expired on December 31, 2022, and the extended relief was not available in 2023 for non-calendar year plans until the beginning of the 2023 plan year.
MHPAEA quantitative treatment limitations (QTLs)	For purposes of compliance with the "substantially all" and "predominant" tests for financial requirements and quantitative treatment limitations under the MHPAEA, relief from enforcement action was granted for any plan or insurer that disregarded mandatory COVID-19 diagnostic testing required by the Families First Coronavirus Response Act. The relief was intended to be temporary and presumably ended on May 11, 2023, meaning that nonmandated COVID-19 coverage must be taken into account for QTL testing.

Outbreak period transition of tolling periods

The Outbreak Period refers to a period that began on March 1, 2020 and ended 60 days after the end of the national emergency, or July 10, 2023. During this Outbreak Period, certain timeframes for ERISA plans were suspended for up to one year or until 60 days after the end of the national emergency, whichever was sooner. Once the Outbreak Period ended on July 10, 2023, any tolling period that had not already expired ended, and the clock for the applicable deadline began running as of July 11, 2023.

The clock for the affected timeframes that were still suspended as of July 10, 2023 would have started ticking again as of July 11, 2023, and many of the deadlines have long since passed (e.g., the 30-day period to request HIPAA special enrollment and the 60-day election period for COBRA continuation coverage). However, for some timeframes, such as the date by which claims or appeals need to be filed, the Outbreak Period may still be operating to extend deadlines. For example, a plan that allows 180 days to file a claim would have suspended that timeframe for claims incurred before July 10, 2023. A claim incurred on January 1, 2023 would not have to be filed within 180 days of January 1, 2023 but instead within 180 days after July 10, 2023, or January 6, 2024. These extensions also apply to claims filed for FSAs and HRAs (e.g. the run-out period following the end of each plan year during the Outbreak Period was suspended in accordance with the rules).

Practice Pointer: Be aware of the potential effect the Outbreak Period rules have on claims, appeals, COBRA elections, and COBRA payments.

IRS Substantiation Guidance

On March 29, 2023, by way of chief counsel memorandum 202317020 (CCM), the IRS reiterated that when it comes to claims substantiation for reimbursement of medical expenses, there are rules that must be followed. The IRS confirmed that practices such as employee self-certification, sampling claims, de minimis claims substantiation level, auto-substantiation for certain favored health care providers, and advance approval of dependent care claims all fall short of what the Code Section 105, 125 and 129 rules require for claims substantiation. In driving this point home, the IRS explained that if a plan's claim substantiation process does not meet IRS requirements, claims for all participants (even otherwise validly substantiated claims) are taxable.

This CCM serves as an important reminder to review your plan's and your third-party administrator's (TPA) claim substantiation process to ensure that all claims adjudication satisfies IRS requirements.

Here are some steps to keep in mind for plans that use debit cards for auto-substantiation to implement pay-and-chase procedures for all claims that are not auto-substantiated (there are no prescribed timelines for completing pay-and-chase):

- Ask for substantiation.
- If substantiation is not provided, turn off the debit card. Turning off the debit card must come before any subsequent steps.
- Demand repayment, offset against good claims, withhold from pay (where permitted by state wage withholding laws). While unclear, the IRS has hinted that the offsets must occur during the same plan year as the unsubstantiated claim. In fact, the CCM suggests, without analysis or explanation, that repayment and offsetting in a subsequent year may violate the prohibition under Code Section 125 against the receipt of deferred compensation. These three steps can be taken in any order as long as they are done uniformly for all participants.
- If demanding repayment, withholding from pay, or offsetting are unsuccessful, then employers must treat such claims as any other bad debt, which can mean:
  - Send the claim to collections.
  - Forgive the debt if not recoverable, which results in W-2 taxable income for the year forgiven (according to the CCM).
  - This step must come last, and defaulting to this step without going through the steps above may be considered evidence of a noncompliant substantiation process.

Practice Pointer: Year-end is a good time to *double-check* your claims substantiation and pay-and-chase processes for compliance. Consult your TPA and legal adviser for assistance.

PBM Legislation and Litigation

The year 2023 saw a flurry of bipartisan legislative activity at the federal level aimed at regulating PBMs. Much of the proposed legislation focuses on reforms in transparency, compensation disclosure, controlling the rising cost of prescription drugs,

rebates, and preemption. HR 5378, the Lower Cost, More Transparency Act, was introduced in September and combines the work of three House committees. Legislation in the Senate includes:

- S. 1339 - Pharmacy Benefit Manager Reform Act
- S. 2973 - Modernizing and Ensuring PBM Accountability Act
- S. 127 - Pharmacy Benefit Manager Transparency Act of 2023

As these bills make their way through House and Senate committees, legislation at the state level continues to be challenged in courts, with the Tenth Circuit opinion in *PCMA v. Mulready* in August marking a big win for ERISA preemption and plan sponsors. *Mulready* involved a preemption challenge to an Oklahoma PBM law and comes just two and a half years after the Supreme Court's decision in *Rutledge v. PCMA*. In *Rutledge*, the Supreme Court identified two types of state laws that are preempted: (1) laws that require providers to structure benefit plans in particular ways; and (2) laws that have an acute but indirect economic impact and, thus, force providers to adopt a certain scheme of substantive coverage. At issue in *Mulready* were the geographic standards imposed on networks (network access standards); prohibition against requirements or incentives for using a particular provider (discount prohibition); the "any willing pharmacy" requirement (AWP); and prohibitions regarding terminations of pharmacists from network if on probation. Glen Mulready, the Oklahoma insurance commissioner, argued that there should be no preemption because Oklahoma law regulates the PBMs and not the ERISA plans. The Tenth Circuit rejected the argument and remanded the case, holding that the network-related provisions were all preempted by ERISA (and the AWP requirement was preempted in part by Medicare Part D) because these provisions impermissibly mandated a particular benefit structure. In essence, PBMs in Oklahoma could only offer a single network tier without any customization. ERISA's savings clause was not addressed in the opinion because Mulready did not raise the issue. The Tenth Circuit distinguished *Rutledge* because Arkansas law merely regulated pricing terms in contracts between PBMs and pharmacies without forcing plans to adopt any particular scheme of substantive coverage.

In September, the Oklahoma insurance commissioner filed a petition for an en banc rehearing. We may hear more from *Mulready* again in 2024.

> ***Practice Pointer:*** Continue to monitor PBM legislation at the state and federal levels. Compliance requirements in this area are very fluid.

Transparency

Consolidated Appropriations Act, 2021

The required prescription drug and health care spending report under Section 204 of Division BB of the CAA, 2021 began in 2023. The first deadline (for 2020 and 2021 data submissions) was again extended from December 31, 2021 to January 31, 2023, and the second deadline was extended from June 1, 2022 to June 1, 2023. All subsequent prescription drug reporting to the Centers for Medicare and Medicaid Services (CMS) is due on June 1 each year for the prior calendar year (regardless of plan year). CMS has provided several resources, including manuals and technical assistance, on its Prescription Drug Data Collection webpage.

FAQs Part 61: New guidance for ACA transparency in coverage rules

The CAA, 2021 also added reporting requirements to the ACA in the transparency in coverage (TiC) rule requirements. These TiC reporting requirements required group health plans subject to the ACA to post publicly available machine-readable files (MRFs) of allowed amounts and to make a cost share estimate tool available.

The MRFs include three different files: in-network rates; out-of-network allowed amounts; and fee-for-service prescription drug costs. Some noted that the fee-for-service prescription drug costs file could be potentially duplicative and overlap with reporting requirements of Section 204 of Division BB of the CAA, 2021. In response to these concerns, enforcement of the fee-for-service prescription drug cost requirement for MRFs was deferred indefinitely by FAQs Part 49, Q1. The departments have now concluded that there is no "meaningful conflict" between these two sets of requirements and rescinded that guidance in September in FAQs Part 61, Q1. The departments will instead address enforcement decisions on a case-by-case basis, as facts and circumstances warrant, and they intend to develop technical requirements and an implementation timeline in future guidance to account for any reliance plans that issuers may have developed on the enforcement deferral.

Through FAQs Part 61, the departments also rescinded the blanket enforcement safe harbor of TiC final rules' disclosure of certain in-network rates as dollar amounts, as described in FAQs Part 53. Enforcement discretion will be case by base and fact specific, and plans must demonstrate compliance with the relevant provisions of TiC. Final rules would have been extremely difficult or impossible, including for reasons stated in FAQs Part 53. The departments stated that plans and issuers that are unable to determine dollar amounts for the in-network rate element should continue to follow the existing technical guidance on GitHub for percentage-of-billed-charges arrangements.

Reminder! TiC's cost share estimate tool is being phased in, with only the 500 services identified by the Department of Health and Human Services (HHS) (if covered by the plan) required to be available for plan years beginning on or after January 1, 2023. For plan years beginning on or after January 1, 2024, all covered services under the plan must be included in the tool.

Electronic Filing of Forms 1094-C and 1095-C for ACA Reporting

On February 23, 2023, the IRS published a final regulation in the *Federal Register* for electronic filing of returns and other documents, including Forms 1094-C and 1095-C. This final regulation reduced the prior mandated electronic filing threshold of 250 forms to just 10 for forms due in 2024. In calculating the number of forms, filers need to aggregate almost all form types covered by the final regulation, including Forms W-2, 1094-C, 1095-C, and 1099. The practical effect this will have on applicable large employers (ALEs) for purposes of ACA reporting requirements is that all ALEs will be filing electronically because of the 50 fulltime or fulltime equivalent threshold to be classified as an ALE. The penalty for failure to file, or failure to file a correct form, for 2023 Forms 1094-C and 1095-C filed in 2024 is $310 for each form, with the total penalty for a calendar year not to exceed $3,783,000. The per-form penalty can be increased for intentional disregard. Waivers are available for reasonable cause and not willful neglect.

Practice Pointer: If an employer was under the 250-form threshold in the past and not filing electronically, the employer will likely need to find a vendor to properly and timely file Forms 1094-C and 1095-C in 2024.

Independent Dispute Resolution Process

Litigation, pauses in process, and backlogs have stymied the federal IDR process ever since it was introduced by the No Surprises Act in CAA, 2021. The departments have had to pause and resume processing of disputes several times in 2023 due to court opinions that vacated portions of the regulations governing the federal IDR process. As of October 6, 2023, the departments have reopened the federal IDR portal for the initiation of certain new single and bundled disputes, but processing and initiation of batched disputes and initiation of new air ambulance disputes remain temporarily suspended as of early November. The departments are conducting a phased reopening of

the portal and should be making additional announcements regarding other suspended dispute categories soon. A timeline of these developments and the departments' responses can be found on CMS's webpage about payment disputes between providers and health plans. Some of the more salient developments include:

Federal IDR Fee: On August 3, 2023, the Eastern District of Texas invalidated the increased federal IDR $350 fee for 2023 (up from $50), and, consequently, disputes initiated after August 3, 2023 reverted to $50. In response to the district court's decision, the departments issued a proposed rule in September that would set the fee at $150 as of January 1, 2024.

Qualifying Payment Amount: The calculation of the qualifying payment amount (QPA) also remains a contested feature of the federal IDR process. On August 24, 2023, the Eastern District of Texas, as part of the ongoing Texas Medical Association litigation, invalidated several provisions of the interim final regulations, including but not limited to the rule that plan sponsors could calculate the QPA based on its service provider's book of business.

In FAQs Part 62, the departments stated that they would not be issuing further guidance on the calculation of QPA but expected a good-faith reasonable interpretation of the applicable regulations in light of this decision. The departments are exercising enforcement discretion in allowing plans to continue to use the definition of QPA before this decision until May 1 2024, with a possible extension until November 1, 2024. On October 20, 2023, the departments appealed this decision to the Fifth Circuit.

New Proposed Regulations for the IDR Process: On November 3, 2023, the departments published a notice of proposed rulemaking (NPRM) in the *Federal Register* that proposed new requirements in the federal IDR process. The departments address the following in the NPRM:

- Communications between providers, payers, and certified IDR entities:
  - Requires plans or issuers to use claims adjustment reason codes and remittance advice codes
  - Payers must include with the QPA a statement notifying the provider of a 30-business-day period for open negotiation
- Allows a 30-business-day open negotiation period before the federal IDR process
- Requires an IDR initiation and response notice
- Establishes an overflow eligibility review system by HHS when the dispute volume is high
- Proposes additional ways to collect fees directly from parties
- Allows more flexibility for batching
- Creates an IDR Payer Registry for plans and issuers subject to the federal IDR process. Registry is required for:
  - Each group health plan subject to the IDR process
  - Issuers of individual and group policies
  - Federal Employees Health Benefits Program carriers

The preamble to the proposed regulations highlights that the current process is hampered by ongoing disputes as to whether a claim is subject to an IDR as well as confusion in identifying the correct plan or provider. Notices and communications that were outside the federal portal, such as the open negotiation process, would go through the federal portal with much more detailed information on the parties, the actual claims in dispute, the basis upon which the claim is subject to the IDR process, the exchange of offers, etc. Under the proposed revised process, the departments believe that the IDR entities would be in a position to make a decision on IDR eligibility without the back-and-forth

communication between the parties and the IDR entity that occurs currently. Further, directing these steps through the portal would eliminate disputes on whether a party acted in a timely manner under the tight timeframes of the IDR process.

2023 Developments in ACA Preventive Services and Contraceptive Coverage

Braidwood Management v. Becerra

In March 2023 a U.S. district court issued an opinion and order under *Braidwood Management v. Becerra* invalidating ACA preventive care requirements recommended by the U.S. Preventive Services Task Force (USPSTF). Initially, all actions taken by the Department of Labor (DOL), HHS, and the IRS to enforce or implement the preventive care coverage requirements in response to an "A" or "B" recommendation by the USPSTF made on or after March 23, 2010 were vacated, and the agencies were enjoined from enforcing these requirements. In June, the Fifth Circuit granted the government's motion for a partial stay of the injunction pending appeal after the parties reached an agreement. Final disposition of this case is likely to take some time, but if the district court's opinion is ultimately upheld, the following ACA preventive services mandates would be unenforceable: screenings for breast, cervical, colorectal, lung, and skin cancer; screenings for diabetes, depression, hepatitis, and vision problems in children; screening and treatment for HIV, including PrEP; and care for those who are pregnant and breastfeeding and care for their young children.

Shortly after the March opinion and order were issued and before the government prevailed in its motion for a partial stay, HHS, the DOL, and the Department of the Treasury issued FAQs Part 59 on April 13, 2023. Although the partial stay of the injunction renders the information in the FAQs less urgent, plans and issuers should still be mindful of the following in the event the district court opinion is upheld in whole or in part:

- The *Braidwood* outcome only affects recommendations by the USPSTF on or after March 23, 2010 and does not have an effect on Advisory Committee on Immunization Practices and Health Resources and Services Administration recommendations.
- States can still require coverage for fully insured plans.
- Any mid-year changes would still be subject to the advance notice requirement for summaries of benefits and coverage and the 60-day notice requirement for a summary of material modifications following a material reduction.
- USPSTF recommendations after March 23, 2010 will still be considered preventive care for purposes of HSA eligibility.

New preventive services for 2023

New and updated guidelines for preventive services that were issued in December 2021 went into effect for calendar plan years beginning January 1, 2023. Included are:

- Updated guidelines on breastfeeding services and supplies, including double electric breast pumps.
- Screening for HIV infection for all adolescent and adult women ages 15 and older at least once during their lifetime and risk assessment and prevention education beginning at age 13.
- Pre-pregnancy, prenatal, postpartum, and interpregnancy well-woman visits.
- Counseling to prevent obesity in women ages 40 to 60 years with normal or overweight body mass index. Previously only covered obesity.
- The "full range of U.S. Food and Drug Administration (FDA)- approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care."

Practice Pointer: Review any plan exclusion for maternity services for dependents/daughters to make sure preventive pregnancy-related services are covered even if other maternity services are excluded. Review plan exclusions for weight loss to make sure preventive services are covered.

Proposed rule to eliminate the moral objection and establish individual contraceptive arrangement

On January 30, 2023, the Department of the Treasury, the DOL, and HHS released a notice of proposed rulemaking related to certain preventive services under the ACA. The proposed changes include rescinding the moral exemption rule (while maintaining the existing religious objection) and establishing a new individual contraceptive arrangement to facilitate the provision of contraception, cost-free, to individuals enrolled in plans sponsored by an objecting entity. Under the current 2018 final regulations, certain types of employers identified in the final rule that sponsor group health plans and have a moral or religious objection to contraceptive coverage do not have to provide that coverage. These objecting employers have the option to provide an accommodation whereby they do not have to contract, arrange, pay, or refer an individual for contraceptive coverage, but contraceptive services are still available through an insurer or TPA. Many objecting employers do not provide the optional accommodation.

The proposed rule would provide a new pathway where individuals in plans of objecting employers that do not provide the accommodation could obtain contraceptives at no cost through an "individual contraceptive arrangement" with a willing provider. Through that arrangement the provider would be able to seek reimbursements from an insurer on the Exchange who has signed an agreement to provide the coverage. The insurer would then be entitled to an adjustment of an Exchange user fee.

Gag Clause Attestation

Group health plans are required to submit an annual gag clause compliance attestation by December 31, 2023 to HHS, which is collecting the attestations on behalf of itself, the DOL, and the Department of the Treasury. The attestation is required to confirm that certain contracts do not prevent disclosures of cost, quality of care data, or certain other information required as part of the CAA, 2021. CMS has posted several compliance resources on its website, including:

- Annual Submission Webform Instructions that provide an overview of the process.
- User Manual for making attestations through the Health Insurance Oversight System that walks through the submission process step by step with screenshots from the webform.
- FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 57 (FAQs Part 57), issued by the departments on February 23, 2023.

Highlights of gag clause attestation requirements

- **Plans subject to gag clause attestation requirement:** The annual attestation requirement applies to most group health plans subject to the ACA, without regard to grandfather plan status, including both self-insured and fully insured ERISA plans, church plans, nonfederal governmental plans.
- **Plans not subject to gag clause attestation requirement:** Account-based plans, such as HRAs (even if otherwise subject to the ACA) and health FSAs, and excepted benefit plans (e.g., hospital indemnity, some EAPs, some onsite clinics, dental, vision, long-term care) are not required to submit attestations. The gag clause attestation also does not apply to stand-alone retiree health plans.

- **Covered period for initial attestation:** The initial attestation due at the end of this year covers the period beginning December 27, 2020 (or the effective date of the applicable group health plan, if later), through the date of attestation. The attestation requires the attester to confirm that the plan has not, since December 27, 2020, entered into any agreement with a provider, network of providers, TPA, or any other service provider offering access to a network or association of providers that contains any prohibited gag clause.
- **Types of contracts subject to the attestation requirement:** The gag clause rules apply to agreements with providers, network of providers, TPAs, or any other service provider offering access to a network or association of providers.
- **Entity responsible for making the attestation:** Insurers and self-insured plans are each responsible for their own plans. Self-insured plans can authorize a TPA or other service provider to be the official attesting entity and submit the attestation on behalf the entire plan or subset(s) of plan benefits, but the plan is ultimately responsible if the TPA fails to make the attestation.
- **Enforcement action for self-insured plans:** Regardless of whether the plan or the TPA submits the attestation, the plan is ultimately responsible if there is a failure to submit an attestation on time. The agencies state in FAQs Part 57, Q7 that failure to submit timely attestations may subject the plan to enforcement action, without specifying what type of action. Presumably the general penalty of $100 per day under the Internal Revenue Code could be applied, but it isn't clear if this would apply per attestation or per person affected by the violation.

Practice Pointer: Going forward, in addition to carefully reviewing new administration agreements for gag clauses (and removing them), plan sponsors should also include affirmative language that clarifies their right to disclose provider-specific cost/quality of care through a consumer engagement tool or other means, access certain de-identified claims and claim encounter information, and share with business associates as permitted by privacy laws.

HIPAA

Proposed HIPAA Privacy Rule for confidentiality of reproductive health care

On April 17, 2023, the HHS Office for Civil Rights (OCR) issued an NPRM to modify the HIPAA Privacy Rule. The NPRM, which only applies to covered entities, health plans, providers, and health care clearinghouses, and their business associates (which the OCR refers to as "regulated entities"), is one of the actions taken pursuant to Executive Orders issued in response to the U.S. Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision.

The NPRM creates a new category of protected health information (PHI) called "reproductive health care," which is defined as "care, services, or supplies related to the reproductive health of the individual" in 45 CFR §160.103. This would be a specially protected category of sensitive PHI similar to psychotherapy notes and would include a broad range of services, treatments, and care.

The NPRM also offers protection against prohibited disclosures of this new category of PHI. Earlier post-*Dobbs* guidance provided that HIPAA-covered entities, including health plans, could only disclose PHI related to reproductive health care in the case of a law that expressly compels a covered entity to disclose the PHI and is enforceable in court. The NPRM would go further and amend 45 CFR §164.502 to prohibit disclosures for non-health care purposes even in the case of a court order or search warrant enforceable in court. These non-health care purposes are aimed at protecting a person from investigations or proceedings related to legally obtaining reproductive care. The NPRM proposes that

neither a HIPAA authorization nor the permissions under 45 CFR §164.512 (relating to uses and disclosure required by law) could be used to bypass the purpose-based prohibition and would require a covered entity to obtain a signed and dated attestation when it receives a request for PHI potentially related to reproductive health care that the use or disclosure is not for a prohibited purpose.

If the NPRM becomes final in its proposed form, plan sponsors and business associates need to be mindful of the following:

- The NPRM proposes to modify 45 CFR §164.520 regarding HIPAA Notice of Privacy Practices to add new provisions explaining that the HIPAA Privacy Rule would prohibit the use or disclosure of PHI in certain scenarios relating to reproductive health care.
- Employers that sponsor covered health plans will need to develop, implement, and maintain compliance documentation in response to the final rule. This includes:
  - An attestation form
  - Updated business associate agreements
  - Policies, procedures, and training materials
- Per the NPRM, when a final rule is issued, the total timeframe for compliance would likely be 240 days (60 days from the publication of the final rule plus 180 days).

HIPAA and Online Tracking Technologies

On December 1, 2022, HHS's OCR issued the bulletin Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates, which was followed by a joint letter published by the OCR and the Federal Trade Commission on July 20, 2023 sent to approximately 130 hospital systems and telehealth providers. The letter alerts recipients about the risks and concerns related to the use of technologies, such as Meta/Facebook Pixel and Google Analytics, that can track a user's online activities. A lawsuit filed in October 2023 against Piedmont Healthcare Inc. cites the letter in its complaint, which alleges that the tracking technologies allowed Meta to have access to nonpublic personally identifiable information and PHI such as the type and date of medical appointments, the name of the provider, medical conditions, and treatment without notifying individuals that their information would be shared, which allegedly violates HIPAA and various other state laws.

> ***Practice Pointer:*** HIPAA covered plan sponsors should monitor vendors' use of embedded tracking technologies as directed by HHS in the 2022 guidance from 2022.

Other HIPAA News

On February 17, 2023, the OCR shared two reports with Congress for 2021:

- Annual Report to Congress on HIPAA Privacy, Security, and Breach Notification Rule Compliance (hhs.gov)
- Annual Report to Congress on Breaches of Unsecured Protected Health Information (hhs.gov)

The OCR frequently noted in the reports the continued need for regulated entities to improve the compliance with the HIPAA Security Rule requirements, including risk analysis and risk management; information system activity review; and audit and access controls.

Proposed STLDI and Excepted Benefit Regulations

On July 12, 2023, federal regulators proposed changes to short-term, limited-duration insurance (STLDI) and fixed indemnity excepted benefits. Regulators believe that consumers may confuse these types of coverages with a more comprehensive (and more expensive) coverage option that complies with the ACA and choose these less expensive options instead. The new proposed changes would affect STLDI coverage in a few ways:

- Cut back the less-than-12-months term to no more than three months after the effective date of the contract.
- Cut back the total duration of an STLDI contract from 36 months to no more than four months in total for renewals and extensions.
- Prohibit stacking so that an individual could not obtain a new STLDI policy from an issuer within 12 months of the effective date of a previous STDLI policy, if from the same issuer.

The proposed rule would also impose new restrictions on certain supplemental fixed indemnity health benefits. In particular, the proposed rule would impose significant new limitations on the structure of hospital indemnity and other fixed indemnity supplement benefits. The proposed rule would also change the tax treatment of benefits under all health indemnity policies (fixed indemnity as well as benefits under specified disease policies such as cancer or critical illness policies). The proposed rule also requested comments on additional issues. The comment period closed on September 11, 2023, and the agencies have reported receiving over 15,000 comments.

Mental Health Parity and Addiction Equity Act Proposed Rule for NQTLs

On July 25, 2023, the IRS, the DOL, and HHS released new proposed regulations under the MHPAEA that, if finalized, would provide significant clarifications and new compliance obligations for group health plans and issuers subject to the MHPAEA's provisions (Proposed Rules). The DOL was originally accepting comments (on behalf of the departments) through October 2, 2023, but due to the "considerable interest expressed" in the Proposed Rules, the departments extended the deadline through October 17, 2023.

Highlights of the new proposed rule

- Creates three new requirements for nonquantitative treatment limitations:
  - **"No more restrictive" requirement.** The "substantially all/predominant" test currently applicable to quantitative treatment limitations (QTLs) would also apply to nonquantitative treatment limitations (NQTLs), which means that an NQTL would need to apply to at least two-thirds of the medical/surgical benefits (Med/Surg) in one of the MHPAEA classifications (i.e., inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs) for the NQTL to apply to any mental health/substance use disorder (MH/SUD) benefits in the same classification. In addition, only the predominant variation (meaning the most common or frequent) of the NQTL can apply.
  - **Design and application requirement.** NQTLs would be subject to an enhanced "design and application" requirement under which the NQTL analysis will also apply "in designing and applying the limitation." The processes, strategies, evidentiary standards, or other factors (terms that are defined for the first time in these Proposed Rules) used in designing and applying the NQTL to MH/SUD benefits would need to be comparable to, and applied no more stringently than, those used in designing and applying the NQTL to Med/Surg benefits within the same classification.
  - **Data gathering requirement.** In designing and applying an NQTL, plans and issuers would need to collect and evaluate relevant data to assess the impact of an NQTL on MH/SUD compared to Med/Surg and to

determine whether there are material differences in access to MH/SUD benefits compared to Med/Surg benefits based on this data. There is also an additional data collection requirement specific to network composition. Technical Release 2023-01P, issued at the same time as the Proposed Rules, provides technical details on this requirement.

  - **Material differences.** For NQTLs other than network composition, a "material difference" in the metrics/data gathering for the NQTL as applied to MH/SUD and medical/surgical benefits would be a "strong indicator" of a violation, and the Proposed Rules detail action that should be taken. For NQTLs related to network composition, a material difference would indicate an actual violation. Comments were sought on how to define "material difference."

- **Requires meaningful benefits in each classification (expansion of 2013 rule).** The 2013 final rule for the MHPAEA made it clear that if a plan or issuer provides MH/SUD benefits in any of the six classifications of benefits (i.e., inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs), the MH/SUD benefits must be provided in every classification in which Med/Surg benefits are provided. The Proposed Rules add that this requirement would not be satisfied unless the MH/SUD benefits provided in each classification are "meaningful benefits" when compared to the Med/Surg benefits in the same classification, and comments were sought on how to define the term.
- **Codifies, reorganizes, and expands CAA, 2021 NQTL comparative analysis requirements.** The Proposed Rules would amend existing guidance, set more specific content requirements for comparative analyses, clarify when the comparative analysis needs to be performed and for which NQTLs, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the departments upon request. The Proposed Rules also require a certification of the comparative analysis by one or more named fiduciaries stating whether they found the comparative analysis to be compliant with the requirements outlined in the Proposed Rules.
- **Provides detail on DOL action for inadequate NQTL comparative analysis.** The Proposed Rules would allow a plan or issuer a minimum of 10 business days to respond to a request from the DOL for a comparative analysis, and a minimum of 45 calendar days to respond to the DOL's initial determination of noncompliance with a corrective action plan. If the DOL still determines that the plan or issuer is not compliant, the noncompliant plan or issuer would be required to provide notice of noncompliance to participants and beneficiaries within seven calendar days of the receipt of the final determination of noncompliance. A copy of the notice would need to be sent to the DOL, any service provider involved in claims processing, and any fiduciary responsible for deciding claims within the same timeframe.
- **Confers ERISA 104(b)(4) status on NQTL comparative analysis.** The Proposed Rules would treat the comparative analysis like an instrument under which the plan is established and operated, thereby allowing participants and beneficiaries to request the comparative analysis to be provided upon request within 30 days. Plan administrators can face up to a $110 per day penalty for not complying with such a request.
- **Sunsets CAA, 2023 opt-out for state and local governmental plans.** The Proposed Rules would implement the sunset provisions of the CAA, 2023 that ended the ability of state and local governmental plans to opt out of the MHPAEA.

In addition to the Proposed Rules, the DOL issued Technical Release 2023-01P, which provides technical details, includes a request for information concerning this data gathering, and discusses a possible safe harbor on network composition based on the data gathering requirements in the Proposed Rules.

More detail on the Proposed Rules and the Technical Release can be found in our August 2023 advisory.

2023 MHPAEA report to Congress

The departments released the second report to Congress on the MHPAEA comparative analysis for NQTLs. This report for the first time, as required by the CAA, 2021, names specific plans that were found by the agencies to not be compliant with the comparative analysis requirement.

Practice Pointers:

- Carefully review the report to Congress and the DOL's recommended compliance tools.
- Develop a practice of regularly checking for what is (and is not) a compliant NQTL, as this is a constantly developing area of MHPAEA compliance.
- Carefully review your plan's NQTL analysis to ensure it includes statutorily required elements.
- For self-insured plans, consult legal counsel and review your agreement with your TPA to ensure that the responsibilities of the TPA and the employer with respect to preparing a proper and comprehensive NQTL comparative analysis are included in that agreement.

Miscellaneous

Air Ambulance. Proposed regulations for the No Surprises Act indicated that 2022 reporting for air ambulance would be due March 31, 2023, and 2023 reporting would be due March 31, 2024. Section 106 of the Act is clear that reporting is not required until "a final rule is promulgated." Because no final rule has been promulgated, CMS confirmed on its website that reporting is not due until there are final regulations.

Patient-Centered Outcomes Research Institute (PCORI) Fees. For plan years ending on or after October 1, 2023 and before October 1, 2024, the updated PCORI fee amount is $3.22 times the average number of covered lives under the plan, up from $3.00. (IRS Notice 2023-70)

DOL Proposed Investment Fiduciary Rule. On November 3, 2023 a new investment advice fiduciary proposed rule was published in the *Federal Register*. The proposed rule reinstitutes the broad investment fiduciary definition and best interest requirement for certain investment fiduciaries (PTE 2020-2). Although this rule will primarily affect retirement plans, it also applies to HSAs.

Section 1557 Proposed Regulations. HHS published proposed regulations in August 2022 for ACA's nondiscrimination requirements under Section 1557. These nondiscrimination rules import the protections against sex discrimination (among others) under Title IX of the Education Amendments of 1972. The Biden Administration has stated that it interprets sex discrimination to include discrimination based on sexual orientation and gender identity, arguing that this interpretation of Title IX is permitted as a result of the Supreme Court's interpretation of sex discrimination under Title VII in *Bostock v. Clayton County*, but a Texas judge later set this interpretation aside for plaintiffs and members of the class in Neese v. Becerra. Litigation under Section 1557 for transgender health care is active and evolving, yet despite (or perhaps because of) this litigation, the proposed regulations have not yet been finalized.

Copay Accumulator Litigation. In September, a U.S district court vacated a 2021 rule that allowed plans and insurers to exclude drug manufacturer coupons and copay assistance from a participant's annual out-of-pocket maximum. The 2021 rule allowed plans and insurers to exclude the portion of drug costs covered by such coupons or assistance to the extent consistent with applicable state law, meaning that participants would have to continue to pay out-of-pocket costs for other services and treatments until the annual maximum is reached. Prior to the 2021 rule, CMS had

issued a final rule that allowed such costs to be excluded from the calculation of annual out-of-pocket maximums, but only if a generic equivalent were available. Given that the 2021 rule has been invalidated just as many employers are beginning annual open enrollment, some plans and insurers are asking whether either rule is valid and whether CMS has the authority to require such rules through its rulemaking process for insured plans. CMS has filed a motion with the court seeking further clarification.

2024 Health Benefit Adjustments

Included in the table below are 2023 and 2024 indexed amounts for some of the health-benefit-related limits and caps:

BENEFIT	2024	2023
HSA contribution max (including employee and employer contributions)	$4,150/$8,300 Rev. Proc. 2023-23	$3,850/$7,750 in 2023
HSA additional catch-up contributions	$1,000	$1,000
HDHP annual deductible minimum	$1,600 ($3,200 family)	$1,500 in 2023
Limit on HDHP OOP expenses	$8,050 ($16,100 family)	$7,500 ($15,000 family)
ACA limit on OOP expenses	$9,450 ($18,900 family)	$9,100 ($18,200 family)
Limit on amounts newly available under an excepted benefit HRA	$2,100	$1,950
Health FSA salary reduction max	$3,200	$3,050
Health FSA carryover max	$640	$610
QSEHRA max reimbursement	$6,150 ($12,450 family)	$5,850 ($11,800 family)
Transit and parking benefits	$315 (monthly)	$300 (monthly)
401(k) employee elective deferral max	$23,000 (catch-up contributions $7,500)	$22,500 (catch-up contributions $7,500)
Highly compensated employee	$155,000 ($150,000 applies for 2024 plan year under look-back rule)	$150,000 ($135,000 applies for 2023 plan year under look-back rule)
Key employee	$220,000	$215,000
ACA pay-or-play affordability threshold for 2024	8.39%	9.12%
Federal poverty level (FPL) for U.S. mainland	$14,580; for employers that use the FPL safe harbor, required employee contribution for self-only coverage cannot exceed $101.93 per month	$13,590; for employers that use the FPL safe harbor, required employee contribution for self-only coverage cannot exceed $103.28 per month

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