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Health and Welfare Plan Compliance FAQs

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What Information is Contained within the Recently Released Final Rules on the Mental Health Parity and Addiction Equity Act (MHPAEA)?

Mental Health Parity (MHPAEA) – Generally

MHPAEA: Current Rules

"A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation."

(Treas. Reg. §54.9812-1(b)(1(i))

MHPAEA: Financial-QTL-NQTL

Three Elements of Parity between MH/SUD Benefits and M/S Benefits

1. Financial Requirements (e.g., Copays/Deductibles/MOOPs)
2. Quantitative Treatment Limitations (QTLs) (e.g., Number of Visits)
3. Non-Quantitative Treatment Limitations (NQTLs) (e.g., Prior Authorizations)
    - » Plan sponsors must perform a comparative analysis for NQTLs that can be provided to the Departments/State authorities

MHPAEA: Current Rules

REQUIRED CLASSIFICATIONS OF BENEFITS USED:

- Inpatient, In-Network
- Outpatient, In-Network
- Emergency Care
- Inpatient, Out-of- Network
- Outpatient, Out-of-Network
- Prescription Drug Formularies

MHPAEA: Final Rules

Final Rules Focus on Comparative Analysis of NQTLs for MH/SUD Benefits and M/S Benefits

Generally, a plan must ensure that, as written and in operation, any NQTL that is applied to MH/SUD benefits is comparable to, and applied no more stringently than, the M/S benefits offered under the plan pursuant to the MHPAEA rules. Although a requirement for health plans to perform and document a comparative analysis between NQTLs that apply to MH/SUD benefits and those imposed on M/S benefits already existed, final rules adopted further instructions and clarifications on what information should be included in a health plan's required comparative analysis.

MHPAEA: Six Elements of NQTL Analysis

Six elements must be contained in NQTL Comparative Analysis (Effective for PYs beginning on or after 1/1/25, except Relevant Data Requirement effective for PYs beginning on or after 1/1/26).

A description of the NQTL

The identification and definition of the factors used to design or apply the NQTL

A description of how factors are used in the design or application of the NQTL

A demonstration of comparability and stringency, as written

A demonstration of comparability and stringency in operation

Findings and conclusions

MHPAEA NQTL: Reasoning Behind NQTL

EFFECTIVE JANUARY 1, 2025

Generally, a plan must ensure that, as written and in operation, any NQTL applied to MH/SUD benefits is comparable to, and applied no more stringently than, the M/S benefits offered under the plan pursuant to the MHPAEA rules.

- Evidentiary Standards
- Factors
  - » Does not include information that was considered early on in the “design process” but focuses more on information that the plan “relied upon and rejected.”
- Processes
- Strategies

Health Plans Must Perform Comparative Analysis on NQTL

Therefore, anything used by a plan to decide whether to apply an NQTL should be **considered and** documented within a health plan’s comparative analysis and will be considered a process, strategy, evidentiary standard, or factor (or as a basis for these standards).

This includes information that the plan/issuer considered but ultimately rejected in their consideration when implementing an NQTL.

MHPAEA and ERISA Fiduciary Duties

MHPAEA: ERISA and Fiduciary Responsibilities

ERISA AND MHPAEA ANALYSIS

Effective first day of PYs beginning on or after January 1, 2025

- **ERISA Plans -** NQTL comparative analysis needs to include a certification by a "named fiduciary" as part of the Findings and Conclusions. Certification confirming the fiduciary'sr engagement in a prudent process to select one or more qualified service providers to perform and document an NQTL comparative analysis, as well as a duty to monitor these service providers.

- According to the preamble, the DOL expects the plan fiduciary making the certification will, at a minimum:

  - Review the comparative analysis

  - Develop an understanding of the findings and conclusions; and

  - Ensure that the third party responsible for the comparative analysis provides assurances (to the best of its ability) that the comparative analysis complies with the MHPAEA rules.

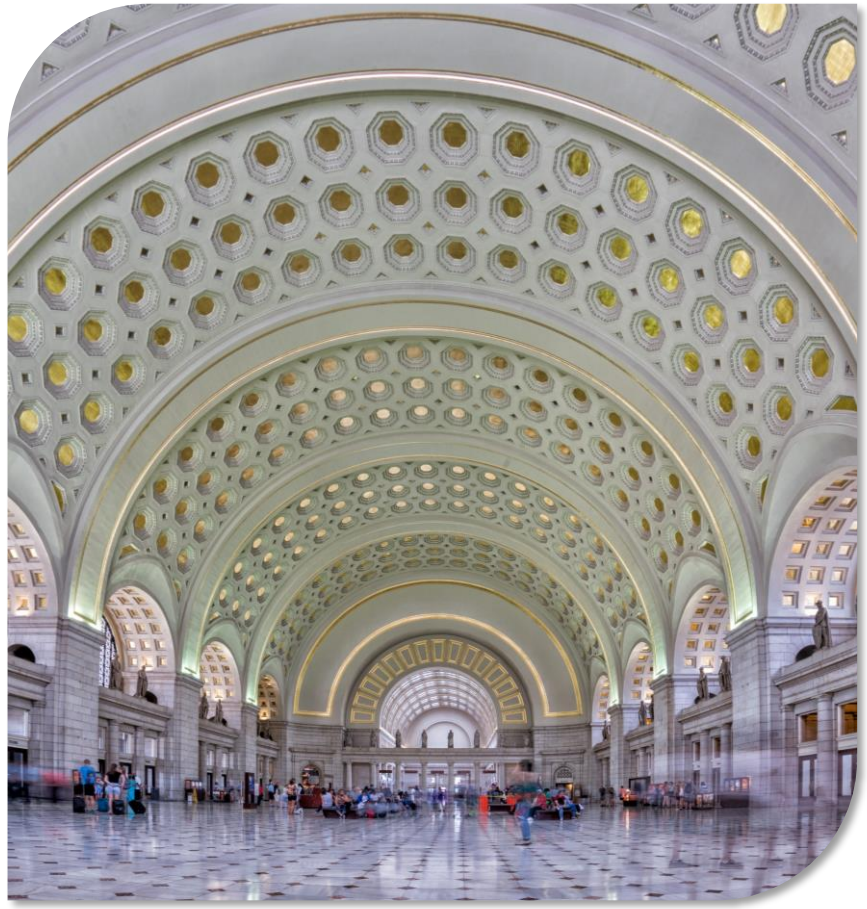
Mental Health Parity (MHPAEA) – NQTL Comparative Analysis Deadlines

NQTLs and The Comparative Analysis

Requirement for Production of NQTL Comparative Analysis to Governmental Agencies

Plans and issuers must provide a plan's NQTL comparative analysis to a requesting governmental agency within ten (10) business days of a request for such information. Further, the final rules state that if a plan fails to submit sufficient information to the government agency to prove that a comparative analysis was performed by the plan, the plan must provide additional information to the agency within ten (10) business days of that demand.

The Departments emphasize in the preamble that a plan/issuer is statutorily required, even if a governmental agency does not request such comparative analysis, to perform and document the NQTL comparative analysis. Plans, therefore, should have been completing the NQTL comparative analysis since February 2021 and should currently be able to provide their comparative analyses to plan participants and the government.(Preamble, Final Rules)



What Implications does the Loper Bright case have on Health and Welfare Benefits?

Loper Bright: Chevron Doctrine Overturned

Background

For approximately 40 years, the *Chevron* doctrine was in place, requiring courts to give deference to certain federal agencies when interpreting a statute that was vague, ambiguous, or silent as to a particular part of the law.

Chevron Doctrine Overturned

Loper Bright case overturned the *Chevron* doctrine, so courts no longer are required to give deference to certain federal agencies when interpreting a statute that is vague, ambiguous, or silent as to a particular part of the law.

Practical Application

- Even before *Loper Bright*, litigants could bring a case to challenge the federal regulations. However, some predictability as to how a court would rule existed under the *Chevron* doctrine
- **The consequences of this case on employee benefit plans is yet to be seen, but most likely this means there will be more court challenges to federal agency regulations, and less predictability than before as to the result of those challenges**

Loper Bright: Chevron Doctrine Overturned

Examples of Legal Challenges to Regulations Imposed on Employee Health and Welfare

Benefit Plans Post-*Loper Bright*

- ACA Section 1557 – Nondiscrimination in health programs and activities (current stay on this law under multiple district courts)
- Mental Health Parity and Addiction Equity Act (MHPAEA) NQTL Regulations
- ACA Essential Health Benefits – Prescription drugs offered under large group and self-funded health plans

Medicare Part D (Prescription Drug Coverage) FAQs

Medicare Part D FAQs

What are the 2025 Medicare Part D prescription drug coverage changes?

- Inflation Reduction Act changes to Medicare Part D effective January 1, 2025 will increase the actuarial value of Medicare Part D prescription drug coverage, which may affect whether a group health plan's prescription drug benefits are creditable for plan years beginning in 2025
  - » "Creditable coverage" must provide an actuarial value that is at least equivalent to Part D coverage
  - » Simplified determination method may be applied in some cases
  - » Part D coverage changes may affect actuarial value/eligibility for Retiree Drug Subsidy program, Part D beneficiary notices and CMS annual disclosure

- Sponsors of retiree drug benefit plans may need to update their plan designs to comply with the minimum standards to qualify for the CMS Retiree Drug Subsidy (RDS) payment

Enrollee Cost Share[3]:

Phase	2024	2025
Deductible	$545	$590
Initial Coverage	Member pays 25% of total drug costs for brand and generics, up to $5,030 in total drug cost (incl. deductible) to member and plan	Member pays 25% coinsurance until $2,000 member out of pocket maximum is reached
Out-of-Pocket Maximum	$8,000	$2,000
Coverage Gap	Member pays 25% of generic drugs, 70% manufacturer's discount on brand drugs, until total member out-of-pocket reaches $8,000	Eliminated
Catastrophic	20% of total drug costs above $8,000 member OOP	0% (Plans typically pay 60% of total cost of covered drugs) New manufacturer's discount program (generally, 20% for applicable drugs, with CMS providing a 20% reinsurance subsidy)

[3] *Maximum drug costs to enrollees under standard benefit design. Actual Part D/Medicare Advantage Rx plan design may vary.*

Medicare Part D FAQs

How do we know if creditable coverage status for the prescription drug benefits under our group health plan is affected?

2009 (current) guidance includes two methods for determining whether a group health plan's drug benefits are creditable:

- Simplified determination (slightly different rules for integrated vs. non-integrated medical/Rx coverage) or
- Actuarial determination (required for plans receiving Retiree Drug Subsidy (RDS) payments from CMS)

Integrated Plans

A plan may be considered an integrated plan when the prescription drug benefit is combined with other coverage offered by the entity (i.e., medical, dental, vision, etc.), if the plan has all of the following plan provisions:

1) a combined plan year deductible for all benefits under the plan,
2) a combined annual benefit maximum for all benefits under the plan, and
3) a combined lifetime benefit maximum for all benefits under the plan)

Non-integrated Plans

A plan that is not considered integrated on the left- hand side of this chart would be considered a non-integrated" plan

Medicare Part D FAQs

What is "creditable coverage" under the "Simplified Determination Method?"

Integrated Plans	Non-integrated Plans
(1) Coverage for brand and generic Rx	Coverage for brand and generic Rx
(2) Reasonable access to retail providers	Reasonable access to retail providers
(3) Designed to pay on average at least 60% of participants' Rx expenses	Designed to pay on average at least 60% of participants' Rx expenses
(4) Plan has: • Combined medical/Rx plan year deductible for all benefits under the plan, not to exceed $250 • No annual benefit maximum, or a combined medical/Rx maximum annual benefit of at least $25,000, and • No less than a $1 million lifetime combined medical/Rx benefit maximum	Satisfies at least one of the following: (a) Plan has no annual prescription drug benefit maximum or a maximum annual benefit payable by the plan of at least $25,000, or (b) Plan has an actuarial expectation that the amount payable by the plan will be at least $2,000 per Medicare-eligible beneficiary

Medicare Part D FAQs

How will creditable coverage be determined in 2025 and later years?

- Per CMS Calendar Year 2025 Part D Redesign Program Instructions:
  - If a plan is found to be creditable under the simplified determination method, it would be considered creditable until December 31, 2025, regardless of whether the plan meets creditable coverage standards under the actuarial method*
    - If the plan cannot be determined to be creditable based on simplified determination method, either plan is non-creditable or an actuarial valuation may be sought to discover whether a plan may be considered creditable based on the actuarial value method
    - To be reevaluated for 2026 and later plan years
  - No changes to CMS policy relative to actuarial value
    - For group health plans who are applying for the RDS, updated benefit design may affect whether plan's Rx benefits are actuarially equivalent to Part D coverage
    - Guidance clarifies that manufacturers' discounts are NOT included in actuarial value, but federal reinsurance subsidies (RDS) are included in the plan paid amount

**Relief does not apply to group Medicare Advantage plans (also referred to as Employer Group Waiver plans, or "EGWPs")*

Medicare Part D FAQs

What notice requirements apply to health plan sponsors?

- Notice of creditable or non-creditable prescription drug coverage must be provided to Medicare-eligible participants and beneficiaries:
    1. Before the start of the Medicare Part D annual coordinated enrollment period (ACEP)*. The ACEP begins October 15 and runs through December 7 for Medicare prescription drug coverage (Part D) and Medicare Advantage plans (Part C) effective the following January 1;
    2. Before the individual's initial Medicare enrollment period;
    3. Prior to the effective date of the individual's coverage under the employer's health plan;
    4. Upon request; and
    5. Within 30 days of the date creditable status for the prescription drug coverage provided by the health plan changes.
- If creditable coverage status changes for plan years beginning on or after 1/1/2025, updated Part D notices must be distributed.

*If the creditable/non-creditable coverage disclosure notice is provided to ***all plan participants annually***, CMS will consider disclosure requirements 1 and 2 to have been satisfied.

Medicare Part D FAQs

How does the creditable or non-creditable determination affect Medicare-eligible participants and beneficiaries?

If coverage remains creditable for 2025 plan year:

- Individuals covered by the group health plan will receive a notice (from the employer) stating that the coverage in which they are enrolled is creditable.
- Employees and covered family members can stay on their existing plans with no late enrollment penalties when they do sign up for Medicare Part D if they sign up for Part D coverage with a gap of no more than 63 days since the last date the individual was enrolled in creditable coverage. If there is more than a 63-day period where the individual was not enrolled in creditable coverage, a surcharge (penalty) for late enrollment applies.
  - The late enrollment penalty for Medicare Part D is 1% of the base national monthly Part D premium (the Part D base beneficiary premium will be $36.78 in 2025) for each month there was no creditable or Part D coverage.
  - The penalty applies for as long as the beneficiary has Part D coverage.

If coverage becomes non-creditable for the 2025 plan year, for an individual to avoid late enrollment penalties:

- Individuals covered by the group health plan will receive a notice (from the employer) stating that the coverage in which they are enrolled is non-creditable.
- Employees can stay on their existing plans and enroll in Medicare or enroll in Medicare and waive the group health plan

Medicare Part D FAQs

Is there a Medicare special enrollment that applies?

- If an employee or employee's covered spouse or dependent is eligible for Medicare due to age or disability, there is a special enrollment period that allows an individual to enroll in Medicare outside of Medicare initial and open enrollment
  - » For Medicare Part D, the special enrollment window is two months after losing other creditable prescription drug coverage.
  - » Late entrants can sign up during the annual general enrollment period that runs from October 15 through December 7 each year, with coverage starting January 1.
- To enroll in Medicare Part D prescription drug coverage, Medicare Part A Hospitalization coverage and Part B Medical coverage are also required. There is no late enrollment penalty for Part B coverage when coverage is delayed on account of group health plan enrollment during active employment.
- Medicare Part B has a special enrollment window (with no penalties) that applies each of the following times:
  - » any time the individual is covered by a group health plan due to active employment, and
  - » within eight months of the earlier of the date the individual is no longer actively working or when the person is no longer eligible for coverage due to active employment.

What are the ERISA Fiduciary Rules?

ERISA Plans

All employee health and welfare benefit plans of private employers (both for-profit and not-for-profit) are subject to ERISA.

There are two kinds of health plans *exempt* from ERISA:

1. Church Plans
2. Governmental Plans

ERISA Plan Fiduciary

ERISA §402

Named Fiduciaries

(1) Every employee benefit plan shall be established and maintained pursuant to a written instrument. Such instrument shall provide for one or more named fiduciaries who jointly or severally shall have authority to control and manage the operation and administration of the plan.

(2) For purposes of this subchapter, the term "named fiduciary" means a fiduciary who is named in the plan instrument, or who, pursuant to a procedure specified in the plan, is identified as a fiduciary (A) by a person who is an employer or employee organization with respect to the plan or (B) by such an employer and such an employee organization acting jointly.

Plan **must** have at least one fiduciary named in the written plan or identified through a process outlined in the plan.
Can be person or entity.

Identifying Plan Fiduciary

Who is a plan fiduciary?

- **Automatic Fiduciaries**: Named fiduciaries, trustees, and ***plan administrators***

- **Functional Fiduciaries**: A person with either:
  (1) ***discretionary authority*** or ***control*** over the plan's management;
  (2) ***any authority*** or ***control*** over the management or disposition of plan assets; or
  (3) ***discretionary authority*** or ***control*** with respect to the administration of the plan.
  - » *Based on the duties performed for the plan, not the individual's job title*

Who is not a plan fiduciary?

- Accountants, attorneys, consultants, and actuaries acting solely in their professional capacities
- Third-party administrators or recordkeepers not exercising discretion over the plan and who do not have control over any plan assets
- An employer acting on behalf of its business and not the plan is not a fiduciary

ERISA: Key Fiduciary Duties

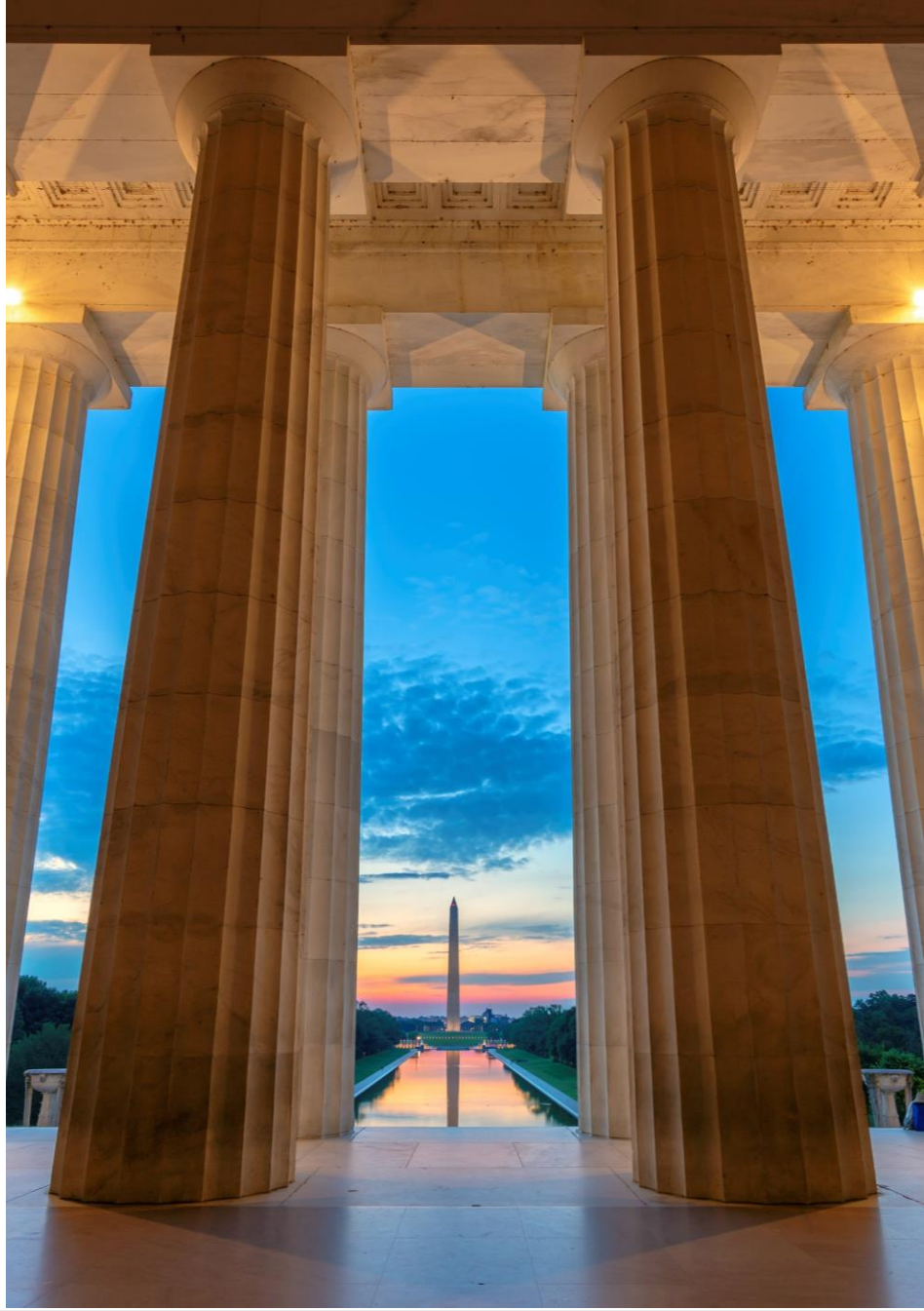
Duty of Loyalty

- Manage the plan solely in the interest of participants and beneficiaries
- Plan assets must be used for exclusive purpose of providing benefits to participants and defraying reasonable expenses of administering plan

Duty to Act Prudently

- Act with care, skill, prudence and diligence that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims

Duty to Administer Plan in Accordance with Its Terms



What are Examples of Fiduciary Duties as they Relate to Health Plans Subject to ERISA?

Managing ERISA Plan Assets

WHAT ARE PLAN ASSETS?

Plan assets can exist in three ways:

1. **Employee Contributions**

2. **Funded Arrangements**
   1) Segregated account where plan has beneficial interest
   2) Account in the name of the health plan
   3) Trust

3. **Amounts Attributable to Plan Assets**

General Assets

Employer dollars that are not segregated into a separate account for the payment of benefits

Managing ERISA Plan Assets

DUTY OF LOYALTY AND EXCLUSIVE BENEFIT RULE

ERISA plan sponsors must use plan assets for the exclusive benefit of plan participants.

- Providing benefits to plan participants; or
- Used to defray reasonable administrative expenses directly “benefitting the plan participants”

Prohibited Uses

- Employer **cannot** use these funds to offset expenses of non-plan participants (e.g., health FSA used to defray costs of the dental plan)
- Employer **cannot** keep plan assets for the company’s benefit

Managing ERISA Plan Assets

EXAMPLES OF MANAGING ERISA PLAN ASSETS

Medical Loss Ratio (MLR) Rebates

- If any portion of the MLR rebate constitutes plan assets, ERISA's fiduciary rules will apply.
  - » Amounts must be used for the exclusive benefit of the plan participants and beneficiaries. The DOL includes two allocation methods available to employers:
    - – Distribution to participants using a reasonable, fair and objective allocation method. *Fiduciary decision*
    - – If fiduciary determines distribution to participants is not cost-effective, plan participants may receive future premium cost reductions or benefit enhancements

Participant Forfeitures and Experience Gains

- **Health FSA: *Use-or-Lose Rule***
  - » Any health FSA contributions or salary reduction amounts not used that remain in health FSA account at the end of the plan year (or grace period) are forfeited. **Forfeited amount = experience gain**
  - » To the extent the experience gains are attributable to participant contributions, they will be considered plan assets
  - » Plan assets must be used to pay reasonable administrative expenses or allocated to participants

Selecting & Monitoring Service Providers - Examples

DUTY TO ACT PRUDENTLY

Selecting Service Provider/TPA

- Selecting plan service providers/TPAs is a **fiduciary function** when the third-party performs services that are fiduciary in nature (e.g., claims adjudication or medical necessity determinations)
- **Considerations when selecting TPAs:**
  - Inevestigating and evaluating
  - Compare multiple providers based on qualifications, experience, costs, financial condition, litigation history, etc.

Monitoring Service Provider/TPA

- Ongoing fiduciary duty to proactively monitor TPA
- **Considerations when monitoring TPAs:**
  - Periodic review/evaluation of plan operations, monitoring deadlines, auditing TPA functions
  - If issues discovered, prompt action should be taken depending on situation

MHPAEA

- Duty to select and monitor third-party vendor completing NQTL Comparative Analysis

Enforcement

Fiduciary Liability

ERISA § 409

- **Personal liability for fiduciary breach**
  - » Person who is a fiduciary with respect to a plan can be personally liable for losses caused to the plan and liable to restore to the plan any profits the fiduciary made through use of plan assets

ERISA § 502

- **Civil enforcement**
  - » Gives power to participants, beneficiaries, fiduciaries, and the Secretary of Labor to bring civil action against plans and plan fiduciaries
  - » **Participant/Beneficiary Right to Request and Examine Documents**
    - ○ Any documents under which the plan was established or is operated (e.g., SPD, TPA contracts, MHPAEA comparative analysis, etc.)
    - ○ Deadline to furnish information: within 30 days of receipt of written request
    - ○ Penalty: $110 per day from date of failure

Fiduciary Liability

ERISA § 502

- **DOL Enforcement**
  - » Any breach of fiduciary responsibility by a fiduciary, or
  - » Any knowing participation in such a breach or violation by any other person, the DOL may assess a civil penalty against the fiduciary or other person in an amount equal to 20% of the amount recovered by the DOL under a settlement agreement.
- **DOL Voluntary Fiduciary Correction Program (VFCP)**
  - » For eligible plan officials who identify and fully correct certain ERISA violations, and who document the correction process and satisfy all requirements, the DOL will issue no-action letters

Fiduciary Rules in Practice

Johnson & Johnson Litigation

Background – Plan participants/beneficiaries (plaintiffs) sued Johnson & Johnson (the health plan sponsor) and other plan fiduciaries for breach of fiduciary duties related to its health plan (among other claims).

- Complaint alleges, among other things, that defendants (J&J) failed to act as prudent experts would have when selecting the plan's pharmacy benefit manager (PBM) and negotiating pricing for prescription drugs covered by the plan.

Issues:

- Employer chose PBM through its insurance broker, who receives potential commissions from PBM, which could be a conflict of interest
- Fiduciary responsible for reviewing/monitoring the contract with PBM, including drug prices to ensure reasonable
- Excessive drug costs paid with plan assets increased costs to administer plan and drove up premiums to employees

NOTE: July 2024 complaint accused Wells Fargo (and its plan fiduciaries) of many of the same fiduciary breaches related to the selection of a PBM and prescription drug costs.

Johnson & Johnson and Wells Fargo

WHAT'S NEXT?

Only a pleading at this time:

- Anyone can file a claim/pleading against an employer/health plan
- **No veracity as to the claims, yet** (Does not mean claims are valid)

Multiple Scenarios:

- There are many scenarios that could play out from this pleading:
  - » Dismissal of Claim (Summary Judgment)
  - » Settlement
  - » Litigation and Discovery related to claims for multiple years
  - » Either party could be successful after trial

Not a Time to Panic

- Anything can happen, and just because a pleading is filed does not mean J&J (or any other plan fiduciary) breached their fiduciary duty to plan participants/beneficiaries
- However, this is a cautionary tale that reminds plan fiduciaries to strongly consider the processes they use in making decisions related to the plan:
  - » Diligently screen the vendors it utilizes, and choose vendors through competitive and reasonable criteria based upon such things as cost, service, offerings, and compliance under the law
  - » Consider creating a benefits committee to act in a fiduciary capacity; and
  - » Protect plan assets for the exclusive benefit of plan participants

Essential Health Benefits: Prescription Drug Coverage

What is FAQ 66 and how does it apply to Large Group/SF plans?

Public Health Service Act (PHS Act) Section 2711

PHS Act Section 2711 (added by the ACA) prohibits group health plans and health insurance issuers who offer essential health benefits (EHB), as defined under section 1302(b) of the ACA, as a part of group or individual health insurance coverage from imposing lifetime or annual dollar limits.

The 2025 Notice of Benefit and Payment Parameters (NBPP) amends the regulations to provide that prescription drugs covered by fully-insured small group plans in excess of those covered by a State's EHB-benchmark plan are considered EHBs and will be subject to the EHB protections (e.g., annual limitation on cost sharing and the prohibition on lifetime and annual limits). Under this amendment, a drug that is mandated by State action and is in addition to EHB pursuant to 45 CFR 155.170, will not be considered an EHB.

FAQ 66

Specifically, the Departments intend to propose rulemaking…that all group health plans and health insurance coverage subject to sections 2711 and 2707(b) of the PHS Act [including self-funded and large group health plans], as applicable, would be required to treat prescription drugs covered by the plan or coverage in excess of the applicable EHB-benchmark plan as EHB for purposes of the prohibition of lifetime and annual limits and the annual limitation on cost sharing, which would further strengthen the consumer protections in the ACA. The final regulations provide that plan years beginning on or after January 1, 2020, must define their EHBs to ensure that lifetime and annual limits are not applicable. This must be consistent with the state EHB-benchmark plans in accordance with 45 CFR 156.11.

Practical Application

This rule only applies to FI small group plans for now, but TPAs/carriers were applying this rule to GLP-1s and fertility prescriptions in large group FI and SF plans, mistakenly.

What are Essential Health Benefits?

Essential Health Benefits

There are 10 categories of items and services that are considered essential health benefits (EHB).

1. Ambulatory patient services
2. Emergency services
3. Hospitalization
4. Maternity and newborn care
5. Mental health and substance use disorder (including behavioral health treatment)
6. Prescription drugs
7. Rehabilitative and habilitative services and devices
8. Laboratory services
9. Preventative and wellness services and chronic disease management
10. Pediatric services (including oral and vision care)

How does this impact employer-sponsored group health plans?

Essential Health Benefits

- Non-grandfathered FI small group and individual plans must offer all ten categories of EHBs, and could also be subject to stricter requirements for EHBs under law of the state in which policy is written

- Self-funded health plans and FI large group plans must choose a state benchmark plan but are not required to adopt all EHBs under the plan. If certain benefits are offered under the health plan that are considered EHBs under the state benchmark plan, then those benefits will be considered EHBs under the health plan

- Health plans cannot impose a lifetime/annual dollar maximum to benefits that qualify as EHBs

Class Action Suit for Wellness Programs Under the ADA and GINA

What are the concerns for employer wellness programs?

General Overview

- Wellness programs are designed to promote health or prevent disease and can be offered as a part of, or related to, an employer's larger group health plan or as a stand-alone program or group health plan.
- These programs can include smoking cessation programs, physical fitness requirements, medical examinations, or educational sessions.
- Many wellness programs offer rewards or incentives to encourage participation by health plan participants - these are typically health-contingent programs and require participants to complete an activity related to a health factor to obtain a reward.

Main Concerns

- Employers should be conscious of whether participation in the program is truly "voluntary" and if their programs offer reasonable alternatives for the rewards/incentives.
- Wellness programs that include disability-related inquires/medical examinations or ask for medical history or genetic information must abide by the ADA's voluntary plan exceptions and GINA guidelines (as well as other applicable regulations).
- Some recent lawsuits have explored the design of employer wellness programs and expanded on these concerns.

What court cases involve wellness programs?

Wellness Program Class Action Lawsuit

- An employer offered a wellness program that provided a premium discount if employees took a biometric test and met other standards for criteria such as blood sugar, blood pressure, and cholesterol.
- Upon enrolling in the medical plan, employees were provided a grace period to decide if they were going to participate in the wellness program.
- Employees who participated in the wellness program automatically received a discount. However, employees who did not elect to participate in the biometric screening received a premium increase of approximately $34 per week once the grace period ended.
- The employer was sued under a class action suit that claimed the plan was not voluntary under the ADA rules. Employer filed a motion to dismiss the case, claiming that it was indeed a voluntary wellness program.

What court cases involve wellness programs?

CONTINUED

Wellness Program Class Action Lawsuit Proceeds

- The court did not allow the case to be dismissed, and therefore the class action lawsuit was allowed to continue against the employer.
- The court found that because there was a medical examination involved (i.e., biometric test) that the Americans with Disabilities Act applied to the wellness program, and because there was not clarity under the EEOC rule as to what a “voluntary” wellness program under the ADA was, there was at least some merit to the plaintiff’s allegations, and the question of whether the program is voluntary needed to be decided by a judge/jury.
- Under ADA guidelines, employees must receive clear notices that explain what medical information will be obtained, how it will be used, who will receive the information, the restrictions on disclosure of the information, and the methods in which an employer will use to prevent improper disclosures of information.

Case No. 1:23-cv-1173

What court cases involve wellness programs?

CONTINUED

Possible Liability under the Genetic Information Nondiscrimination Act (GINA)

- While the focus of this lawsuit was ADA wellness requirements, there could be additional concerns under GINA.
- The GINA law prohibits genetic discrimination for employment and health insurance (i.e., employers and insurance companies are not able to obtain and/or use a person's genetic information for purposes of discrimination)
- GINA rules also address the extent to which an employer can incentivize employees to complete health risk assessments or medical exams (as a part of wellness programs) as a way for employees to provide information about the health of their dependents
- If an employer requests or requires genetic information as part of a wellness program, the employer must receive knowing and voluntary written authorization from an individual before acquiring this information.

It is recommended that employers who offer incentives for participation in wellness programs (that could be subject to ADA due to disability-related inquires or medical exams or GINA) should review the structure of these programs with their legal counsel.

What court cases involve wellness programs?

CONTINUED

Wellness Program Class Action Lawsuit

- An employer began charging employees who use tobacco with extra fees per pay period for their health insurance coverage.
- Employees claimed that they were required to pay an additional $30 in premium per pay period ($780 per year) to continue enrollment under their company-sponsored health plan.
- The case alleges that the tobacco surcharge violates Employee Retirement Income Security Act (ERISA) regulations that prohibit employers from discriminating against plan participants that have health status related factors (i.e., the HIPAA nondiscrimination rules).
- The class action suit alleges that the company failed to offer a reasonable alternative (such as a smoking cessation program) that would allow employee to avoid the entire fee upon completion of the program, to be compliant with HIPAA.

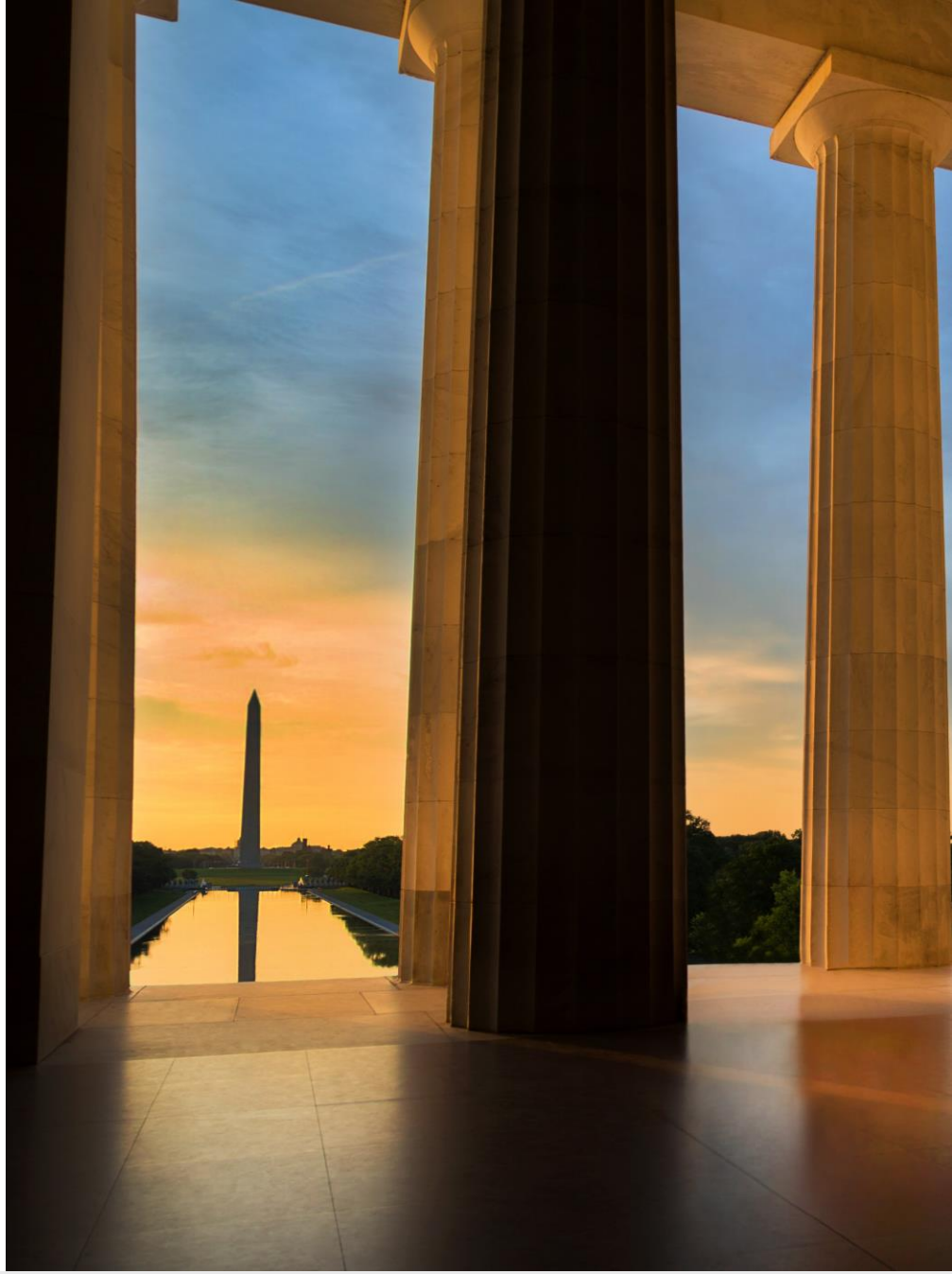
Case 3:24-cv-01612-JFS

What are the HIPAA Final Rules on Reproductive Healthcare Records of Individuals

Background - HIPAA

- The HIPAA privacy and security rules generally apply to covered entities (e.g., group health plan) and regulate the use and disclosure of an individual's protected health information (PHI)
  - » Most health plans are required to have policies and procedures, business associate agreements with business associates, authorizations for release of PHI, and a Notice of Privacy Practices that is disclosed to plan participants.

- On June 24, 2022, the Supreme Court of the United States issued a ruling in Dobbs v. Jackson Women's Health Organization (Dobbs), which allowed states to create laws that could restrict access to reproductive healthcare
  - » Certain healthcare providers felt compelled to disclose the PHI of patients to agencies that could use the information against a patient or provider/facility assisting with reproductive healthcare needs, even if lawfully obtained where services were provided.



What is the HIPAA Final Rule on Reproductive Healthcare Records?

- On April 26, 2024, the Office for Civil Rights (OCR) at the Department of Health & Human Services (HHS) published its “Final Rule to Support Reproductive Health Care Privacy”
- The final rule adopts a “purpose-based prohibition” on the disclosure and use of reproductive healthcare-related information of covered individuals under HIPAA
- Effective date of final rule was **June 25, 2024**
- Covered entitles must comply with the final rule by **December 23, 2024** (updates to NPP by February 16, 2026)

What is the HIPAA Final Rule on Reproductive Healthcare Records?

- The new privacy protections **prohibit** a health plan and its business associates from using or disclosing PHI of a covered individual for the following purposes:
  - When conducting a criminal, civil or administrative investigation into any individual that seeks, obtains, provides or facilitates lawfully-provided reproductive healthcare
  - Imposing liability (criminal, civil or administrative) on any person that seeks, obtains, provides or facilitates lawfully-provided reproductive healthcare
  - When identifying any individual for the purpose of investigating or imposing liability on any covered entity concerning the above-listed matters

- The use or disclosure of PHI is prohibited when the reproductive healthcare is lawful under federal or state law where the care is provided

What is the HIPAA Final Rule on Reproductive Healthcare Records?

- The prohibition on using or disclosing PHI would **not** apply, even if the information is related to reproductive healthcare PHI, for the following purposes:
  - When a healthcare provider uses/discloses PHI to help defend itself against an investigation related to professional misconduct or negligence involving reproductive healthcare
  - A covered entity using/disclosing PHI to help defend anyone involved in a criminal, civil or administrative proceeding where liability could exist in providing reproductive healthcare.
  - A covered entity or a related business associate uses/discloses PHI to a Statutory Inspector General that seeks to conduct an audit for health oversight purposes

What are the attestation requirements?

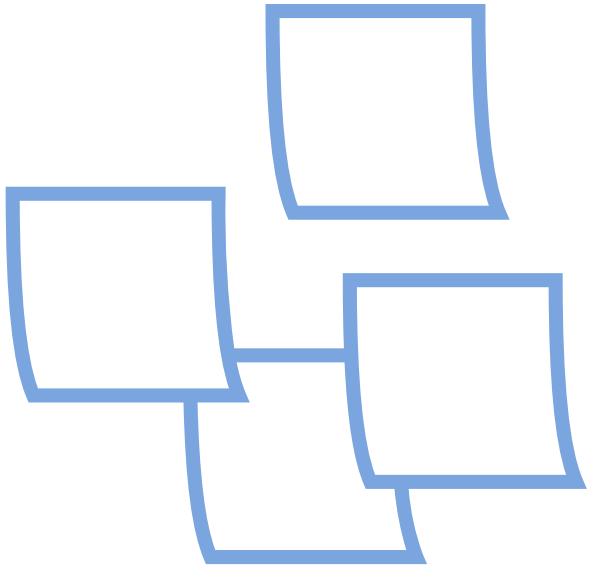
- If a health plan or its business associate receives a request for reproductive healthcare PHI, it must collect a signed attestation(in certain situations) from the person/entity requesting the PHI that the collection of PHI it is not for a prohibited purpose.

- This attestation requirement applies to PHI requests in the following instances:
  - Health-related oversight activities
  - Judicial and administrative proceedings
  - Law enforcement activities (in limited situations)
  - Disclosure to medical examiners and coroners

- HHS Model Attestation: HHS OCR Model Attestation Form re Reproductive Health Care Use of Attestation Required

What are the required changes to the Notice of Privacy Practices?

- Health plans must revise their HIPAA Notice of Privacy Practices (NPP) to reflect the following:
  - The final rule on HIPAA reproductive healthcare privacy and disclosure
  - Provisions on confidentiality of medical records relating to individuals with substance use disorders
- NPP must be updated by **February 16, 2026**
- HHS and OCR may release sample language to include in the NPP



HIPAA Final Rule – Pending Litigation

- On September 4, 2024, the Texas Attorney General filed suit against HHS in federal District Court to block the HIPAA final rule prohibiting the disclosure of reproductive healthcare PHI in certain situations

- Texas's primary claims are that the HIPAA final rule (and other HIPAA rules) unlawfully prevent states from utilizing their oversight and investigative authority and the OCR does not have the authority to issue rules that limit how covered entities may share information with states

- Case is currently pending and does not affect the effective dates of the HIPAA final rule at this time

What actions should I take as the employer?

- Customers should review their current HIPAA policies and procedures and business associate agreements and update them as necessary by **December 23, 2024**

- Customers should update their Notice of Privacy Practices by **February 16, 2026**

- If a customer receives a request to disclose its plan participants'/employees' reproductive healthcare information, the customer should consult with legal counsel on whether an attestation must be obtained and whether disclosure of the PHI is permissible

2025 FSA and Commuter Benefit Limits

2025 Limits – FSA/Commuter Benefits

Benefit	2024	2025
FSA (general purpose and limited purpose FSA)	$3,200	$3,300
FSA Carryover	$640	$660
Dependent Care FSA	$5,000	$5,000
Commuter Benefits		
• Qualified Transportation Expenses	• $315/month	• $325/month
• Qualified Parking Expenses	• $315/month	• $325/month

THANK YOU!

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