Health Care Legal and Legislative Update

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International Foundation OF EMPLOYEE BENEFIT PLANS

Agenda

- Legislative update
- No Surprises Act and transparency in coverage rule roundup
- Gender-affirming care and Section 1557
- Preemption, prescription drugs and fiduciaries
- Preventive services update
- HIPAA privacy and cybersecurity
- Mental health parity new regulations

Legislative Update

Lame Duck Health Care Package

- Likely to be part of end-of-year government funding bill in December
- Backbone of package is must-have tax extenders: Medicare telehealth flexibilities, Medicare physician payment bump, community health center funding

Lame Duck Health Care Package

- Potential legislation that could be attached
  - PBM disclosure requirements
  - Transparency in coverage disclosure requirements
  - $35 cost-sharing cap for insulin in employment-based coverage
  - Telehealth coverage in High Deductible Health Plans and bills to prohibit hospital facility fees for telehealth

What Rolls Over to the 119th Congress?

- PBM legislation banning spread pricing or requiring 100% rebate pass through (for employer-sponsored coverage and Part D)
- Longer-term community health center funding
- Attempts to modify ERISA preemption
- Medicare coverage for GLP-1s for obesity
- Continue Inflation Reduction Act policies – more Medicare drug price negotiations, extend prices to private plans

PBMs Under the Microscope in Congress

- Various Senate and House bills introduced concerning pharmacy benefit manager ("PBM") reform
- Key focus areas include:
  - Requiring transparency in reporting, including rebates
  - Prohibiting spread pricing, in which PBMs charge health plans more than they reimburse to pharmacies
  - Requiring PBMs to pass on all rebates and fees collected from manufacturers to health plans
  - Prohibition on clawbacks, which are frequently obtained through high copayments
  - Making plan fiduciaries attest to having certain contract terms in place.

House *Lower Costs More Transparency Act*

- **Energy and Commerce, Ways and Means and Education and the Workforce Committees combined legislation into the Lower Costs, More Transparency Act (HR 5378)**
- **Passed House December 11, 2023**
  - General hospital transparency provisions that expand current laws
  - PBM transparency and employer reporting requirements
  - Bans spread pricing in Medicaid
  - Community health center pricing

Taxes and the 119th Congress

- 119th Congress likely to be dominated by tax policy in 2025
  - 2016 Tax Cuts and Jobs Act expires in 2025
    - $1.6 trillion price tag
  - ACA enhanced premium assistance tax credits expire in 2025
    - $335 billion price tag
  - Proposals to cap the tax exclusion for employment-based health coverage

Proposals to Tax Health Care Benefits

- March 20, 2024, the **Republican Study Committee** released its Fiscal Year 2025 Budget proposal
- The proposal would cap the exclusion from income for employer-sponsored health insurance and promote the use of Individual Coverage Health Reimbursement Arrangements (ICHRA)
  and individual insurance
  under the ACA Exchanges

Proposals to Tax Health Care Benefits

- **Paragon Institute**
  - Would cap tax exclusions at 125 percent of the national average, adjusted for certain factors
- **Project 2025**
  - Would cap tax exclusion at no more than $12,000 per year per full-time employee

According to CBO, the tax preference for employer-provided health coverage is among the largest tax expenditures, and thus one of the largest potential "pay-fors" for other tax legislation

Courtney Opposes Taxation of Benefits

- Representative Joe Courtney (D-Conn) wrote op-ed in Roll Call April 10, 2024
  - Taxing health insurance: The Republican zombie that refuses to die

House Committee on Education and the Workforce RFI on ERISA

- RFI requests information on broad scope of issues, including preemption, fiduciary requirements, reporting requirements, prohibited transactions, data sharing, cybersecurity, broker compensation, the ERISA Advisory Council, and COBRA
- Multiple groups provided comments, including National Coordinating Committee for Multiemployer Plans (NCCMP), American Benefits Council, the ERISA Industry Committee

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Members of the Employee Health Benefits Community:

The Committee on Education and the Workforce (the Committee) has jurisdiction over employer-sponsored health coverage. Employer-sponsored insurance (ESI) covers over half of the non-elderly population, an estimated 153 million employees and their dependents.[1] Employer-sponsored health benefits are governed by several laws, including the Employee Retirement Income Security Act (ERISA).

As the 50th anniversary of ERISA approaches, the Committee is seeking feedback on ways to build upon and strengthen ERISA, the foundation of employer-sponsored health care.

Enacted in 1974, ERISA established federal guidelines governing the conduct of employee benefit plans, including employer-sponsored group health plans. Private employers that establish group health plans may implement uniform benefit plans because ERISA preempts state regulation of such plans. Approximately 90 million employees and family members have coverage from employers that self-insure their own health plans, making them subject to regulation only under ERISA and the Internal Revenue Code (the "Code").[2] The remainder of private employers offering health benefits purchase fully insured coverage from traditional insurance companies, which is generally governed by ERISA, the Code, the Public Health Service Act (PHSA), and state insurance laws.

ERISA generally allows multi-state employers to offer uniform health benefits to their employees, irrespective of location, by freeing the employer-sponsored plan from regulation by the states. For example, state laws mandating that specific health benefits must be included in a health plan are generally preempted by ERISA, and plans covered by ERISA can thus tailor their plans to meet the needs of their employees. ERISA's federal preemption of state insurance laws

Committee Holds ERISA Hearing

- April 16, 2024 Subcommittee on Health, Employment, Labor, and Pensions held hearing
  - *ERISA's 50th Anniversary: The Path to Higher Quality, Lower Cost Health Care*
- Witnesses emphasized the importance of ERISA preemption, which ensures that multi-state plan sponsors can provide uniform and consistent benefits to plan participants

No Surprises Act and Transparency in Coverage Rule Roundup

Litigation Update: IDR Process and TMA III

- On August 24, 2023, in *Texas Medical Association, et al. v. United States Department of Health and Human Services*, the U.S. District Court for the Eastern District of Texas issued a judgment and order vacating certain portions of the Departments' August 2022 final rules (TMA III)
- IDR was paused, and then reopened October 6, 2023, for certain single and batched disputes but continued to pause air ambulance disputes

TMA III Holding

- The district court vacated:
  - Portions of the QPA methodology, including counting rates for all items and services regardless of the number of claims paid; using book of business rates instead of each plan's rates; rules governing calculation of QPA for providers in the same or similar specialty; exclusion of bonus, incentive and risk sharing payments, and exclusion of single case agreements
  - The "clean claim" rule for air ambulance services, which states that the 30-day initial payment period starts when the plan has a clean claim
- The ruling will likely require changes to plan administrators' QPA methodology calculations and cause disruption
- Departments appealed

Departments Respond in FAQ 62

- FAQ 62 issued FAQs in response to the TMA III decision
- Plans must calculate QPAs consistent with the rules that remain in effect after TMA III using a good faith, reasonable interpretation
- The Departments will exercise enforcement discretion for plan QPA calculation in accordance with the July 2021 IFR in effect before TMA III for items and services furnished before May 1, 2024
- In FAQ 67, the Departments extended the enforcement discretion to November 1, 2024
- Plans must still disclose the QPA to providers and participants and should disclose which methodology is used

Final Rule IDR Fees for 2024

- On December 21, 2023, the Departments published a final rule establishing IDR fees effective for disputes initiated on or after the later of the rule effective date or January 22, 2024
- Nonrefundable Administrative Fee: $115 per party per dispute
  - Departments proposed flexibility to modify the fee with notice and comment rulemaking rather than annually to account for program needs
- Entity Fees (refunded to the prevailing party)
  - Single Determinations: $200 to $840
  - Batched Determinations: $268 to $1,173; Batched Determinations with more than 25 line items: $75 to $250 for every additional 25 line items within a batched dispute beginning with the 26th line item

Status of IDR Program

- Between July 1, 2023, and December 31, 2023, 390,346 disputes through the Federal IDR portal
- The majority of disputes were initiated by a small number of initiating parties
- Providers won approximately 82% of resolved cases, often receiving substantial awards

Gender Affirming Care and Section 1557

ACA Section 1557 (Nondiscrimination in Health Benefits)

- In May, HHS released new final 1557 regulation
  - Entities that receive federal financial assistance from HHS cannot discriminate on the basis of race, color, national origin, sex, age or disability with regard to health programs
  - Appears to only affect those plans that receive the Retiree Drug Subsidy
    - However, insurers and ASO/TPA that are covered entities because of insurance payments (e.g., on the ACA exchange) may ask clients to comply with the rules

Requirements for 1557 Covered Entities

- Effective for plan years beginning on or after 1-1-25, cannot exclude or limit services related to gender-affirming care
  - Requirement is stayed by court action

Requirements for 1557 Covered Entities

- Must have policies and procedures
  - Section 1557 coordinator
  - Written policies and procedures
  - Training
  - Notice of nondiscrimination
  - Notice of availability of language assistance and auxiliary aids and services
- Accessibility requirements for disability and languages

Required Notice of Nondiscrimination

- Covered entities must provide a Notice of Nondiscrimination to participants, beneficiaries, enrollees, and applicants on an annual basis and upon request
- The notice must be available at a conspicuous location on the covered entity's health program website, if it has one, and in clear and prominent physical locations in no smaller than 20 point sans serif font
- The notice may be combined with other required civil rights notices

Required Notice of Availability of Language Assistance Services and Auxiliary Aids

- Notice must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant states in which a covered entity operates and must be provided in alternate formats for individuals with a disability who require auxiliary aids
- Must be included with multiple communications, including the Notice of Privacy Practices
- Individuals may be able to opt-out of receiving this notice.
- The Notice of Availability must be provided with the Notice of Nondiscrimination, and the two notices may be integrated together
- No more “taglines” from previous rule

Section 1557 Effective Dates

Section 1557 Requirement	Compliance Deadline
General effective date	July 5, 2024
Designate 1557 Coordinator	November 2, 2024
Implement Policies and Procedures	July 5, 2025
Training	No later than 30 days following the implementation of policies and procedures, and no later than May 1, 2025
Notice of Nondiscrimination	November 2, 2024
Notice of Availability of Language Assistance Services and Auxiliary Aids and Services	July 5, 2025
Health benefit design change requirements, including gender affirming care	First day of first plan year beginning on or after January 1, 2025

Chart takes into consideration weekends and holidays.

Section 1557 Litigation

- In *Tennessee v. Becerra*, a Mississippi District Court ruled there was a substantial likelihood that HHS exceeded its statutory authority when it interpreted the phrase “on the basis of sex” in Title IX
  - The Court stayed the effective date of the regulation nationwide as to certain provisions, in so far as they extend “discrimination on the basis of sex” to include gender identity
  - It also enjoyed HHS on a nationwide basis from implementing or enforcing the provisions as to gender identity

Section 1557 Litigation

- In *Texas v. Becerra*, a Texas District Court stayed the entire final regulation in Texas and Montana
- In *Florida v. Becerra*, a Florida District Court enjoined HHS from enforcing the entire final rule in Florida

ERISA Preemption, Prescription Drugs and Fiduciaries

Mulready v. PCMA

- In *PCMA v. Glen Mulready*, August 15, 2023, the Tenth Circuit Court of Appeals found ERISA preempted state pharmacy benefit regulation
- The court rejected the argument that the Oklahoma Act escapes preemption because it regulates PBMs (not health plans)
- Held that ERISA preempts four provisions of the Oklahoma Act that interfere with central matters of plan structure and administration
- Petition for rehearing filed but denied on December 12th
- Oklahoma petitioned for Certiorari to the US Supreme Court, and USSC has requested Solicitor General to file a brief

Lewandowski v. Johnson & Johnson and Navarro v. Wells Fargo & Co

- Plan participants filed class actions against plan and its fiduciaries alleging breach of fiduciary duty and other violations under ERISA related to the plan's prescription drug benefit
- The cases assert injury to participants via higher drug payments, deductibles, coinsurance, copays, and lower wages
- Many consider these cases to be the beginning of litigation against fiduciaries—Highlights the importance of selection process and monitoring service providers

FTC v. The Big Three

- FTC published a report on Pharmacy Benefit Mangers in July 2024
- On September 17, 2024, Express Scripts filed a lawsuit demanding that FTC retract the report
- On September 20, 2024, FTC filed an administrative complaint against Caremark, ESI, and OptumRx alleging that they accepted money from drugmakers in exchange for keeping lower cost insulin off their formulary lists

Preventive Services Update

Preventive Services Update

- The ACA's preventive services mandate requires non-grandfathered group health plans and insurers to cover certain preventive services with no cost-sharing on an in-network basis

No Cost Sharing Preventive Services

- The following preventive services are covered:
  - The USPSTF recommends "A" or "B" ratings[1] for specific evidence-based items and services for all patient demographics
  - The Health Resources and Services Administration (HRSA[2]) issues guidance regarding preventive care and screening for infants, children, adolescents and women
  - The Advisory Committee on Immunization Practices (ACIP[3]) recommends certain immunizations

1 https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations
2 https://www.hrsa.gov/
3 https://www.cdc.gov/vaccines/acip/index.html

Litigation Update: *Braidwood Management Inc. v. Becerra*

- On March 30, 2023, Judge Reed O'Connor of the U.S. District Court for the Northern District of Texas ruled that part of that mandate violates the Constitution and vacated all agency action taken to implement or enforce the USPSTF "A" or "B" preventive care recommendations on or after March 23, 2010

The Case Continues . . .

- June 13, 2023: Fifth Circuit Court of Appeals stayed the lower court's order
  - Provider groups agreed not to oppose agencies' motion to stay the lower court's decision
  - Agencies agreed not to seek penalties or enforcement for periods before the case is resolved
- June 21, 2024: Fifth Circuit affirmed district court decision but limited remedy to plaintiffs, and remanded case for further consideration

IRS Guidance on Preventive Benefits

- On Oct. 17, 2024, the IRS issued Notice 2024-75 to expand the list of preventive care benefits permitted to be provided by a high deductible health plan (HDHP) without a deductible including over-the-counter (OTC) oral contraceptives and male condoms
  - Also clarifies that all breast cancer screenings, glucose monitors, and insulin are preventive services for HDHP purposes

OTC Contraceptive Proposed Rule

- On October 21, 2024, DOL/Treasury/HHS proposed that plans would have to cover OTC contraceptive items without requiring a prescription or imposing cost sharing; and
- Cover every FDA-approved contraceptive drug or drug-led combination product without cost sharing unless the plan also covers a therapeutic equivalent of the drug or drug-led combination product without cost sharing

Departments Release FAQ 68

- On October 21, 2024, the Departments also released guidance addressing:
  - Coverage of pre-exposure prophylaxis (prep) medication that reduces the risk of HIV infection
  - Coding and processing claims for preventive services
  - Coverage requirements of chest wall reconstruction with aesthetic flat closure, if elected by the patient in connection with a mastectomy, under the Women's Health and Cancer Rights Act

HIPAA Privacy and Cybersecurity

HIPAA Reproductive Care Regulation

- HHS Office for Civil Rights (OCR) published HIPAA Privacy Rule to Support Reproductive Health Care Privacy (April 22, 2024)
- Prohibits the use or disclosure of protected health information (PHI) related to lawful reproductive health care in certain circumstances
- Compliance date December 23, 2024; New Notices of Privacy Practices due February 16, 2026
- Will require new HIPAA Policies, Training, and Notice

HIPAA Reproductive Care Regulation

- Prohibits the use or disclosure of PHI when it is sought to investigate or impose liability on individuals, health care providers, or others who seek, obtain, provide, or facilitate lawful reproductive health care, or to identify persons for such activities
- Requires a regulated health care provider, health plan, clearinghouse, or their business associates, to obtain a signed attestation that certain requests for PHI potentially related to reproductive health care are not for these prohibited purposes
- Requires regulated health care providers, health plans, and clearinghouses to modify their Notice of Privacy Practices to support reproductive health care privacy

HIPAA Reproductive Health PHI rule challenge

- On September 4, 2024, Texas sued HHS seeking declaratory and injunctive relief against enforcement of ***both*** the 2000 privacy rule and the 2024 reproductive rule, alleging that the rules lack statutory authority and are arbitrary and capricious
  - Texas alleges that no text in HIPAA authorizes HHS to limit the documents that medical providers may produce to a State law enforcement agency

DOL Cybersecurity Guidance

- On September 6, 2024, DOL updated current cybersecurity guidance confirming that it applies to all types of plans governed by ERISA, including health and welfare plans, and all employee retirement benefit plans
- Includes Tips for Hiring a Service Provider; Cybersecurity Program Best Practices; and Online Security Tips

Mental Health Parity and Addiction Equity Final Regulation

Background: MHPAEA 2013 Final Regulations

- MHPAEA requires parity between medical/surgical (med/surg) benefits and mental health (MH) and substance use disorder (SUD) benefits
- 2013 final regulations set out parity standards in the following areas:
  - Quantitative parity analysis (financial requirements and treatment limits)
  - Parity with respect to non-quantitative treatment limits (e.g., medical management)
  - Certain designs specifically prohibited (e.g., separate deductibles or out-of-pocket limits)
- No requirement to provide MH or SUD coverage (but IF covered, must cover in every classification where med./surg. services are provided)

2013 Regulations General Rule for Parity in NQTLs

GHPs (and health insurance issuers) prohibited from:

Imposing **a nonquantitative treatment limit** on mental health/substance use disorder benefits **unless** processes, strategies, evidentiary standards or other factors used to apply it to MH/SUD are **comparable and not more stringently applied** than standards used for med/surg

Compare within each classification.

Strengthening Parity Mental Health/Substance Use Disorder

- Enacted December 27, 2020 through CAA 2021
- Requires group health plans to perform and document comparative analyses of the design and application of nonquantitative treatment limitations (NQTLs)
- Plans were required to be prepared to make these comparative analyses available to the Departments of Labor and/or Health and Human Services upon request beginning 45 days after the date of enactment (February 10, 2021)

Proposed Mental Health Guidance Released

- On July 25, 2023, the Departments issued a package of guidance
  - Proposed rules, later formally published in the FR on August 3
  - Technical release seeking information and comments with respect to guidance for proposed data collection and evaluation requirements for nonquantitative treatment limitations related to network composition
  - The 2023 MHPAEA Comparative Analysis Report to Congress
  - Enforcement Fact Sheet regarding fiscal year 2022 enforcement results
  - Press Release announcing guidance

Mental Health Parity Proposed Regulations

- The August 3, 2023, proposed rules revise the 2013 final rules as well as include new, additional requirements related to documented NQTL comparative analyses.
- The Departments received over 9,500 comments in response to the proposed regulations.

Final MHPAEA Regulations Released

- On September 9, 2024 the Departments publicly released final regulations; these were officially published in the Federal Register on September 23, 2024.
- The rules have staggering effective dates with some provisions becoming applicable for plan years on or after January 1, 2025 and others for plan years on or after January 1, 2026.

Examples of NQTLs

- Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative
- Formulary design for prescription drugs
- For plans with multiple network tiers (such as preferred providers and participating providers), network tier design
- Plan methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates
- Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols)
- Exclusions based on failure to complete a course of treatment
- Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan

Examples of NQTLs

- Network composition NQTLs include but are not limited to:
  - Standards for provider and facility admission to participate in a network or for continued network participation
  - Methods for determining reimbursement rates
  - Credentialing standards
  - Procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage.

How the Final Rules Incorporated Key Proposed Requirements

- Application of predominant/substantially all testing to NQTLs
  - Not included in the final regulations. Alternatively the Departments reiterate the standard that factors and evidentiary standards must be comparable and not applied more stringently to MH/SUD as compared to Med/Surg, as written and in operation. The Departments incorporate a prohibition on any discriminatory factors or evidentiary standards. Exceptions related to clinical standards and fraud and abuse have been eliminated, leaving these to be addressed within the NQTL analysis.
- Outcomes data collection and review requirements
  - Included in the final regulations. Plans have a duty to identify and substantiate or remedy “material” differences. More guidance is anticipated regarding the outcomes data requirements. De facto noncompliance based on outcomes is not included in the final regulations.

How the Final Rules Incorporated Key Proposed Requirements

- Meaningful benefit requirement
  - Included in the final regulations. This includes the requirement to provide “core treatments” with respect MH/SUD benefits in classifications where Med/Surg benefits are provided.
- Expanded list of NQTLs
  - The Departments declined to provide an exhaustive list.

How the Final Rules Incorporated Key Proposed Requirements

- Documented comparative analysis content, timing, findings of noncompliance
  - The Departments provide additional detail regarding the comparative analysis content. Plans may be asked to cease unsupported NQTLs in the context of findings of noncompliance. Strict timing expectations were retained.
- Named Fiduciary Certification
  - This has been revised to require prudent selection and monitoring of service providers involved in NQTL compliance.

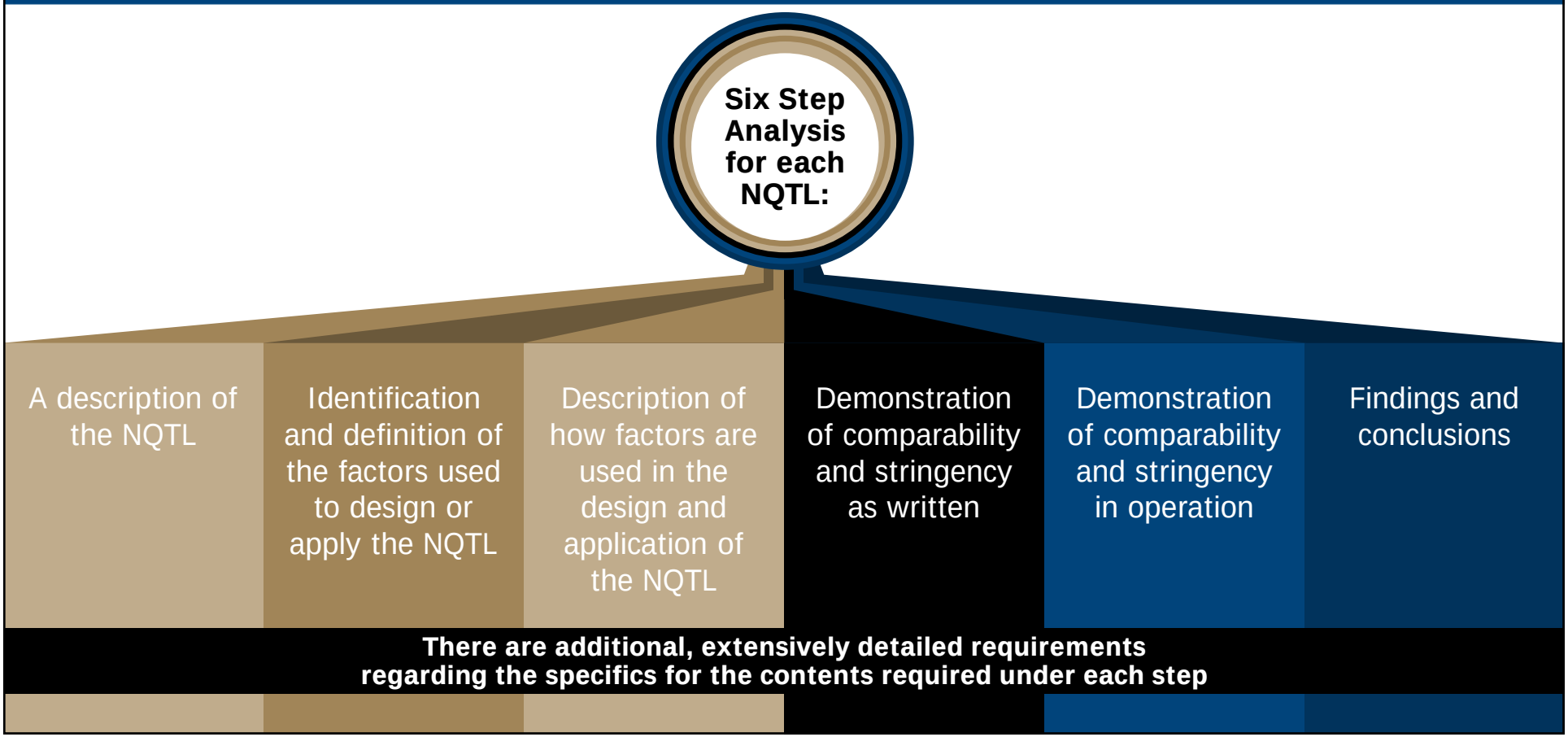
Additional Key Elements of the Final Rules

- New Definitions have been added such as to help differentiate among factors, evidentiary standards, and strategies.
- For purposes of defining MH/SUD conditions the Departments define these according to the most current versions of the Diagnostic and Statistical Manual (currently the DSM-V) and The International Classification of Diseases (currently the ICD-10)

Additional Key Elements of the Final Rules

- Plans must have a list of the NQTLs applicable under the plan.
- The Departments reiterate in the final rules that the comparative analysis is an instrument of the plan.

Content Requirements for NQTL Comparative Analyses Reports



Requests and Findings of Noncompliance

10 business days to respond to an initial request

10 business when an initial response is found insufficient and DOL or HHS requests supplemental information

7 days to notify participants and beneficiaries when a final determination of noncompliance is issued.

Significant enforcement is anticipated once rules are finalized.

Key Concerns Persist

- Continued subjectivity in the general standards as well as in the new “meaningful benefits” rule
- Reasonable timing to allow for implementation
- Network composition standards
- Data collection and evaluation standards
- Cost estimates
- Named fiduciary certification though revised may present challenges

Key Takeaways for MHPAEA

- **Read** the final regulations and watch for additional guidance
- **Contact vendors** to ascertain their capabilities to support compliance efforts
- **Consider revising agreements,** such as adding details to administrative service agreements related to expected obligations under MHPAEA
- **Share your concerns** with the Federal Departments and/or your federal government liaison
- **Resolve complaints.** As always, plans should work diligently to investigate and resolve any parity compliance complaint to help avoid it advancing to a complaint to DOL or HHS

Key Takeaways

- Congress, courts, and regulators increasingly looking to plan sponsors to exercise fiduciary responsibilities and monitor service providers
- Success of cost-control measures like the No Surprises Act still unknown
- Plans must continue to be vigilant in regulating plan administration

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Session Evaluation

Questions