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HEALTH & WELFARE PLAN LUNCH GROUP

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2024 Year-End Agenda

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News for Account-Based Plans

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2024 Guidance for Account-Based Plans

- IRS Notice 2024-71: Condoms qualify as 213(d) medical care for FSAs/HRAs/HSAs
- IRS Notice 2024-75 recognizes the following as preventive care for HSA HDHP purposes (i.e., reimbursable below the deductible)
  - OTC oral contraceptives and condoms
    - Does not allow male sterilization or other male contraceptives
  - Breast cancer screenings other than mammograms (e.g., MRI, ultrasound) – retro expansion/clarification to Notice 2004-23
  - Continuous glucose monitors (as is the case with other glucometers) – retro clarification to Notice 2019-45
    - Limited to monitors that pierce the skin for a reading (n/a smart watch or rings)
  - Insulin and insulin delivery products – retro expansion to accommodate IRC 223(c)(2)(G)
- Employee Choice Program: IRS approves (in PLR 202434006) an arrangement that allows annual choice to direct employer funds between HSA, HRA, education/tuition/loans, and employer DC plan contribution.
  - Choice made annually before start of calendar year; IRS concluded did not constitute an elective deferral (e.g., for 401(k) purposes); Remaining amounts could not be cashed out
  - Compliance and cost considerations: Employer contribution (not salary reduction); Plan limits and nondiscrimination testing issues ; Administrative complexity

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More on HSAs

- Possible expiration of CARES Act HDHP virtual care exception (unless re-enacted) on December 31, 2024
  - Plan year exception so impacts calendar year plans 1/1/25
  - Potential problem areas for any "treatment" below the deductible
  - Possible exceptions
    - Health coach
    - Disease management
    - Treatment that (in the aggregate) is not significant
      - How do you measure significance?

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Final Rule for ERISA Investment Advice Fiduciaries

Final ERISA Investment Fiduciary Rule

- DOL Proposed Rule on **Definition of an Investment Advice Fiduciary** and Proposed Changes to Related PTEs (Nov. 3, 2023); comment period ended Jan. 2, 2024; Final Rule published in FR on April 25, 2024.
- **Top Line Review:**
  - HSAs are subject to the Final Rule
    - No exception as a non-investment deposit product
  - HSA service providers who receive compensation in connection with investment recommendations will be considered fiduciaries, and must fit prohibited transaction exemption 2020-02 "Best Interest Contract Exception"
  - Is there a possible exception for platform provider that merely selects menu . . .
    - But questions abound especially if compensation received
  - BCE PTE expanded to include NBTs and their service providers
  - Two court challenges each have resulted in a stay on enforcement
    - ACLI case
    - FACC case

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MHPAEA FINAL RULE: WHAT SHOULD PLAN SPONSORS BE DOING NOW?

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COMPARATIVE ANALYSIS

- Comply with the comparative analysis requirements for 2025.
- Do you have a comparative analysis?
  - If not prepare one.
  - If you do, then review the six detailed requirements and be prepared to update the comparative analysis for the Final Rule except for:
    - The meaningful benefits standard,
    - The prohibition on discriminatory information used in the design and application requirements, and
    - The relevant data evaluation requirements.
  - How to handle "carve-out" service providers (behavioral health, PBMs, telehealth, , musculoskeletal and diabetes programs etc.).
  - ***Technically required on January 1, 2025 for a calendar year plan.***
    - Will the Departments exercise enforcement discretion if the process of preparing an updated comparative analysis is underway? Remember time periods responding to a Department's request are very short.
    - The Departments refused to provide an example of a compliant comparative analysis but will "continue to consider what additional resources and guidance are necessary to assist the regulated community" and that they are "committed to providing additional guidance."

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COMPARATIVE ANALYSIS

- Review the certification requirement with applicable plan fiduciaries.
  - Who will be selected to prepare the comparative analysis?
  - Document a "prudent process" to select one or more "qualified service providers" to prepare the comparative analysis.
  - How will the required monitoring of the qualified service provider be accomplished and documented?
  - In the preamble DOL states that it expects that the service provider will make an assurance that, to the best of its ability, the comparative analysis complies with the requirements of MHPAEA and applicable regulations.
    - Will the service provider make that assurance?
  - Applicable to fully insured ERISA-covered plans as well.
  - In the preamble DOL states that, alternatively, the fiduciary could provide a certification that the comparative analysis is in compliance.

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PLANNING FOR 2026

- Identify any areas where there may be a plan design issue with the "meaningful benefits/core treatment" requirement and be prepared to address those in 2026.
  - Are any plan/SPD amendments required?
- Review the information used in designing NQTLs. Is any of it biased or not objective in a manner that discriminates against MH/SUD benefits? Who will make that determination?
- ***Data collection will be the most challenging aspect of the Final Rule.***
  - Still many unknowns on what the final data collection requirements will be.
  - Watch for further guidance on data collection including an updated MHPAEA Self-Compliance Tool from the Departments.
    - DOL has informally stated that the Self-Compliance Tool will be available in the near future.
  - Discuss with TPAs/ASOs on the ability to collect the data.
  - Does the TPA/ASO have the technology to collect this data?
  - Based on the data, who will determine whether there are "material differences" in access to MH/SUD benefits as compared to Med/Surg benefits? How will that determination be made? Statistical or actuarial experts?
  - What action will be taken if there are material differences?

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SERVICE PROVIDER AGREEMENTS

- Make sure any ASO/TPA agreement addresses responsibilities for a comparative analysis.
- Will the ASO/TPA be the "qualified service provider" to perform the comparative analysis for purposes of the fiduciary certification?
  - Issues with carve-out service providers.
  - Providing the DOL expected service-provider "assurance" of compliance.
- If the ASO/TPA will not be the qualified service provider does the agreement provide for cooperation with that provider? Timing in providing information to that provider? Consequences if information is not provided?
- Specifically address data collection and meaningful benefits/core treatments?
- Don't forget QTL testing.

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WATCH FOR FURTHER DEVELOPMENTS

- Will the Final Rule be challenged under *Loper Bright* or otherwise:
  - In particular, there may be challenges to the relevant data evaluation and meaningful benefits requirements.
- What about the Congressional Review Act?
  - Bipartisan support around addressing MH/SUD benefits but maybe Congress will want the Departments to "start over".
- There should be additional sub-regulatory guidance.
  - Additional guidance repeatedly promised in the preamble.
  - Updated MHPAEA Self-Compliance Tool. Soon?
  - Prior Trump administration attempted to stop reliance on any sub-regulatory guidance (guidance that had not gone through notice and comment).

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Welfare Plans-- Fiduciary Checkup

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Fiduciary Breach Litigation

- Two recent lawsuits filed in 2024 allege claims for fiduciary breaches for failure to monitor PBMs and negotiate lowest prescription drug prices
- Both lawsuits allege breach of fiduciary duty for failure to monitor the PBM, including the prices charged and the incentives for which drugs are placed on the formularies.
- Both lawsuits allege harm to the plan as a whole, resulting in not only higher drug costs to individuals but higher premiums for all participants, and even lower wages.
- One lawsuit alleged a prohibited transaction for paying excessive fees and insinuated that even consultants improperly profit from "market derived income" from PBMs.
- What should health & welfare plan sponsors be doing now?

Basic Best Practices

- Formally establish and document a fiduciary committee for the health & welfare plans.
- Consider a committee charter to provide clarification of the responsibilities delegated to the committee and specify any limitations on committee authority.
- Schedule routine committee meetings and maintain a compliance calendar to stay on top of routine compliance items.
- Obtain fiduciary liability insurance for the health & welfare committee. If your organization already has fiduciary liability insurance, check the policy to make sure that it covers the health & welfare plan fiduciaries.
  - Note that fiduciary liability insurance is *not* the same as an ERISA bond.
- Train fiduciaries on key responsibilities related to their fiduciary duties.
  - Fiduciaries should also be able to identify when an arrangement with a service provider could raise prohibited transaction red flags.
- Establish a prudent process for selecting and monitoring service providers and hire experts to assist where the committee lacks expertise.

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Litigation Updates 2024

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Secretary of Labor v. Macy's Inc. et al.

- Action brought by the DOL against Macy's, Macy's group health plan and plan's two TPAs in August 2017 in federal court in Ohio.
  - Pending over four years before motions to dismiss were decided.
- Decision on the motions to dismiss in November 2021 and DOL's motion for reconsideration on February 10, 2022.
- No findings of any liability at this point, simply letting limited claims go forward with some claims dismissed. Two claims—
  - Discriminatory wellness program under HIPAA/ERISA §702 (against Macy's alone),
  - Failure to follow out-of-network reimbursement methodology as stated under the plan document (against all defendants).
- Post-Loper-Bright Update: Macy's challenging the statutory language under ERISA 702(b)'s requirement that rewards be granted for "adherence to programs of health promotion and disease prevention."

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Smoking Cessation Program Litigation

- 20+ class action cases filed
- 3 general claims are being made:
  - No notice of alternative standard
    - Rules require notice of right to alternative standard in all materials describing the program
  - Reward not applied retroactively when alternative standard satisfied
    - Rules require that same reward be available to those who complete the alternative standard
  - Time period for completing alternative standard too short
    - Rules do NOT prescribe a specific time period
- Action Items:
  - Review wellness program; ensure the RAS is available and communicated along with other program information

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TMA III

- The calculation of the Qualifying Payment Amount (QPA) under the No Surprises Act (NSA) has been subject to a number of challenges by the Texas Medical Association (TMA) in in a district court in Texas (known as TMA I, TMA II, TMA III and TMA IV).
- For NSA covered claims (out-of-network emergency; out-of-network provider in an in-network facility; and out-of network air ambulance) QPA is used in determining a participant's cost-sharing as well as a factor in what the insurer/plan will pay the provider if a NSA claim goes to independent dispute resolution (IDR). TMA cases involved the weight given to QPA when a claim goes to IDR and also how to calculate QPA.
- Biden Administration lost each of the TMA decisions in district court.
- But, in somewhat of a surprise, on October 30th the 5th Circuit Court of Appeals reversed the district court and upheld the Biden Administration regulations on several aspects of calculating QPA.

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TMA III

- QPA generally involves a median contracted rate for a specific service. In TMA III, the Fifth Circuit reversed the district court in three areas where the district court found the regulations to be invalid:
  - "Ghost rates"—These are described as rates for a service negotiated between a provider and a plan/insurer but for which there are no actual claims. The district court held these "ghost rates" could not be used in calculating QPA. The Fifth Circuit ruled they could.
  - Incentives—The district court held that risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments must be included in calculating QPA. The Fifth Circuit, upholding the regulatory provision, said they could be excluded.
  - Special case specific agreements with provider—The district court held that these agreements must be taken into account when calculating QPA even though the regulations stated they could be excluded . The Fifth Circuit, again upholding the regulatory provision, held that they cannot be taken into account.
- This generally means the regulations were upheld as written for these provisions.

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TMA III

- The Fifth Circuit also held that plans/insurers do not have to provide more information on QPA than is currently provided by the regulations.
- The Fifth Circuit did not address (because the government apparently did not appeal this issue) the district court's prohibition of a third-party administrator calculating QPA based on its entire self-funded plan "book of business" rather than on a plan-by-plan basis. This aspect of the district court's decision in TMA III appears to be still applicable and may be an issue—especially for smaller self-funded plans. How this could possibly work for a small level funded plan is unknown.
- The Fifth Circuit ***upheld*** the district court on the 30-day statutory deadline for a plan to make a decision on an NSA claim. The regulations provided that the 30-day period was only triggered by a "clean claim." The district court held, and the 5th Circuit agreed, that this was contrary to the statutory text. The 30-day period begins to run from the receipt of the claim, whether clean or not.
- CMS website states: "The Departments and OPM are reviewing the Fifth Circuit's decision and intend to issue further enforcement guidance in the near future."
- Litigation may not be over. *En banc* or Supreme Court review is possible.

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Issues in Prescription Drug Coverage

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Copay Accumulators, Copay Maximizers, and Alternative Funding Programs—What are they?

- All involve how a group health plan (GHP) treats drug manufacturer's assistance programs or charitable programs to either help with drug copays for those with GHP coverage or to pay for the drugs for those who are uninsured or without coverage for a specific drug. These programs typically involve specialty drugs.
- GHPs with copay accumulators do not count the manufacturer's assistance toward the GHP's deductible or maximum out of pocket.
- GHPs with copay maximizers typically set the copay for the drug at the amount of the manufacturer's assistance.
- GHPs with alternative funding programs typically exclude coverage for specialty drugs altogether and the participant or beneficiary seeks to have the drug paid with the manufacturer's assistance or charitable program.

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Copay Accumulators

- Copay accumulators have been in existence for a number of years. They were addressed in the HHS Notice of Benefit and Payment Parameters (NBPP) in 2020 and 2021.
- Tri-agencies issued guidance in FAQs About Affordable Care Act Implementation Part 40 which contained a non-enforcement policy allowing GHPs to not count copay assistance in the ACA MOOP in all instances—even when there was not a generic equivalent.
- Formalized and adopted into HHS regulations in the 2021 NBPP.
- Advocacy groups challenged 2021 NBPP in a D.C. district court, arguing that not counting the copay assistance was inconsistent with the ACA definition of cost-sharing.
- In late September 2023. the D.C. district court agreed in *HIV and Hepatitis Policy Institute et al. v. HHS*, vacating 2021 NBPP and remanding the issue back to HHS. In December, after a request by HHS, the court clarified its ruling to state that by vacating the 2021 NBPP the 2020 NBPP was once again in effect (do not have to count if a generic is available) .

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Copay Accumulators

- In briefing the request for clarification, HHS indicated that it would not enforce the district court's decision pending the issuance of new regulations.
- The Biden administration initially appealed the D.C. district court decision but, after bi-partisan pressure from the Senate, dropped that appeal.
- Regulations promised (including in the proposed 2026 NBPP) but no proposed rule yet.

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Copay Maximizers, Alternative Funding Programs, What To Do Now?

- Final 2025 NBPP requires Rx drugs in excess of those covered by a state's EHB benchmark plan to be treated as EHBs for non-grandfathered individual and small group insurance market plans.
  - This means drugs in excess of the EHB benchmark must count toward the ACA's maximum out of pocket (MOOP).
- Final 2025 NBPP did not apply this requirement to large group and self-funded plans.
  - However, regulators indicated that they intend to propose rulemaking that would apply this requires to large group and self-funded plans. *See* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66 Plans with copay accumulator and maximizer programs in particular should watch for these regulations.
- Understand that manufactures and healthcare providers are opposed to these programs.
- Recognize that a copay maximizer or alternative funding vendor will be assisting participants and beneficiaries in obtaining manufacturer's assistance which could be viewed as a representation by the GHP itself. How does a GHP make sure these representations are accurate?
- PHI is likely involved in identifying participants and beneficiaries for the program and make sure appropriate HIPAA privacy and security protections are in place.
- Possible ADA and HIPAA nondiscrimination issues if changes in GHP formularies or increases in copays targeted to specific disabilities or health status.

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Rebate Retention Practices

- In Fall 2024 the Federal Trade Commission (FTC) issued an administrative complaint against three PBMs alleging the PBMs "created a perverse drug rebate system that prioritizes high rebates from drug manufacturers, leading to artificially inflated insulin list prices."
- The complaint charges that even when lower list price insulins became available that could have been more affordable for vulnerable patients, the PBMs systemically excluded them in favor of high list price, highly rebated insulin products."
- On November 19, 2024, the PBMs filed suit against the FTC in the District Court for the Eastern District of Missouri seeking an injunction against the FTC's administrative proceedings.
- PBMs allege:
  - The Constitution prohibits the FTC from deciding private rights and revising private contracts.
  - FTC proceedings violate their due process rights because the same FTC commissioners that issued the complaint will decide it.

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Mulready PBM Litigation Update

10th Circuit: *Pharmaceutical Care v. Mulready*

- Supreme court stated in Rutledge that there are two types of state laws that are preempted:
  - Laws that require providers to structure benefit plans in particular ways
  - Laws that have an acute but indirect economic impact such that it forces providers to adopt a certain scheme of substantive coverage
- At issue in *Mulready*:
  - Geographic standards imposed on networks (Network Access Standards)
  - Prohibition against requirements or incentives for using a particular requirement (Discount Prohibition)
  - Any willing pharmacy requirement (AWP)
  - Prohibitions regarding terminations of pharmacists from network if on probation
- 10th Circuit found ERISA and Medicare Part D preemption.
  - Oklahoma's insurance commissioner, Glen Mulready, filed a petition for writ of certiorari in May 2024.
  - In October 2024, the Supreme Court asked the federal government to weigh in on the case.

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HIPAA Updates

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New HIPAA Privacy Protections for Reproductive Health Care

- The Department of Health and Human Services' ("HHS") published its final rule on HIPAA Privacy Rule and Reproductive Health Care on April 26, 2024 (Rule).
- The Rule prohibits HIPAA covered entities and their business associates (collectively "regulated entities") from using or disclosing PHI related to reproductive health care for certain investigatory-type purposes if the health care itself is provided lawfully.
- The Rule adds an attestation requirement for certain *permitted* purposes for PHI that may be "potentially related" to reproductive health care. Attestation requirement does not apply to requests from other covered entities or business associates.
- Regulated Entities will need to (i) Update NPPs ; (ii) Review/update HIPAA policies and procedures; (iii) Review/update business associate agreements and amend to ensure compliance; (iv) Train any personnel that handle requests for PHI on the Rule's requirements.

Requirement	Date by which covered entities must comply
Update HIPAA Policies and Procedures ("P&Ps")	December 23, 2024
Update the Notice of Privacy Practices ("NPPs")	February 16, 2026
HIPAA Training for 2024 Privacy Rule	December 23, 2024
Obtain Attestations for Certain Uses and Disclosures	December 23, 2024
Revise existing business associate agreements ("BAAs")	December 23, 2024

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Final Part 2 Regulations Align with HIPAA Rules

- On February 8, 2024, HHS U.S. Department of Health and Human Services (HHS) through the Substance Abuse and Mental Health Services Administration and the Office for Civil Rights (OCR) issued final regulations on the confidentiality of substance use disorder (SUD) patient records under 45 CFR Part 2 ("Part 2").
- The final regulations were published February 16, 2024, 2024-02544.pdf (govinfo.gov) and are effective April 16, 2024. Compliance deadline is **February 16, 2026**.
- In general, Part 2 protects SUD information obtained by any federally assisted program.
- The Part 2 requirements are more stringent than HIPAA and generally prohibit disclosure of the records in investigations or procedures against the patient absent written consent or court order.
- The final regulations align aspects of the Part 2 rules regarding patient confidentiality of SUD records with the HIPAA Privacy Rules as required by Section 3221 of the CARES Act.
- Many of the entities that use, disclose, and maintain SUD records are also covered entities under HIPAA or HIPAA business associates.
- Plan Sponsors will also need to update the following documents: (i) Notice of Privacy Practices; (ii) HIPAA Policies and Procedures Manual; (iii) Participant forms

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Changes Ahead for HIPAA Security?

- Proposed HIPAA Security Regulations Coming for Year-End?
  - An upcoming proposed rule from HHS would formalize cybersecurity requirements and allow the Office for Civil Rights (OCR) to expand enforcement. (see the **abstract** HHS filed with the White House Office of Information and Regulatory Affairs)
    - The proposed rule is a response to ransomware and hacking to access ePHI and will likely align with HHS' Cybersecurity Performance Goals HHS released earlier this year HPH Cybersecurity Gateway.
    - The proposed rule may also codify HHS' tracking technologies guidance.
    - The proposed rule is expected to be published by the end of the calendar year.
- New Legislation on Health Care Security – Health Infrastructure Security and Accountability Act
  - The Health Infrastructure Security and Accountability Act (HISA) was introduced in September 2024 in an effort to counter cyber security attacks against the U.S. health care system.
  - The Act would require HIPAA covered entities and their business associates to maintain minimum security requirements and removes the statutory caps on fines for HIPAA violations.
  - A one-page summary of the bill can be found here. A section-by-section summary can be found here. The legislative text can be found here.

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Online Tracking Technologies and HIPAA

- December 1, 2022: OCR/HHS issued the bulletin "Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates"
- March 18, 2024: OCR/HHS updated this guidance to "increase clarity"
  - User data collected from visits to unauthenticated pages that have nothing to do with treatment – for example, pages related to hospital visiting hours or job postings – is not PHI.
  - Other visits to unauthenticated pages *might* be PHI depending on subjective intent:
    - "If a student were writing a term paper on the changes in the availability of oncology services," letting pixels collect info from his visit to a healthcare website does not share PHI, "even if the information could be used to identify the student."
    - However, if "an individual were looking at a hospital's webpage listing its oncology services to seek a second opinion on treatment options for their brain tumor," then letting pixels collect that user's "IP address, geographic location, or other identifying information" results in a disclosure of PHI.
- June 20, 2024: the U.S. District Court N.D. TX issued an order declaring unlawful and vacating a portion of the tracking technology guidance.
  - Specifically, the Court vacated the guidance to the extent it provides that HIPAA obligations are triggered in "circumstances where an online technology connects (1) an individual's IP address with (2) a visit to a[n] [unauthenticated public webpage] addressing specific health conditions or healthcare providers."
  - HHS is evaluating its next steps.

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Updates to the 2021 EBSA Cybersecurity Guidance

- On September 6, 2024, EBSA issued Compliance Assistance Release No. 2024-01 (Release) confirming that the cybersecurity guidance issued by EBSA in April 2021 generally applies to *all employee benefits plans*, including health and welfare plans. Previously appeared to apply only to retirement plans.
- EBSA Cybersecurity Guidance has 3 parts:
  - **Tips for Hiring a Service Provider**: contains recommended RFP questions and contract terms for plan sponsors
  - **Cybersecurity Program Best Practices**:
    - Lists 12 cybersecurity best practices for service providers that EBSA would expect to see if auditing the plan or service provider.
    - States that pension and health and welfare plans are tempting targets for cyber criminals because the plans: (i) often hold millions of dollars in assets; and (ii) store and/or transfer participants' personally identifiable data.
  - **Online Security Tips**: Contains tips for participants and beneficiaries to reduce the risk of fraud.
- EBSA also referred to HHS publications for health plans and their service providers to maintain good cybersecurity practices
  - Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients
  - Technical Volume 1: Cybersecurity Practices for Small Healthcare Organizations
  - Technical Volume 2: Cybersecurity Practices for Medium and Large Healthcare Organizations

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Takeaways From the Cybersecurity Guidance

- EBSA is auditing cybersecurity practices of health and welfare plans and their service providers.
  - This includes *all welfare plan benefits* – not just health plans covered by HIPAA.
- EBSA thinks that ERISA plan fiduciaries have a duty under ERISA to prudently select a service provider with strong cybersecurity practices and monitor its activities.
- EBSA also thinks that responsible plan fiduciaries have an obligation to ensure proper mitigation of cybersecurity risks.
- EBSA expects plan fiduciaries to distribute the online security tips to plan participants and beneficiaries who check their plan information online.

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Miscellaneous

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Association Health Plan

Recently Finalized Rules

- DOL **Definition of "Employer"--Association Health Plan** Notice of Proposed Rulemaking to rescind 2018 AHP Rule (December 20, 2023); comment period ended February 20, 2024; Final Rule published in FR on April 30, 2024.
- ERISA 3(5) defines "employer" to include a bona fide group or association of employers.
- Pre-2018 Rule interpretative guidance was drawn from several ERISA opinion letters.
- Under the pre-rule guidance it was generally understood that no bona fide group or association of employers can exist if several unrelated employers without any genuine organizational relationship merely execute participation agreements or similar documents as a way to fund ERISA-covered benefits.
- The 2018 AHP Rule established alternative criteria that set the bar significantly lower than pre-rule guidance (e.g., allowed the provision of health coverage as a primary purpose).
- Rescission of the 2018 Rule raises the bar back to where it was under the pre-rule guidance.

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Nondiscrimination in Health Programs and Activities (1557)

- HHS-OCR Proposed Rule on **Nondiscrimination in Health Programs and Activities (1557)** (Aug. 4, 2022); comment period ended October 2022; Final Rule published in FR on May 6, 2024.
- Generally, any health program or activity that receives Federal financial assistance (FFA) from HHS or that is administered by an executive agency or by an entity established by Title I of the ACA is covered by the 2024 Rule (limited exemption for Federal religious freedom and conscience objections).
- Definition of "health program or activity":
  - Includes "health insurance issuer," which has implications for insurer TPAs and the self-insured plans they administer.
  - Does not include GHPs, though GHPs could be subject to the 2024 Rule if the GHP itself receives FFA.
- 2024 Rule does not apply to any "employer or other plan sponsor" of a GHP with regard to its "employment practices", including the "provision of employee health benefits", which "includes when the Federal financial assistance received is for their employee health benefits."
- Applies to telehealth; Medicare Part B is FFA.

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Final Rule for STLDI and Fixed Indemnity Coverage

Final rule published on April 3, 2024 in Fed. Reg. Core purpose of final rule was to reduce confusing STLDI and fixed indemnity coverage with ACA-compliant coverage. Proposed Rule:

- Cut back the current 36-month max renewal limit on STLDI to three months with one month extension (also includes an anti-stacking provision)—this provision was finalized.
- Redefine "excepted benefits" status for hospital indemnity and other fixed indemnity supplement benefits—This provision was not in the final rule.
- Impose new notice requirements—This provision is in the final rule but has been challenged.
  - On 12.4.24 a Texas court vacated the notice requirement for fixed indemnity (see ManhattanLife Insurance and Annuity Company et al v. United States Department of Health and Human Services et al E.D.Tex. 6:24-cv-00178-JCB)
  - A separate challenge on STLDI restrictions is ongoing (see *American Association of Ancillary Benefits et al. v. Becerra et al.*, 4:24-cv-00783, August 29, 2024)
- Change the tax treatment of all fixed indemnity health policies, including specified disease coverage--This provision was not in the final rule.

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Proposed Rule: Enhancing Coverage of Preventive Services

- On October 28, 2024, HHS-CMS published in the FR the proposed rule for Enhancing Coverage of Preventive Services under the Affordable Care Act.
  - Clarifies and codifies an exception process for reasonable medical management techniques for preventive items/services not generally covered by the plan.
  - Proposes that plans cover OTC contraceptive items without a prescription or imposing cost-sharing.
  - Proposes that plans cover certain recommended contraceptive items that are drugs and drug-led combination products without imposing cost-sharing requirements, unless a therapeutic equivalent is covered without cost-sharing.
  - Proposes a disclosure for coverage and cost-sharing for OTC contraceptive items.
- Applicable to non-grandfathered GHPs and health insurance issuers offering non-grandfathered group or individual health insurance coverage

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ACA FAQs Part 68

- On October 21, 2024, DOL, HHS and IRS issued FAQs Part 68,.
- GHPs that cover mastectomies are required to provide coverage for chest wall reconstruction with aesthetic flat closure as a type of breast reconstruction under Women's Health and Cancer Rights Act (WHCRA).
- Plans and issuers must cover, without cost sharing, specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services, consistent with the 2023 USPSTF recommendation published on August 22, 2023, for plan years beginning on or after one year from the issue date of the recommendation (in this case, plan or policy years beginning on or after August 31, 2024).
- Proper medical service coding is required to identify when item/service are furnished as preventive items or services not requiring cost-share.
  - FAQs provide guidance and several examples for proper coding.

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Disaster Relief: IRS Filing Extensions

Deadlines vary depending upon the disaster and locality. Details on all recent disaster relief for presidentially-declared disasters are on the Around the nation page on IRS.gov. Currently:

- Taxpayers in all or parts of Connecticut, Florida, Illinois, Kentucky, Louisiana, Minnesota, Missouri, New York, Pennsylvania, Puerto Rico, South Dakota, Texas, Vermont, Virgin Islands and Washington state have until Feb. 3, 2025, to file their 2023 tax year returns.
- Until May 1, 2025, to file 2023 tax year returns:
  - For Helene or Milton, taxpayers in **all of** Alabama, Florida, Georgia, North Carolina, South Carolina, and in affected parts of Tennessee and Virginia will have.
  - For severe storms and flooding that began on Oct. 19, 2024 for Chaves County, New Mexico
  - For flooding that began on August 5, 2024 for Juneau, Alaska
- The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area. The DOL automatically recognizes these extensions for Form 5500 filing. Visit https://www.irs.gov/newsroom/tax-relief-in-disaster-situations for more information.

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Disaster Relief: Extensions of Timeframes

- DOL/EBSA and Treasury/IRS published **Extension of Time Frames** in FR on Nov. 8, 2024 for Hurricane and Tropical Storm Helene and Hurricane Milton. *Note: "Disaster areas" are those areas designated as eligible for Individual Assistance by FEMA due to a particular storm. It is narrower in some states than the IRS tax filing relief.*
- Extensions for Participant, beneficiary, qualified beneficiary, or claimant apply to Special Enrollment requests (30 or 60 days); COBRA 60-day election period; COBRA premium payment deadlines; Deadline for disability determination notices; Claim filing deadline; Deadline for filing appeals of adverse benefit determinations; Deadline for filing requests for external review; Deadline for filing information to perfect a request for external review.
- Extensions for GHP, sponsor or TPA: Providing COBRA election notice.
- EBSA also published Disaster Relief Notice 2024-01, as well as general FAQs for participants and beneficiaries impacted by Hurricane Helene or Hurricane Milton.
  - EBSA Notice 2024-01 extends deadlines for furnishing notices, disclosures, and other documents required by provisions of Title I of ERISA to plan participants, beneficiaries, and other persons so that employers, plan fiduciaries, and plan sponsors have additional time to meet their obligations.

Health & Welfare Benefits
MONTHLY UPDATE

Disaster Relief Period

- Sept. 23, 2024-May 1,2025: Florida disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane Helene.
- Sept. 24, 2024-May 1,2025: Georgia disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane Helene
- Sept. 25, 2024-May 1,2025: North Carolina, South Carolina and Virginia disaster areas designated as eligible for Individual Assistance by FEMA due to Hurricane or Tropical Storm Helene
- Sept. 26, 2024-May 1,2025: Tennessee disaster areas designated as eligible for Individual Assistance by FEMA due to Tropical Storm Helene
- Oct. 5, 2024-May 1,2025: Florida disaster areas *not* designated as eligible for Individual Assistance by FEMA due to Hurricane Helene but designated as eligible for Hurricane Milton.

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Year-End Compliance Reminders

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MONTHLY UPDATE

Year-End Compliance—Gag Clause Instructions

Group health plans (GHPs) and health insurance issuers must annually attest compliance with Gag Clause Prohibition and submit Gag Clause Prohibition Compliance Attestations (GCPCAs) by December 31st every year.

- CMS says brokers, agents, TPAs, PBMs and other entities attesting on behalf of GHPs and issuers should notify the GHP or issuer.
- GHPs or issuers, or those submitting on their behalf, should submit GCPCAs via https://hios.cms.gov/HIOS-GCPCA-UI.
- GCPA Instructions, User Manual, and Excel Template are available at https://www.cms.gov/marketplace/about/oversight/other-insurance-protections/gag-clause-prohibition-compliance-attestation.

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Year-End Compliance— Nondiscrimination in Health Programs and Activities (1557) (cont.)

Although the 2024 Rule is generally effective on July 5, 2024, the complexities of this rule require separate effective dates for various provisions:

Section 1557 Requirement	Date by which covered entities must comply
Designate a §1557 Coordinator	Within 120 days of July 5, 2024 ("within" 120 days seems to mean November 2, 2024).
§1557 Policies and Procedures	Within one year of July 5, 2024.
§1557 Training	Following a covered entity's implementation of the policies and procedures, and no later than 300 days of July 5, 2024.
Notice of Nondiscrimination	Within 120 days of July 5, 2024.
Notice of Availability of Language Assistance Services and Auxiliary Aids and Services	Within one year of July 5, 2024.
Nondiscrimination in health insurance coverage and other health-related coverage (benefit design changes)	For health insurance coverage or other health-related coverage that was not subject to the 2024 Rule as of May 6, 2024, by the first day of the first plan year beginning on or after January 1, 2025.

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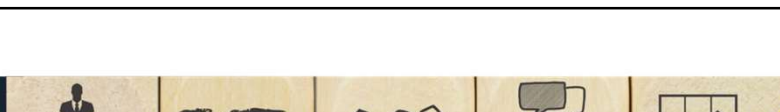

Year-End Compliance— Federal Grab Bag (not exclusive list)

- *Non-discrimination testing* – Some non-discrimination tests for health FSAs, dependent care FSAs, HRAs, and group term life require corrections, which might include refunds, before the end of the year.
- *Amendment for Family Glitch* – In, 2022 the IRS added a new election change event for cafeteria plans to coordinate with enrollment in a qualified health plan (QHP) through an exchange. Plans that offered this new election change event for a plan year beginning in 2023 must be amended and participants must be notified by the end of the cafeteria plan's 2024 plan year (12/31/2024 for calendar year plans).
- *Summary Annual Report* - If Form 5500 is extended, the SAR is due December 15, 2024.
- *CHIPRA notice* – provide to all employees annually (no date specified). DOL model notice available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/2010-2409 (as visited November 7, 2024).

Health & Welfare Benefits
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Year-End Compliance— Federal Grab Bag (not exclusive list – cont.)

- *Telehealth (covered earlier)* - Unless Congress acts, after December 31, 2014 calendar year HSA compatible HDHPs cannot cover telehealth before a participant reaches their deductible. Non-calendar year HDHPs can allow pre-deductible telehealth through the end of the plan year beginning before January 1, 2025.
- *HIPAA Reproductive Rights Compliance (covered earlier)* - By December 23, 2024, HHS requires business associates and covered entities (including, but not limited to, plans like HRAs and FSAs) to:
  - Revise existing business associate agreements ("BAAs")
  - Update HIPAA Policies and Procedures
  - Provide HIPAA Training for 2024 Privacy Rule
  - Obtain attestations when making Certain Uses and Disclosures
- January 2025:
  - *2023 Form W-2-Health Plan Coverage Reporting* - The W-2 must report the total value of "applicable employer sponsored coverage" provided to the employee during 2024 no later than January 31, 2024. See https://www.irs.gov/affordable-care-act/form-w-2-reporting-of-employer-sponsored-health-coverage (as visited November 7, 2024).

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Year-End Compliance— State and Local Reminders (not exclusive list)

- *California Flexible Spending Account Notice* - Notify FSA participants of rules regarding withdrawal of funds before end of year. This law is unclear as to whether it applies in any situation other than a situation where an employee terminates mid-year and is subject to a short run out period. Regardless of when it applies, it must be provided in two forms, one of which can be electronic. See https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201920200AB1554 (as visited November 7, 2024).
- *Illinois Essential Health Benefits Comparison Chart* - The state DOL utilizes the employee's "base of operations" test to determine whether an employer and its employees are subject to this Act. Chart must be provided upon hire, annually thereafter, and upon request. See https://labor.illinois.gov/laws-rules/fls/consumer-coverage-disclosure-act.html; https://labor.illinois.gov/faqs/consumer-coverage-disclosure-faq.html; https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=4217&ChapterID=68 (as visited November 7, 2024).
- *Massachusetts HIRD Form* - Applicable to employers who employed 6 or more employees in Massachusetts in any month in the 12 months preceding the due date of the report (12/15/24). Must file no later than December 15, 2024, for 2024. See https://www.mass.gov/info-details/health-insurance-responsibility-disclosure-hird-faqs (as visited November 7, 2024).
- *2024 Form MA 1099-HC (early 2025)* - Furnish 1099-HC by January 31, 2025 to any Massachusetts residents (including COBRA enrollees) if they were covered at least one month with "creditable coverage" as defined by Massachusetts.
- *Vermont Health Care Contribution Fund* - File form WHT-436 with Department of Taxes by the 25th day after the quarter ends. No contributions owed for "uncovered" employees if you have less than 5 full-time equivalents working in Vermont. See https://tax.vermont.gov/business/hcfca (as visited November 7, 2024).
- *Washington Partner Access Line Assessment* - Insurers and employer sponsors of self-funded plans must pay a quarterly assessment for covered lives of Washington residents. The "Overview" section of the website states that quarterly filings are due April 30, July 30, October 30, and January 30, but the FAQs state that assessment payments are due within 45 days following the end of the quarter (i.e., February 15, May 15, August 15, and November 15). See https://www.wapalfund.org/ui/payers (as visited November 7, 2024).
- *San Francisco HCSO payments for those not enrolled in plan* - No later than 30 days after the end of the quarter for employers making health care expenditures to the City Option on behalf of HCSO-covered employees. See https://www.sf.gov/information/health-care-security-ordinance (as visited November 7, 2024).
- *San Francisco HCAO/ HAO "Know Your Rights" Form* - Applies only to employers of employees covered by SFO's Quality Standards Program (QSP). must be provided within the first pay period an employee becomes a QSP employee, and annually thereafter. Must use the latest form from the OLSE, links for which can be found at https://sf.gov/information/understanding-healthy-airport-ordinance (as visited November 7, 2024).

Health & Welfare Benefits
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2024-2025 Cost-of-living Adjustments

	2025	2024
HSA contribution max (including employee and employer contributions)	$4,300/$8,550 in 2025 Rev Proc 2024-25	$4,150/$8,300 Rev. Proc. 2023-23
HSA additional catch-up contributions	$1,000	$1,000
HDHP annual deductible minimum	$1,650/$3,300 in 2025 Rev Proc 2024-25	$1,600 ($3,200 family)
Limit on HDHP OOP expenses	$8,300 and $16,600 in 2025 Rev Proc 2024-25	$8,050 ($16,100 family)
ACA limit on OOP expenses	$9,450 ($18,900 family)	$9,200 ($18,400 family)
Limit on amounts newly available under an Excepted Benefit HRA	$2,150 in 2025	$2,100
Health FSA salary reduction max	$3,300 in 2025	$3,200
Health FSA carryover max	$660 in 2025 (carried into 2026)	$640 (carried into 2025)
Transit and parking benefits	$325 in 2025	$315

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Employee Benefits & Executive Compensation Advisory | 2024 Health Benefits Year: A Year to Remember

December 10, 2024

Advisories

By: Steven C. Mindy, John R. Hickman, Ashley Gillihan, Kenneth M. Johnson, Laurie Kirkwood, Amy Heppner

The year 2024 was a tumultuous one for health and welfare benefit guidance, which included disaster relief, a detailed final rule for Mental Health Parity and Addiction Equity Act (MHPAEA) compliance, and a Supreme Court ruling that might impact the interpretation of even well-established benefit regulations. The year ends with uncertainty about whether health savings account (HSA)-compatible high-deductible health plans (HDHPs) will be able to continue first-dollar telehealth coverage for plan years commencing in 2025. HSA vendors also face compliance with the final rule for investment advice fiduciaries, as well as uncertainty about whether the incoming Trump Administration will retain the rule in its current form. Flexible spending accounts (FSAs) and other consumer directed health plans saw guidance on expanding eligible medical expenses, as well as the usual cost-of-living updates. Employers are reminded that they might face a 2024 year-end deadline to amend their cafeteria plans to allow new election change events involving Exchange enrollment.

Health and welfare plans faced increased litigation risks over the past year. More plans found themselves facing litigation involving tobacco use surcharges and wellness programs. Prescription drug coverage was also a source of litigation, as well as regulator involvement, involving plans and their service providers. Such litigation brought renewed focus on health and welfare plan fiduciary committees.

Plans and their vendors saw significant guidance about data privacy and security compliance from multiple federal agencies, including the Department of Labor (DOL) and Department of Health and Human Services (HHS). HHS provided final regulations on reproductive health rights that require plans to act by December 23, 2024. Plans also need to be aware of 2024's Part 2 final regulations for the confidentiality of substance use disorder records, as well as watch out for proposed HIPAA security rule updates at the end of 2024. The DOL also clarified that its cybersecurity guidance applies not only to retirement plans but to all ERISA health and welfare plans.

The year was likely just the beginning of a busy time for health and welfare plan compliance because the incoming Trump Administration is likely to have its own priorities and goals.

Mental Health Parity and Addiction Equity Act Final Rule

The HHS, Labor, and Treasury departments published the final rules on MHPAEA requirements in the *Federal Register* on September 23, 2024 (first issued online for public inspection on September 9, 2024). These lengthy rules primarily focused on requirements for nonquantitative treatment limitations (NQTLs) and the codification of the requirement to perform an NQTL comparative analysis as mandated by the Consolidated Appropriations Act, 2021 (CAA) (and as further described in related

FAQs and self-compliance tools). Although the final rules are generally effective January 1, 2025, some of the requirements are not effective until January 1, 2026, including the requirement that the MHPAEA apply to individual policies of health insurance. See our in-depth advisory Final Mental Health Parity Rules: A Plan Sponsor's Implementation Guide for a detailed explanation of the final rule, including effective dates for various parts of the rule.

What plan sponsors need to be doing now for MHPAEA compliance

- Plan sponsors should be prepared to have an updated comparative analysis completed by the first day of the plan year beginning on or after January 1, 2025. We would expect that all comparative analyses would need to be updated. There are very short turnaround times if a department or a participant or beneficiary asks for this comparative analysis. Now that the rule is final, we anticipate the departments' investigations of plans for MHPAEA compliance will accelerate.
- Agreements with service providers need to be reviewed – in particular, administrative services only (ASO) and third-party agreements (TPA) – to make sure that they are clear on the allocation of responsibilities for preparing a comparative analysis.
- Plan fiduciaries for ERISA-covered plans should be made aware of the certification requirement and the need to engage in "a prudent process to select one or more qualified service providers to perform and document a comparative analysis." That fiduciary certification should be in place on January 1, 2025 for calendar-year plans.
- Work with your ASO or TPA to identify any areas where there may be a plan design issue with the meaningful benefits/core treatment standard and be prepared to address those for plan years beginning in 2026.
- For the design and application requirements, seek verification from the TPA/ASO that they are not using any biased or discriminatory information in designing the NQTL, including historical data.
- There are still many unknowns about the relevant data collection requirement, but at the very least, plans should start collecting the data identified in the final rule as well as other relevant data suggested in the preamble and examples – especially related to the network composition NQTLs. Discuss with the TPA/ASO their ability to collect and analyze the data, including whether they have the technology required for data collection.
- Watch for developments in the courts and whether the final rule is challenged under *Loper Bright* or otherwise. In particular, there may be challenges to the relevant data evaluation and meaningful benefits requirements. Action from the incoming Administration or Congress is also possible, such as under the Congressional Review Act or by administrative procedure.

Loper Bright Enterprises v. Raimondo

In *Loper Bright Enterprises v. Raimondo*, the Supreme Court ruled that courts cannot defer to agency interpretation of laws because a statute is ambiguous. This decision overruled the Court's 1984 decision in *Chevron U.S.A. vs. Natural Resources Defense Council*, which the Court believed was based incorrectly on the assumption that Congress intended to delegate interpretative authority to federal agencies when the law is ambiguous. The Court noted that the Administrative Procedure Act of 1946 requires courts, not agencies, to "decide all relevant questions of law" when reviewing agency action.

Currently, the full impact of the Court's decision on benefits regulations and subregulatory guidance is unknown. Ultimately, it seems likely that parties to litigation will challenge agency interpretations based on *Loper*. The scope of the impact of *Loper* on current and future benefits regulations and guidance is yet to be determined.

Health Savings Accounts, Flexible Spending Accounts, and Other Consumer Directed Accounts

HSA/telehealth extension ends for plan years beginning on or after January 1, 2025

Generally, telehealth services provided before the statutory minimum HDHP deductible is met (except for permissible coverage like preventive care or certain permitted insurance/coverage) can cause a loss of HSA eligibility. The CARES Act

enacted during COVID allows pre-HDHP deductible coverage for telehealth and other remote care services. This provision has been extended twice in the past but is set to expire at year-end for new plan years commencing in 2025. Without a further extension, for plan years beginning on or after January 1, 2025, pre-HDHP deductible coverage for telehealth and other remote care services will disqualify an individual from contributing to an HSA.

Final rule for ERISA investment advice fiduciaries

On April 25, 2024, the DOL published its final rule on the definition of an ERISA investment advice fiduciary. Although most discussions on this final rule focus on ERISA qualified retirement plans, the rule also applies to HSAs. This means entities that provide investment recommendations (which the new final rule broadly defines) and receive compensation must comply with the rule (and prohibited transaction exemption 2020-02) or they risk engaging in a prohibited transaction. The final rule was initially set to begin on September 23, 2024 (150 days after publication), but challenges in two Texas courts have blocked the rule from going into effect. It also remains to be seen if the incoming Administration will retain the rule in its current form. In the meantime, entities that provide investment recommendations to HSAs should get familiar with the new rule and compliance steps for prohibited transaction exemption 2020-02. Also see Interpretive Bulletin 96-1 ,which includes a limited exception for investment education.

Employee choice programs – Private Letter Ruling 202434006

In Private Letter Ruling 202434006, which is binding only on the taxpayer requesting it, the IRS approved an arrangement that allows employees to make an annual irrevocable election to direct employer contributions to an HSA, retiree health reimbursement arrangement (HRA), education assistance program, or the employer 401(k) plan. This arrangement apparently avoids violating the constructive receipt doctrine and HRA rules because the choice is made annually before the start of the calendar year and employees do not have a choice to receive the contribution in the form of taxable income. Compliance considerations for such an arrangement include: the funds must be an *employer* contribution, not salary reduction; the arrangement must conform to plan limits; potential nondiscrimination testing issues; and the variety of choice creating additional administrative complexity.

New eligible expense for HSAs, FSAs, and HRAs, as well as pre-deductible preventive care for HSAs

The IRS issued a safe harbor that treats condoms as medical care under Code Section 213(d). As a result, FSAs, HRAs, and HSAs can now reimburse expenses for condoms. Similarly, the IRS expanded pre-deductible preventive care coverage for HSA-compatible HDHPs to include condoms, as well as over-the-counter oral contraceptives, breast cancer screenings other than mammograms (for example, MRI or ultrasound) for individuals who have *not* been diagnosed with breast cancer, continuous glucose monitors for individuals diagnosed with diabetes (as is the case with other glucometers), and insulin products regardless of whether prescribed to treat an individual diagnosed with diabetes or prescribed to prevent exacerbation of diabetes or development of a secondary condition. However, the IRS did not extend pre-deductible preventive care for HDHPs to include other male contraceptives, such as male sterilization.

Cafeteria plan amendment for enrollment in a qualified health plan

In 2022, the IRS added a new election change event for cafeteria plans to coordinate with enrollment in a qualified health plan through an exchange.

The IRS allowed employers to amend their cafeteria plans for this new election change event at any time on or before the last day of the plan year that begins in 2024. Thus, employers that offered the new permitted election change event for a plan year that begins in 2023 should adopt an amendment and notify participants by the end of their cafeteria plan's 2024 plan year, which for calendar-year plans is December 31, 2024.

Cost-of-living adjustments

The IRS has adjusted certain limits for 2025, including:

	2025	2024
HSA contribution max (including employee and employer contributions)	$4,300 ($8,550 family)	$4,150 ($8,300 family)
HSA additional catch-up contributions	$1,000	$1,000
HDHP annual deductible minimum	$1650 ($3,300 family)	$1,600 ($3,200 family)
Limit on HDHP OOP expenses	$8300 and $16,600	$8,050 ($16,100 family)
ACA limit on OOP expenses	$9,200 ($18,400 family)	$9,450 ($18,900 family)
Limit on amounts newly available under an Excepted Benefit HRA	$2,150	$2,100
Health FSA salary reduction max	$3,300	$3,200
Health FSA carryover max	$660	$640
Transit and parking benefits	$325	$315

Health and Welfare Fiduciary Committees

Litigation aimed at fiduciaries of health and welfare plans was on the rise in 2024, particularly with respect to the cost of prescription drugs and fees paid to pharmacy benefit managers (PBMs). Transparency requirements that went into effect in recent years, which require plans to post their prescription drug costs online, may have played a role, as well as increased scrutiny at the federal level of PBMs generally. When excess fee litigation began to hit qualified retirement plans a couple of decades ago, plan sponsors responded by appointing fiduciary committees to manage and oversee the process of choosing and monitoring plan services providers, but often these committees do not have oversight of the health and welfare plans. These lawsuits serve as a reminder to plan sponsors that ERISA's fiduciary duties also apply to the selection and monitoring of service providers to the health and welfare plans.

Some basic best practices to get started include:

- Formally establish and document a fiduciary committee for the health and welfare plans.
- Consider a committee charter to provide clarification of the responsibilities delegated to the committee and specify any limitations on committee authority.
- Schedule routine committee meetings and maintain a compliance calendar to stay on top of routine compliance items.
- Obtain fiduciary liability insurance for the health and welfare committee. If your organization already has fiduciary liability insurance, check the policy to make sure that it covers the health and welfare plan fiduciaries. Note that fiduciary liability insurance is not the same as an ERISA bond.
- Train fiduciaries on key responsibilities related to their fiduciary duties. Fiduciaries should also be able to identify when an arrangement with a service provider could raise prohibited transaction red flags.
- Hire experts to assist with the selection and monitoring of service providers when the committee lacks expertise.

Tobacco Use Surcharge Litigation

In addition to DOL actions, over 20 class action cases have been filed against plans with tobacco use surcharges. These actions typically have three common claims:

1. The plan did not provide proper notice of a reasonable alternative standard. Regulations require notice of a right to a reasonable alternative standard in all materials describing the terms of the program.

2. The plan did not apply the reward retroactively when the participant satisfied the reasonable alternative standard. Regulations require the same reward to be available to those who complete the reasonable alternative standard.
3. The time for completing the reasonable alternative standard is too short. Notably, the regulations do *not* specify a specific period to complete the reasonable alternative standard.

Plans should review their wellness programs (including tobacco surcharges) to ensure compliance with applicable rules, particularly with respect to reasonable alternative standards. Litigating and settling claims involving tobacco surcharges can be costly. Plaintiffs have even been known to add tobacco surcharge claims to other unrelated claims, such as wage-and-hour claims.

Preventive Services Litigation

In *Braidwood Management Inc. v. Becerra*, the Fifth Circuit held unconstitutional the requirement under the Affordable Care Act (ACA) for plans to provide certain preventive services recommended by the U.S. Preventive Service Task Force (USPSTF). The Fifth Circuit ruled the requirement unconstitutional because the USPSTF's members were not nominated by the President and confirmed by the Senate as required by the Constitution. However, the Fifth Circuit reversed the lower court's earlier decision to vacate all actions to enforce the USPSTF recommendations and enjoin enforcement nationwide. Accordingly, HHS is only enjoined from enforcing the USPSTF recommendations against the parties named in the suit. The Fifth Circuit remanded to the lower court the decision of whether the Constitution requires members of the Health Resources and Services Administration and Advisory Committee on Immunization Practices, which also have input on ACA preventive coverage, to be nominated by the President and confirmed by the Senate.

No Surprises Act Qualifying Payment Amount

The Texas Medical Association (TMA) has launched numerous challenges to the qualifying payment amount (QPA) under the No Surprises Act (NSA). The QPA is used to determine a participant's cost sharing and factors into what the plan pays the provider if a claim goes to the NSA's independent dispute resolution (IDR) process. The Biden Administration lost each of the TMA's challenges involving the QPA in district court. However, in *Texas Medical Association v. Becerra*, the Fifth Circuit reversed the district court and upheld the Biden Administration regulations on several aspects of calculating the QPA.

- "Ghost rates" – These are described as rates for a service negotiated between a provider and a plan/insurer for which there are no actual claims. The district court held these "ghost rates" could not be used in calculating the QPA. The Fifth Circuit ruled they could.
- Incentives – The district court held that risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments must be included in calculating the QPA. The Fifth Circuit said they could be excluded.
- Special case-specific agreements with providers – The district court held that these agreements must be considered when calculating the QPA even though the regulations said they could be excluded. The Fifth Circuit held that they cannot be considered.

The Fifth Circuit also held that plans do not need to provide more information on the QPA than the regulations require currently. However, the Fifth Circuit upheld the district court's decision that a 30-day period for a plan to decide an NSA claim runs from the receipt of the claim rather than 30 days from the receipt of a "clean claim," as the regulations provided. The Fifth Circuit did not address the district court's ruling that a third-party administrator must calculate the QPA on a plan-by-plan basis rather than its entire self-funded plan "book of business." This aspect of the district court's decision appears applicable and could present an issue for smaller self-funded plans in particular. It is not clear how calculating the QPA on a plan-by-plan basis works for a small level-funded plan.

Issues in Prescription Drug Coverage

Prescription drug coverage has been under scrutiny from several directions for the last few years, from PBMs to drug

manufacturer assistance programs. We review where we are and what's ahead in 2025.

Which drugs are EHBs

The final 2025 notice of benefit and payment parameters (NBPP) requires prescription drugs in excess of those covered by a state's essential health benefit (EHB) benchmark plan to be treated as EHBs for non-grandfathered individual and small group insurance market plans. This means drugs in excess of the EHB benchmark must count toward the ACA's maximum out-of-pocket amount (MOOP). Regulators have not applied this requirement to large group and self-funded plans. However, regulators indicated that they intend to propose rulemaking that would apply to large group and self-funded plans. Plans with copay accumulator and maximizer programs in particular should watch for these regulations.

Suits against copay accumulator programs

In late 2023, in *HIV and Hepatitis Policy Institute, et al. v. HHS*, the U.S. District Court for the District of Columbia vacated a 2021 NBPP drafted by the first Trump Administration that allowed plans to exclude manufacturer assistance in calculating the ACA MOOP. HHS dropped its appeal and, consistent with the 2020 NBPP, now plans are not required to count copay assistance for EHBs toward the ACA MOOP if a generic drug is available. If a generic is not available then, under the district court's decision, there is a requirement to count the manufacturer assistance toward the ACA MOOP. In the litigation, however, HHS indicated that, pending final rulemaking, it would not take legal action against employers who continued to not to apply the manufacturer's assistance toward the ACA MOOP in all instances. That informal nonenforcement position of HHS would not apply to private litigants. Additionally, fully insured plans might be required by state law to count copay assistance toward the ACA MOOP. It remains to be seen if and how the incoming Trump Administration will react to the court's decision to vacate its rule.

Note that this applies to the ACA MOOP and not the issue of whether to apply the manufacturer's assistance to the deductible. HDHPs are still prohibited from counting the manufacturer assistance toward the HDHP minimum deductible. This could ultimately create systems issues where "accumulators" are tracked differently – excluding the manufacturer assistances for the deductible but including them for the ACA MOOP.

Attack on rebate retention practices by the Federal Trade Commission

The Federal Trade Commission (FTC) issued an administrative complaint against three PBMs. The complaint alleges that these PBMs "created a perverse drug rebate system that prioritizes high rebates from drug manufacturers, leading to artificially inflated insulin list prices. The complaint charges that even when lower list price insulins became available that could have been more affordable for vulnerable patients, the PBMs systemically excluded them in favor of high list price, highly rebated insulin products." On November 19, 2024, the PBMs filed suit against the FTC in the Eastern District of Missouri, seeking an injunction against the FTC's administrative proceedings. The PBMs allege that the Constitution prohibits the FTC from deciding private rights and revising private contracts. The PBMs also allege that FTC proceedings violate their Due Process rights because the same FTC commissioners that issued the complaint will decide it.

Preemption of state PBM laws by ERISA

In August 2023, in *Pharmaceutical Care Management Association v. Mulready*, the Tenth Circuit reversed a district court's ruling and held that ERISA and Medicare Part D preempted parts of Oklahoma's Patient's Right to Pharmacy Choice Act. At issue are the law's:

- Geographic standards imposed on networks (network access standards).
- Prohibition against requirements or incentives for using a particular network (discount prohibition).
- Any willing pharmacy requirement (AWP).

- Prohibitions against terminating pharmacists from networks because they are on probation.

Oklahoma petitioned for a rehearing and filed a motion to stay so that it could enforce the law, but the Tenth Circuit denied both. In May 2024, Oklahoma petitioned the U.S. Supreme Court for review. The Court has not decided whether to review the case yet, but on October 7, 2024, it invited the U.S. solicitor general to file a brief expressing the views of the United States.

HIPAA Privacy Updates

Reproductive health care updates

HHS published its final HIPAA Privacy Rule to Support Reproductive Health Care Privacy on April 26, 2024. The rule prohibits HIPAA covered entities and their business associates from using or disclosing protected health information (PHI) related to reproductive health care for certain investigatory-type purposes if the health care itself is provided lawfully. For uses and disclosures for certain permitted purposes, the plan will need to obtain an attestation from the requestor even if the PHI is only "potentially" related to reproductive health care. This attestation is not required for uses and disclosures to other covered entities or business associates, but it is still required for uses and disclosures for investigatory-type purposes when the health care was not provided lawfully.

Unless the covered entity is the same person or entity that provided the reproductive health care related to the request, the final rule allows HIPAA-regulated entities that receive such requests to presume that the reproductive health care was provided lawfully. The requestor can provide information to rebut that presumption, but even then, the regulated entity can deny the request.

- The final rule is effective June 25, 2024, and the compliance deadline is generally December 23, 2024.
- The compliance deadline for updating notices of privacy practices (NPP) is February 16, 2026.
- Regulated entities will need to take the following compliance steps by December 23, 2024:
  - Review HIPAA policies and procedures and update to comply with the final rule.
  - Review business associate agreements and amend if inconsistent with the final rule.
  - Train any personnel that handle requests for PHI on the use of attestations and changes to the policies and procedures.

Final Part 2 regulations align with HIPAA rules

On February 16, 2024, HHS, through the Substance Abuse and Mental Health Services Administration and the Office for Civil Rights (OCR), published final regulations on the confidentiality of substance use disorder (SUD) patient records under 45 CFR Part 2. Many of the entities that use, disclose, and maintain SUD records are also covered entities under HIPAA or HIPAA business associates. In general, Part 2 protects SUD information obtained by any federally assisted program and are more stringent than HIPAA. They generally prohibit disclosure of the records in investigations or procedures against the patient without written consent or a court order. The final regulations align aspects of the Part 2 rules regarding patient confidentiality of SUD records with the HIPAA Privacy Rule as required by Section 3221 of the CARES Act.

Plan sponsors need to be mindful of the ways HIPAA Part 2 regulations affect compliance for their own employer health plans. For example, SUD records may be used or disclosed for an employee assistance plan (EAP), or for mental health/substance use disorder benefits offered through the major medical plan. Updates consistent with these new Part 2 requirements include amendments to service agreements and HIPAA business associate agreements for any vendors with access to SUD records. Plan sponsors will also need to update the HIPAA notice of privacy practices, HIPAA policies and procedures, and participant forms.

The Part 2 regulatory update:

- Applies the HIPAA breach notification rules to SUD records.
- Applies HIPAA enforcement approach and authorities (including the HITECH culpability tiers) to noncompliance with Part 2 regulations.
- Allows complaints to HHS regarding SUD records.
- Adds a patient notice obligation for SUD records and allows covered entities to combine with the HIPAA notice of privacy practices.

Enforcement of the Final Part 2 Regulations begins February 15, 2026.

Proposed rule on cybersecurity and expanded OCR enforcement forthcoming

HHS filed recently an abstract of a proposed rule with the White House Office of Information and Regulatory Affairs. According to the abstract, the proposed rule will formalize certain cybersecurity requirements and allow OCR to expand enforcement. The proposed rule is likely a response to the rise of ransomware and hacking incidents to gain access to electronic protected health information. The proposed rule will likely align with HHS's cybersecurity performance goals released earlier this year. The proposed rule may also include HHS's tracking technologies guidance. HHS is expected to publish the proposed rule by the end of 2024.

DOL Cybersecurity Guidance

In September 2024, the DOL clarified that its April 2021 cybersecurity guidance generally applies to *all* employee benefit plans, including health and welfare plans. The DOL intended the 2021 guidance to help plan sponsors, fiduciaries, service providers, and participants in plans safeguard plan data, personal information, and plan assets. The guidance has three parts:

1. *Tips for hiring a service provider*: Includes recommended RFP questions and contract terms for plan sponsors.
2. *Cybersecurity program best practices*:

- Lists 12 cybersecurity best practices for service providers that the DOL would expect to see if auditing the plan or a service provider.
- States that pension and health and welfare plans are tempting targets for cyber criminals because the plans (1) often hold millions of dollars in assets; and (2) store and/or transfer participants' personally identifiable data.

3. *Online Security Tips*: Includes tips for participants and beneficiaries to reduce the risk of fraud.

Health and welfare plans should ensure compliance with the DOL's cybersecurity guidance now that the department has clarified that the guidance does not apply only to retirement plans.

Gag Clause Changes

Group health plans (GHPs) and health insurance issuers must *annually* attest compliance with gag clause prohibitions and submit gag clause prohibition compliance attestations (GCPCAs) by December 31 *every* year. The Centers for Medicare and Medicaid Services says brokers, agents, TPAs, PBMs, and other entities attesting on behalf of GHPs and issuers should notify the GHP or issuer. GHPs or issuers, or those submitting on their behalf, should submit GCPCAs via the CMS portal.

Short-Term, Limited-Duration Insurance Notice Requirement

On March 28, 2024, HHS, the DOL, and the Department of the Treasury released final rules for short-term, limited-duration

insurance (STLDI) and certain fixed-indemnity-excepted benefit coverage. The rule is intended to reduce confusing STLDI and fixed-indemnity coverage with ACA-compliant coverage. For STLDI, the final rule adopted the proposed rule published on July 12, 2023. However, the final rule did not adopt most of the proposed rules for fixed-indemnity coverage, with the notable exception of the proposed rule's notice requirement for fixed-indemnity coverage that as finalized takes effect January 1, 2025.

This notice requirement applies to both plans and insurance issuers. The plan or issuer must display the notice prominently on the first page (either in paper or electronic form, including on a website) of any marketing, application, and enrollment materials provided to participants before the time they are given the opportunity to enroll. The notice must be in 14-point font and include the language in the final rule. Employers should ensure they are in compliance with this notice requirement because it applies to plans and, depending on the circumstances, might not be satisfied by the insurance issuer for their plan.

Although the final rule is in effect, it has been challenged by the American Association of Ancillary Benefits, as well as Manhattan Life Insurance and Annuity Company, in the Eastern District of Texas. In a December 4, 2024 "final judgment" in favor of Manhattan Life, the district court vacated the rule's notice requirements for *fixed-indemnity* insurance policies, but the court did not rule on the notice requirement for STLDI policies. The court ruled that the notice requirement for fixed-indemnity coverage exceeded HHS's statutory authority and was not a logical outgrowth of the compelled notice in HHS's notice of proposed rulemaking. The scope of the court's decision and whether HHS chooses to appeal remain to be seen. Additionally, the court's decision in *American Association of Ancillary Benefits* is still forthcoming.

Disaster Relief Filing Extensions

Deadlines vary depending upon the disaster and locality. Details on all recent disaster relief for presidentially declared disasters are on the IRS's Around the nation page. Currently:

- Taxpayers in all or parts of Connecticut, Florida, Illinois, Kentucky, Louisiana, Minnesota, Missouri, New York, Pennsylvania, Puerto Rico, South Dakota, Texas, Vermont, Virgin Islands, and Washington State have until Feb. 3, 2025 to file their 2023 tax year returns.
- For Hurricanes Helene or Milton, taxpayers in *all of* Alabama, Florida, Georgia, North Carolina, South Carolina, and in affected parts of Tennessee and Virginia will have until May 1, 2025 to file their 2023 tax year returns.

The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area. The DOL automatically recognizes these extensions for Form 5500 filing.

The DOL Employee Benefits Security Administration and the Treasury/IRS also published an extension of time frames in the *Federal Register* on November 8, 2024 for Hurricane and Tropical Storm Helene and Hurricane Milton. These "disaster areas" are those areas designated as eligible for individual assistance by FEMA due to a particular storm. It is narrower in some states than the IRS's tax filing relief. The extension of time frames for relief applies to:

- A participant, beneficiary, COBRA-qualified beneficiary, or claimant in group health plans, disability, and other employee welfare benefit plans (including pension) subject to ERISA or the Internal Revenue Code who (1) *resided, lived, or worked* in one of the disaster areas at the time of the hurricanes or tropical storm; or (2) whose coverage was under an employee benefit plan that was directly affected.
- Group health plans subject to ERISA and the Internal Revenue Code and their sponsors and TPAs *affected by* the hurricanes or tropical storms.

For participants, beneficiaries, COBRA-qualified beneficiaries, and claimants, the DOL and IRS provide mandatory extensions until May 1, 2025 that operate similar to those of the COVID outbreak period in that the "relief period" must be disregarded for certain deadline and timeframes. The agencies give group health plans the ability to disregard a "relief period"

for COBRA election notices.

Please see our advisory for more details: When Disaster Strikes: Issues and Relief for Health Benefit Plans.

ACA Nondiscrimination 1557

On May 6, 2024, HHS finalized the latest rule for nondiscrimination in health programs and activities under Section 1557 of the ACA. Section 1557 prohibits a "health program or activity" that receives federal financial assistance (FFA) from discriminating against an individual on the basis of race, color, national origin, sex, age, or disability. The mandate also applies to a program or activity that is administered by an executive agency or by an entity established by Title I of the ACA. HHS has issued final regulations under Section 1557 twice before – once in 2016 and again in 2020. The 2024 rule resurrects and revises several concepts and policies from the 2016 rule that the 2020 rule had repealed or amended (e.g., notices and grievance procedures). HHS also revised its interpretation of Medicare as constituting FFA (and thus triggering Section 1557) and provisions related to discrimination on the basis of sex.

Generally, any health program or activity that receives FFA from HHS or that is administered by an executive agency or by an entity established by Title I of the ACA is covered by the 2024 rule (with a limited exemption for federal religious freedom and conscience objections).

In a departure from the 2020 rule (and a return to the 2016 rule), the definition of "health program or activity" includes "health insurance issuer," which has implications for insurer TPAs and the self-insured plans they administer.

The 2024 rule does not apply to any "employer or other plan sponsor" of a group health plan with regard to its "employment practices," including the "provision of employee health benefits," which "includes when the Federal financial assistance received is for their employee health benefits." The 2024 rule applies to telehealth and treats Medicare Part B as FFA. What does a covered entity need to do to comply with the 2024 rule?

- Provide an assurance when applying for FFA that it will comply as a condition of receiving the FFA. Duration of this obligation lasts for as long as the FFA is extended.
- If the covered entity employs 15 or more employees, the covered entity must designate a Section 1557 coordinator to ensure compliance, manage the grievance procedure, and coordinate training.
- Implement written policies and procedures, including a nondiscrimination policy, grievance procedures, language access procedures, effective communication procedures, and reasonable modification procedures.
- Provide training to the relevant employees to implement the policies and procedures.
- Provide the following notices:
    - Notice of nondiscrimination, which must include (among other things) how to obtain language assistance services and appropriate auxiliary aids, contact information for the Section 1557 coordinator, and how to file a grievance with the covered entity and a complaint with OCR.
    - Notice of availability of language assistance and auxiliary aids and services.

Conclusion

Those involved with health and welfare plan administration and compliance have a lot to think about before 2024 closes. It's not likely that 2025 will bring any respite for year-end efforts. It seems inevitable that the incoming presidential administration will have new goals and priorities that will require action by health and welfare plans and their vendors.

If you have any questions, or would like additional information, please contact one of the attorneys on our Employee Benefits & Executive Compensation Team.

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