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HEALTH & WELFARE PLAN LUNCH GROUP

September 5, 2024

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1. Health & Welfare Benefits Monthly Update Presentation

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Health & Welfare Benefits
MONTHLY UPDATE

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MONTHLY UPDATE

September 2024 Agenda

- ERISA Investment Fiduciary Cases
- Regulatory Update
- AI in Benefit Plan Administration: It's All Bot Inevitable
- IRA and Creditable coverage notices and impact of Medicare Part D changes
- HIPAA Updates: Reproductive Rights and Part 2 Compliance, Developments with Online Tracking
- ERISA Welfare Fiduciary Cases
- Compliance Grab Bag

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ERISA Investment Fiduciary Cases and HSAs

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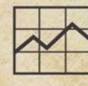

A Little History

- Original definition of fiduciary
  - 1975 5 Part test
    - Investment related recommendation
    - Advice provided on a regular basis
    - Pursuant to mutual understanding
    - The advice will serve as primary basis for decision making
    - The advice is individualized
- DOL believed changes needed
  - Did not apply to rollovers to IRAs
  - Misleading statements and disclaimers regarding fiduciary status made 1975 rule too easy to avoid
  - Environment has changed. In 1975, rule primarily applicable in context of advisers and (more sophisticated) DB plans
- An example: The vacation home chat

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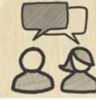

Regulatory Update

Final ERISA Investment Fiduciary Rule

- **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 exception (PTE) 2020-2 "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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When does the Rule apply?

- Effective generally 150 days after published (9/23/24)
  - One year phase in period if comply with Impartial Conduct Standards and acknowledge fiduciary status in writing

- This period is much shorter than period (even without extensions) under 2016 proposal

- But won't the Rule be tied up in litigation?
  - Litigation will most definitely ensue, and many argue that the new Rule is essentially the same as the old Rule invalidated by the Fifth Circuit

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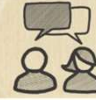

What does PTE 2020-02 Require ?

- Acknowledge Fiduciary Status in writing
  - Must be an actual acknowledgment not a "may be a fiduciary if . . ."
- Impartial Conduct Standard
  - Care and Loyalty obligation (fka "BIC" or "Best Interest" requirement)
  - Reasonable Compensation and Best Execution
  - No Materially Misleading Statements
- Policies and Procedures
- Pre-Transaction Disclosures
  - Care and Loyalty Obligations
  - Fees and Conflicts
- Retrospective annual review and reporting
- 10 year bar on services for certain convictions
  - Including flagrant noncompliance with the rule

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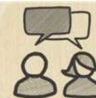

DOL Model Disclosure Form

Model Disclosure Covering Care and Loyalty Obligation

- We are making investment recommendations to you regarding your [HSA] as fiduciaries within the meaning of Title I of the Employee Retirement Income Security Act and/or the Internal Revenue Code, as applicable, which are laws governing retirement accounts. The way we make money or otherwise are compensated creates some conflicts with your financial interests, so we operate under a special rule that requires us to act in your best interest and not put our interest ahead of yours.
- Under this special rule's provisions, we must:
  - Meet a professional standard of care when making investment recommendations (give prudent advice) to you;
  - Never put our financial interests ahead of yours when making recommendations (give loyal advice);
  - Avoid misleading statements about conflicts of interest, fees, and investments;
  - Follow policies and procedures designed
  - Charge no more than what is reasonable for our services; and
  - Give you basic information about our conflicts of interest to ensure that we give advice that is in your best interest;

Additional language required to address

- Material facts related to services and fees
- Material facts related to conflicts of interest

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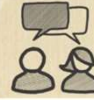

Fiduciary Rule Challenges in Court

- Two separate TX courts have issued stays pending litigation outcome
  - *Fed'n of Am. for Consumer Choice, Inc. v. United States Department of Labor, No. 6:24-cv-00163 (E.D. Tex. July 25, 2024)*
  - *Am. Council of Life Insurers v. United States Department of Labor, No. 4:24-cv-00482-O (N.D. Tex. July 26, 2024).*

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Employee Choice Program - -PLR 202434006

- IRS approves (in PLR) an arrangement that allows annual choice to direct employer funds between HSA, HRA, education/tuition/loans, and employer DC plan contribution
- But Wait! Doesn't that violate constructive receipt and HRA rules?
  - 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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REGULATORY UPDATE

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Regulations Status Update

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.
- 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.
- HHS Office of Civil Rights (OCR) Final Rule on the **HIPAA Privacy Rule and Reproductive Health Care** (Apl. 17, 2023); comment period ended June 16, 2023; Final Rule published in FR on April 26, 2024.
- 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.

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Regulations Status Update

At the Office of Management and Budget

- DOL-EBSA Final Rule for **Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021**; received at OMB July 1, 2024; comment period for proposed rule ended Oct. 17, 2023; meetings currently scheduled through Sept. 13, 2024 (but more could be added; nearly 20 meetings so far).
- HHS-CMS proposed rule **Notice of Benefit and Payment Parameters 2026**; received at OMB July 17, 2024; proposed rule will most likely be published in November/December, based on prior years.
- HHS-CMS proposed rule for **Enhancing Coverage of Preventive Services under the Affordable Care Act**; proposed rule received at OMB Aug. 30, 2024; no sign of final rule for HHS-CMS final rule at OMB for **Coverage of Certain Preventive Services Under the Affordable Care Act** (published Feb. 2, 2023).

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AI in Benefit Plan Administration: It’s All Bot Inevitable

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Role of AI in health plan administration (today)

- Review claims
  - Prior authorizations
  - Utilization management
  - Medical necessity determinations
- Plan design
- Fraud/abuse monitoring
- Customer service
- Underwriting
- Others?

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Liability Hot Spots for Health Plans

- Breaches of fiduciary duty:
  - Failures to process claims in accordance with the terms of the plan
  - Failures to process claims in accordance with other governing instruments (e.g. coverage policy bulletins)
- Administrative and plan design compliance issues
  - Violations of ERISA’s claims procedure rules
    - ERISA demands a “full and fair review” process by a named fiduciary
- Violations of MHPAEA
- HIPAA privacy violations

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Does AI increase or mitigate potential liability?

- Case Studies regarding claims:
  - *Hannah Veinbergs vs. Cigna* (SD of California)
  - *Lokken v. UHC* (District of Minnesota)
  - Snyder v. The Cigna Group, et al. (District Court of Connecticut)
- Each involve systematic denial of claims/prior authorization requests and assert that individual review is required.

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Other considerations

- Can AI/processes decisions satisfy the "fiduciary" standard under ERISA?
  - Is a "human in the loop" approach required?
  - Are risks of overpayments (as opposed to denials) real?
- What HIPAA privacy concerns arise through the use of AI?
- Should service agreements address the use of and risks associated with AI?

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Medicare Part D Update

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Medicare Part D Creditable Coverage: Generally

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a Part D to Medicare (the prescription drug benefit).
- Generally, if enrolled in Medicare Part A or Part B an individual is eligible for Medicare Part D.
- MMA requires group health plan sponsors to disclose to individuals and CMS whether their prescription drug coverage offered under the group health plan is "creditable".
- Disclosure is intended to inform plan participants whether they will have to pay a higher Part D premium if they do not enroll in Part D when first eligible to do so.
- To avoid a penalty, ***once eligible for Part D*** individuals must enroll in Part D within 63 days of the loss of the creditable coverage.

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Medicare Part D Creditable Coverage: Generally

- Once eligible for Part D, an individual cannot switch from a group health plan that was not creditable to one that is credible to avoid the penalty for the months the individual did not have creditable coverage.
  - For example, Bob was in a non-creditable employer group health plan from the age of 65-66 but switches to a creditable plan at ag 67. Bob then applies for Part D benefits. Bob will be assessed a permanent penalty for the months he was in a non-creditable plan.
  - Some have questioned whether, if Bob did not enroll in Medicare Part A or Part B whether he would be considered eligible for Part D. We believe the likely position of CMS is that he was eligible for Part D at age 65.

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Medicare Part D Creditable Coverage: Late enrollment penalty

- The monthly late enrollment penalty is 1% of the monthly “national base beneficiary premium” (this amount changes from year to year: it is $34.70 in 2024) multiplied by the number of full, uncovered months that the individual, after becoming eligible for Part D, was without creditable coverage prior to actually joining a Part D drug plan (and then rounded to the nearest $0.10). The late enrollment penalty is permanent: It is imposed continuously for all months in which the individual remains enrolled in Part D.
- Example—Individual without creditable coverage for 24 months after being eligible for Part D but then enrolls in Part D.
  - Here’s the math: .24 (24% penalty) x $34.70 (2024 base beneficiary premium) = $8.33. $8.33 rounded to the nearest $0.10 = $8.30. $8.30 will then be added to the Part D monthly premium.

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Medicare Part D Creditable Coverage: Plans subject to the notice requirement

- Notice requirement applies generally to group health plans that provide prescription drug coverage.
- Benefits like stand-alone dental and vision, if they offer prescription drug coverage, are subject to disclosure but will almost always be non-creditable.
- HRAs likely cover prescription drugs so they are subject to disclosure, but CMS officials have informally stated that plan sponsors can issue a single, combined disclosure notice covering both an HRA and another group health plan offered by the same employer, if the Part D eligible individual participates in both the group health plan and the HRA.
- Employers cannot say they just do not know whether their coverages is creditable.

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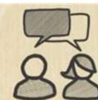

Medicare Part D Creditable Coverage: Timing of notice to individuals

- Notice must be provided:
  1. Before the Medicare Part D annual coordinated election period—beginning Oct. 15 through Dec. 7 of each year (i.e. on or before October 14th),
  2. Prior to an individual's initial enrollment period for Medicare Part D,
  3. Prior to the effective date of coverage for any Medicare-eligible individual who joins the plan,
  4. Whenever prescription drug coverage ends or changes so that it is no longer creditable or becomes creditable,
  5. Upon a participant's or beneficiary's request.
- 1-2 will be satisfied with the annual notice on or before October 14th.
- 3 likely should be included in enrollment materials for new hires.

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Medicare Part D Creditable Coverage: Which individuals are entitled to notice.

- Entitled to a notice if:
  - Enrolled in Medicare Part A or Part B.
  - Lives in a service area of a Part D plan.
- Not limited to retiree plans. Active employees (or their spouses) can be enrolled in Medicare Part A or Part B and the employer would have no way of knowing.
- Employers will likely provide the creditable coverage notice to all participants since it will be unable to determine who is entitled to the notice.

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Medicare Part D Creditable Coverage: Notice to CMS

- Online disclosure to CMS is due no later than 60 days after the beginning date of the plan year (contract year, renewal year, etc.).
- Also, within 30 days of change of the plan's creditable coverage status or termination of a prescription drug plan.

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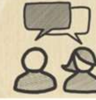

Medicare Part D Creditable Coverage: What coverage is creditable?

- Creditable coverage is when the actuarial value of prescription drug coverage equals or exceed the actuarial value of the defined standard Part D coverage.
- Two ways of determining creditable coverage.
  - Simplified determination method (safe harbor) and actuarial equivalence determination.

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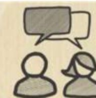

Medicare Part D Creditable Coverage: What coverage is creditable?

- Safe harbor has separate methods where prescription drug coverage is integrated with other group health plan coverage and where it is not.
  - Integration can be a complex determination because it involves lifetime limits and other definitions that are generally not applicable to post-ACA.
  - To be integrated there must be, among other things (a) a combined annual benefit maximum for all benefits under the plan; and/or (b) a combined lifetime benefit maximum for all benefits under the plan.
    - ACA prohibition on lifetime and annual limits and its requirement for maximum out of pocket (MOOP) only applies to essential health benefits (EHBs) and some plans have separate caps or MOOP for non-EHBs so may not be integrated (cap or MOOP does not apply *to all benefits*).
  - If integrated Plan cannot have a deductible in excess of $250.
  - Integrated safe harbor cannot be used for HDHPs which must have a deductible higher than $250. Also, most non-HDHPs will also have a deductible higher than $250.

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Medicare Part D Creditable Coverage: What coverage is creditable?

- Actuarial Equivalence Determination
  - Considered to be creditable if the actuarial value of the coverage equals or exceeds the actuarial value of "*defined standard prescription drug coverage*" using generally accepted actuarial principles and following CMS actuarial guidelines.
  - Standard prescription drug coverage consists of coverage of Part D drugs meeting certain requirements regarding access to negotiated prices, deductibles, cost-sharing, initial coverage limits, annual out-of-pocket thresholds, and protection against high out-of-pocket expenditures.
  - Not an individual-by-individual determination—some individuals may receive less than they would under a Part D plan as long as the plan as whole meets the actuarial equivalence.

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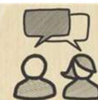

Medicare Part D Creditable Coverage: What coverage is creditable?

- Actuarial Equivalence Determination (cont.)
- Standard prescription drug coverage can change from year to year and employer plan design can change from year to year. So creditable in one year does not mean creditable in the next under actuarial equivalence determination method.
  - Issue brought into sharper focus by changes to standard prescription drug coverage under the Inflation Reduction Act.

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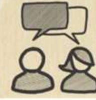

Medicare Part D Creditable Coverage: Effect of the Inflation Reduction Act

- Inflation Reduction Act (IRA) changes to standard Part D prescription drug coverage effective for 2025.
  - A number of changes, but lowers the deductible to $2,000 (inflation adjusted afterward).
  - Also, elimination of the coverage gap phase.
  - ***Changes increased the actuarial value of the Part D standard prescription drug coverage.***
  - Group health plans do not have to match the Part D standard prescription drug program provision by provision (e.g. the $2,000 deductible) but employers need to make sure of actuarial equivalence if they want the plan to remain creditable.
- ***Many group health plans that were creditable in 2024, especially HDHPs, will not be creditable in 2025 because of these changes.***
- CMS guidance makes clear that a group health plan (if it qualifies) can still use the safe harbor method for 2025 but may prohibit use of the safe harbor in future years.

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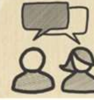
Medicare Part D Creditable Coverage: Effect of the Inflation Reduction Act

- Employer takeaways:
  - Many plans will not or cannot use the safe harbor method so make sure that you have an actuarial determination of creditable coverage.
  - HDHP plans are especially susceptible to being non-creditable.
  - If you want the coverage to remain creditable consider prescription drug enhancements.
  - If the coverage is non-creditable consider a notice that goes into more detail than the model notice on the consequences for coverage being non creditable.
  - Who will perform the creditable analysis—TPA or ASO (is it in the provider contract)? Consultant or broker (is it in the contract)?
  - Remember that enrollment in a Medicare Part D plan will disqualify and individual from making HSA contributions (next slides).



Medicare Coverage and HSA Eligibility

- Medicare enrollment disqualifies and individual from making HSA contributions. Mere Medicare eligibility does not.
- Notice 2004-50
  - Q-2. May an otherwise eligible individual who is eligible for Medicare, but not enrolled in Medicare Part A or Part B, contribute to an HSA?
  - A-2. Yes. Section 223(b)(7) states that an individual ceases to be an eligible individual starting with the month he or she is entitled to benefits under Medicare. Under this provision, mere eligibility for Medicare does not make an individual ineligible to contribute to an HSA. Rather, the term "entitled to benefits under" Medicare means both eligibility and enrollment in Medicare. Thus, an otherwise eligible individual under section 223(c)(1) who is not actually enrolled in Medicare Part A or Part B may contribute to an HSA until the month that individual is enrolled in Medicare.

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Medicare Coverage and HSA Eligibility

- Notice 2008-59
- Q-5 Does an individual fail to be an eligible individual merely because the individual is eligible for, but not enrolled in, Medicare Part D (or any other Medicare benefit)?
  - A-5. No. However, an individual is not an eligible individual under § 223(c)(1) in any month during which such individual is both eligible for benefits under Medicare and enrolled to receive benefits under Medicare. See also Notice 2004-50, Q&A-2 and 3, regarding Medicare Parts A and B.
- Q-6. Does an individual fail to be an eligible individual merely because the individual is enrolled in Medicare Part D, or any other Medicare benefit?
  - A-6. Yes. Under § 223(b)(7), an individual who is enrolled in Medicare is not an eligible individual in any month during which the individual is enrolled in Medicare.

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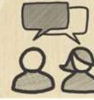

Medicare Coverage and HSA Eligibility

- Individuals that enroll in Social Security benefits will automatically be enrolled in Medicare Part A.
  - Medicare Part A generally cannot be waived if receiving Social Security benefits.
- If an individual delays Social Security benefits and Medicare coverage until after age 65 and then applies for Social Security benefits enrollment in Medicare Part A is ***retroactive to the month the individual turned 65 or for six months, whichever*** **is less. The individual will be retroactively disqualified from making HSA contributions.**
  - If over age 65 individual will generally want to stop HSA contributions six months before they collect Social Security.
  - If contributions continue, they will be "excess contributions" and subject to a 6% excise tax for each year until the contributions (and earnings are removed.). If excess contributions and earnings are removed before an individual's tax return is due (i.e. April 15th) then there will be not excise tax.
- If an individual is eligible for Medicare but has not filed an application for either Social Security benefits or Medicare, he or she does not need to do anything. The individual can open/contribute to the HSA and postpone applying for Social Security and Medicare until he or she stops working. There is no penalty for this delay for Medicare Part B as long as an individual covered by an employer's group health plan (but see prior slides on Part D).

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HIPAA Updates: Reproductive Rights and Part 2 Compliance, Developments with Online Tracking

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 is effective June 25, 2024, and the compliance deadline is December 23, 2024.
- The compliance deadline for updating Notice of Privacy Practices ("NPP") is February 16, 2026.
- 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.

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Reproductive Health Care

- The Rule adds a new defined term—"reproductive health care"—and limits the use and disclosure of PHI containing information about ***lawfully*** provided reproductive health care.
- "Reproductive health care" is that which affects the health of an individual in all matters relating to the reproductive system and to its functions and processes.
- Examples given in the regulations:
  - contraception, including emergency contraception;
  - preconception screening and counseling;
  - management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination;
  - fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components (e.g., in vitro fertilization);
  - diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis); and
  - other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products) .

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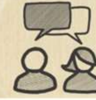

The Rules Prohibits Certain Uses and Disclosures of PHI

The Rule prohibits regulated entities from using or disclosing reproductive health care for:

- the purpose of identifying any person in a criminal, civil or administrative investigation, or
- imposing liability on any person for "the mere act" of seeking, obtaining, providing, or facilitating reproductive health care.

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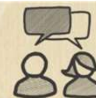

Presumption of Lawfulness

- The reproductive health care must be ***lawful*** for the prohibition on uses and disclosures to apply.
- If the plan sponsor or TPA receiving the request for PHI did not actually provide the reproductive health care, then a ***presumption of lawfulness*** applies if the following can be reasonably determined:
  - The regulated entity does not have actual knowledge that the health care was unlawful under state or Federal law under the circumstance; and
  - Does not have factual information from the person requesting the PHI that the reproductive health care was not lawful under the specific circumstances in which it was provided.
- This presumption of lawfulness applies until the person requesting the PHI can provide additional information to overcome the presumption.
- Even if the person requesting the PHI can overcome the presumption, or even if the regulated entity has actual knowledge that such care was not lawful, the regulated entity is not required to provide the PHI to the requester.
- The Rule only permits, and does not require, the regulated entity to use or disclose reproductive health care PHI if such care was unlawful.

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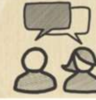

Attestation Required for Certain Permitted Purposes

- The Rule adds an attestation requirement for certain *permitted* purposes for PHI that may be "potentially related" to reproductive health care.
- The attestation requirement applies when the PHI is requested for:
  - health care oversight,
  - judicial and administrative proceedings,
  - law enforcement purposes, and
  - decedents to coroners and medical examiners.
- Upon receiving such a request, the regulated entity must first determine that the use or disclosure of any PHI "potentially related" to reproductive health care is not for a prohibited purpose.
- If it is not for a prohibited purpose, the regulated entity must then obtain a valid attestation from the person requesting the PHI verifying that the purpose is permissible.

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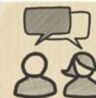

Attestation Required for Certain Permitted Purposes

- The attestation generally must include:
  - a statement that the use or disclosure is not for a prohibited purpose, and
  - a statement that the requester may be subject to criminal penalties if he or she knowingly and in violation of HIPAA obtains the information or discloses it to another person.
- Compound attestations are generally invalid with some exceptions.
- No attestation can be valid if a "reasonable" regulated entity would not believe the attestation is true (or has actual knowledge that it is not true).
- HHS issued a model attestation form, which can be accessed here.

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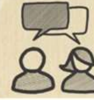

Notice of Privacy Practices

The Rule includes changes that covered entities must make to their NPP by February 16, 2026.

- Plan sponsors will need to update their NPPs to add a description, including at least one example of:
  - the types of uses and disclosures of reproductive health care PHI that the Rule prohibits;
  - the types of uses and disclosures for which an attestation is required.
- A statement explaining to individuals that PHI disclosed pursuant to the Privacy Rule may be subject to redisclosure and no longer protected by HIPAA's privacy rule.

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Next Steps

Regulated Entities will need to take the following compliance steps:

- Update NPPs
- Review HIPAA policies and procedures
- Review business associate agreements and amend to ensure compliance
- Train any personnel that handle requests for PHI on the Rule's requirements.

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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.

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Final Part 2 Regulations Align with HIPAA

Highlights to the Final Part 2 Regulations:

- 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 NPP.
  - Content requirement for the patient notice and the NPP will be discussed in future guidance by HHS/OCR.

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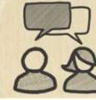

Final Part 2 Regulations Align with HIPAA

- Importantly, the new regulations allow a single patient consent for future uses and disclosures for treatment, payment, and health care operations (TPO) under Part 2 and HIPAA.
- HIPAA covered entities and business associates that receive records under this consent may redisclose the records in accordance with the HIPAA regulations, but cannot use or disclose such records for civil, criminal, administrative, or legislative proceedings *against the patient.*
- Segregation of records received by a covered entity or business associate under this consent for TPO is not required.
  - ***Caution:*** SUD records disclosed under a consent for TPO still retain the continuing prohibition on use and disclosure of the records in investigations or proceedings against the patient. Thus, covered entities and business associates will need to ensure that the SUD records can be tracked within their data systems to prevent impermissible disclosures.

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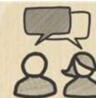

Potential Impact on Health Plans

- SUD records may be used or disclosed with respect to an employee assistance plan (EAP), or for mental health/substance use disorder benefits offered through the major medical plan.
- Updates require 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 following documents:
  - Notice of Privacy Practices
  - HIPAA Policies and Procedures Manual
  - Participant forms

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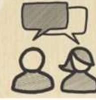

Updates to HHS Guidance on HIPAA Tracking Technologies

- On June 20, 2024, the U.S. District Court for the Northern District of Texas issued an order declaring unlawful and vacating a portion of HHS' guidance document regarding use of third-party tracking technologies. *See Am. Hosp. Ass'n v. Becerra*, (N.D. Tex. June 20, 2024).
  - Online third-party tracking technologies such as cookies, tracking pixels, web beacons, session replay scripts, and fingerprinting scripts through websites or mobile apps collect and analyze info about user interaction with an entity's websites or mobile apps and then send info directly to 3rd party developers, which may continue to track users even after the user navigates to other websites.
- OCR's view is that information collected from covered entity's publicly accessible, unauthenticated webpage could be IIHI/ePHI ***even if a user has no current relationship with the covered entity***, and even if the user does not actively provide any specific health care information.
- The Court vacated OCR's 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." *Id.* at *2.
- HHS is evaluating its next steps in light of the order.

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ERISA Welfare Plan Fiduciary Cases

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Litigation Update: Fiduciaries, Fees, and…Fingolimod?

- Two recent lawsuits allege claims for fiduciary breaches for failure to monitor PBMs and negotiate lowest prescription drug prices
  - For example, a 90-day supply of fingolimod costs nearly $10,000 through one plan, while a competing pharmacy charged only $648 even for uninsured patients.
- 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.

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Litigation Update: Rx Cost

- Do fiduciaries really need to compare every single drug in the formulary to competitors? Complaints focused on
  - Benchmarks—NADAC vs. AWP (National Average Drug Acquisition Cost vs. Average Wholesale Price)
  - Rebates—Are they pass-through? How are rebates defined?
  - Steering—Sending beneficiaries to higher-priced pharmacies for specialty drugs and refusing to cover specialty drugs obtained elsewhere.
- Plaintiffs are accessing publicly available information to make side-by-side comparisons of drug costs.
- Too soon to know whether possible counterarguments will prevail (e.g., plan is better off as a whole under the arrangement)

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Litigation Update: Fiduciary Processes

- Complaint alleges the fiduciary processes were "fundamentally flawed"
  - Defendant didn't take advantage of leveraging power to negotiate better deal
  - Defendant failed to prudently exercise their rights under the contract
    - What are your plan's audit rights? Do you exercise them to monitor and follow-up with your service provider?
  - Plaintiffs seemed fixed on pass-through PBMs and carve-out specialty programs as superior to defendant PBMs
  - Defendant renewed contract without conducting open RFP
    - Will routine RFPs become the standard for a "prudent process" for H&W plans?

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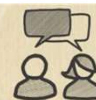

Litigation Update: Prohibited Transactions

- Reasonable Arrangements with third-party service providers: ERISA §408(b)(2) provides an important statutory exemption that accommodates service contracts or arrangements between a plan and a party in interest for office space, legal, accounting, or other services if—
  - the contract or arrangement is reasonable;
  - the services are necessary for the establishment or operation of the plan; and
  - no more than **reasonable compensation** is paid for the services.
- What is a "reasonable" contract or arrangement?
  - Certain disclosures must be made.
  - Plan must be able to terminate the contract on reasonably short notice and without penalty (recoupment for reasonable startup costs is permitted)
  - "Reasonable" arrangement is not enough if service provider is also a plan fiduciary.
- Are the services "necessary" for the establishment or operation of the plan?
  - Services must be "appropriate and helpful" to the plan in carrying out its purpose.
- What is a "reasonable" compensation?
  - Cases-by-case and fact & circumstances.

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Best Practices: Monitoring of Service Providers

- Access to claims data.
  - Verifying that the plan is paying medical providers the correct amount.
  - What does your services agreement say?
  - How often can you audit? How many claims?
  - What are the restrictions on the audit results and expanding the audit?
  - What is the remedy under the agreement if claims are erroneously paid or paid at the incorrect amount?
  - Employers/plans in current litigation with ASOs/TPAs on allegedly failing to provide claims data as well as erroneous payment of claims.

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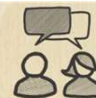

Best Practices: Service Provider Fees

- Compare all services to be provided with the total cost for each provider.
- Consider whether the estimate includes services that were not requested or are not wanted.
- If not covered under the CAA's ERISA §408(b)(2) disclosures, ask prospective providers whether they receive any third-party compensation, such as finder's fees, commissions, or revenue sharing. Establish a process to regularly monitor plan fees for reasonableness.
- Look at payments to subcontractors and any related parties.
- Consider conducting an RFP every few years (or use a consultant) to benchmark fees, compare available pricing options and service providers, and evaluate negotiated pricing for products and services accessed through the service provider.
- No contract with a service provider is reasonable unless it provides for "termination by the plan without penalty to the plan on reasonably short notice under the circumstances to prevent the plan from becoming locked into an arrangement that has become disadvantageous."

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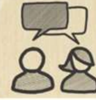

Best Practices: Service Provider Fees

- Fees based on "shared savings". For example, a fee based on 25% of the difference between billed charges and what was allowed for an out of network provider. Fees as a percentage of any class action recovery on behalf of the plan. Fees as a percentage of subrogation or reimbursement.
  - Not prohibited but ask for estimates and ongoing reports.
- What is the fee for engaging in the IDR process.
- For PBMs look at:
  - Spread pricing (charging the plan a higher price for medications than what they pay to pharmacies and keeping the difference).
  - Manufacturer's rebates. How are they defined and who keeps them.
  - Proprietary specialty pharmacies.

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Compliance Grab Bags

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Compliance Deadlines for Fall 2024

Although the 2024 Rule is generally effective on July 5, 2024 (60 days after its May 6th publication in the Federal Register), the complexities of this rule require separate effective dates for various provisions:

ITEM	DEADLINE
Summary Annual Report	Due **September 30**, unless Form 5500 is extended. If the Form 5500 is extended by timely filing Form 5558, due **December 16** (normally December 15, but it falls on a Sunday).
Medicare Part D Creditable Prescription Drug Coverage Notice	Furnish to Medicare beneficiaries seeking enrollment in a health plan that provides prescription drug coverage prior to **October 15**
Form 5500 (if extended)	**October 15**
Massachusetts HIRD Form	Must file no later than **December 15, 2024**
California Flexible Spending Account Notice	Notify FSA participants of rules regarding withdrawal of funds before end of the plan year.

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Compliance Deadlines HIPAA Reproductive Rights Final Rule

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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Compliance Deadlines for ACA 1557--Nondiscrimination in Health Programs and Activities

Although the 2024 Rule is generally effective on July 5, 2024 (60 days after its May 6th publication in the Federal Register), 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.
§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. [NOTE: The table in the final rule says no later than one year of July 5, 2024, but the rule itself clearly says 300 days]
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.

Disaster Relief Filing Extensions

- Weather-related disasters extended several filing deadlines (hurricanes Debby and Ernesto; storms in the Midwest). Those in designated areas have until February 3, 2025, to file various individual and business tax returns, including Form 5500s (normally due October 15, if an extension was filed), and make tax payments originally due within the applicable period.
  - U.S. Virgin Islands and Puerto Rico from **August 13, 2024**-February 3, 2025
  - All of Vermont from **August 8, 2024**-February 3, 2025
  - 66 counties in North Carolina from **August 5, 2024**-February 3, 2025
  - All 46 counties in South Carolina and 55 counties in Georgia from **August 4, 2024**-February 3, 2025
  - 61 counties in Florida from **August 1, 2024**-February 3, 2025
  - Certain parts of Minnesota and South Dakota from **June 16, 2024**-February 3, 2025
- The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area. Visit https://www.irs.gov/newsroom/tax-relief-in-disaster-situations for more information.

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Other Updates—Gag Clause Instructions

DOL, HHS, and IRS jointly updated the Submission Instructions and User Manual for the Gag Clause Prohibition Compliance Attestation (GCPCA):

- Webform and template allow for precisely defining the date range to which the attestation applies.
- Employer plan types are expanded to include 3 categories for GHPs: (1) ERISA group health plan (GHP) or sponsor of ERISA plan,* including a plan sponsored or established by a union; (2) (Non-Federal) governmental group health plan; (3) Church plan
- "Reporting Entity" changed to "Responsible Entity" and Responsible Entity types expanded in the instructions to clarify that ERISA group health plan (GHP), or sponsor of ERISA plan, includes a plan sponsored or established by a union.
- Clarified labels in webform and template regarding types of provider agreements: (1) Medical network; (2) Pharmacy benefit manager network; (3) Behavioral health network; (4) Other
- Modified attestation language to remove forward-looking agreement actions to accommodate date range and information provided through the submission process: I attest that […] the group health plan(s) […] on whose behalf I am signing ~~will not enter into an agreement, and has not, subsequent to December 27, 2020~~has not, for the dates specified and as provided in the foregoing information, entered into an agreement with a health care provider, network or association of providers […]

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2024-2025 Cost-of-living Adjustments

	2025	2024
HSA contribution max (including employee and employer contributions)	4300/8550 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	1650/3300 in 2025 Rev Proc 2024-25	$1,600 ($3,200 family)
Limit on HDHP OOP expenses	$8300 and 16,600 in 2025 Rev Proc 2024-25	$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	$2150 in 2025	$2,100
Health FSA salary reduction max	TBD est 3300 in 2025	$3,200
Health FSA carryover max	TBD est 660 in 2025	$640
Transit and parking benefits	TBD est 325 in 2025	$315

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Questions

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