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Cooking Up a Compliant Benefits Strategy

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Agenda

- *Prepping the Dish*: Staying Ahead of Compliance Deadlines
- *Mixing Ingredients for Inclusion:* The Key Compliance Components of Gender-Affirming Care
- *It's Getting Spicy*: Wellness Program Litigation
- *The Right Ingredients*: Employer Accountability in Fiduciary Duties
- *The Recipe for Parity*: Equal Ingredients for Mental and Physical Health
- *Is the Dish Done?*: HIPAA Security Proposed Rule
- *Finishing Touches:* Mid-Plan Year Amendment Reminders

Prepping the Dish:
Staying Ahead of Compliance Deadlines

March 1: Medicare Part D Coverage Disclosure to CMS (Calendar Year Plans)

- Employers whose group health plans provide prescription drug coverage must report to CMS within 60 days after the beginning of the plan year whether the benefits are creditable with respect to Medicare Part D coverage

March 3: MEWA Annual M-1

- Multiple Employer Welfare Arrangements (MEWAs) must file their Form M-1 annual report by March 1 with the DOL
- This filing requirement applies to all MEWAs, including insured and self-insured arrangements

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March 3: Deadline for Furnishing 1095-B/1095-C*

- A self/level-funded employer with less than 50 full-time employees must provide 1095-B individual statements to covered employees
- ALE must provide 1095-C individual statements to full-time employees with specific information for each employee's offer of coverage for every month during the 2024 year

**Paperwork Burden Reduction Act*: Employers are no longer required to send Forms 1095-B / 1095-C to FT employees/covered individuals unless requested. Employers must give clear and conspicuous notice of this option in a timely manner. Notice must be posted on an accessible website by March 3 and be retained until October 15, 2025, and must include an email address, address and phone number to which a request may be made. If employees request a form, the employer must provide by later of 30 days of the request, or by January 31.

March 31: Deadline for Electronically Filing Forms 1094-C and 1095-C with the IRS*

- A self-funded employer with fewer than 50 full-time employees will file Forms 1094-B/1095-B with the IRS
- An ALE must file Forms 1094-C/1095-C with the IRS

* *IRS lowered 250-return threshold for mandatory electronic reporting to 10 returns. This means almost every employer is now required to complete their ACA reporting electronically*

June 1: Prescription Drug Data Collection (RxDC) Reporting

- Plan sponsors must report information about prescription drugs and health care spending to the Centers for Medicare & Medicaid Services (CMS) each year. Data for the 2024 reference (calendar) year is due by June 1, 2025. This reporting is required for fully insured and self-funded group health plans of all sizes.

July 31: PCORI Fee

- Employers sponsoring a self-funded health plan are required by the ACA to submit an annual Patient Centered Outcomes Research Institute (PCORI) Fee. Fees are due on July 31 of the calendar year following the plan year for which the fees are calculated by filing on IRS Form 720 (e.g., the fee for a plan ending in 2024 is due on July 31, 2025).

July 31: Form 5500 (Calendar Year Plans)

- Generally, a Form 5500 must be filed by the last day of the seventh month after the end of the plan year for ERISA pension and welfare benefit plans. For calendar-year plans, the deadline is July 31. With few exceptions, an employer must file a 5500 if any of its ERISA benefit plans had 100 or more covered participants on the first day of the plan.

Mixing Ingredients for Inclusion:
The Key Compliance Components of Gender-Affirming Care

Key Compliance Components of Gender-Affirming Care
Ingredient 1: Title VII

- Title VII applies to all employers and their group health plans
- Prohibits discrimination (including sex-based discrimination) in employment-related decisions.
- In 2020, SCOTUS ruled in *Bostock v. Clayton County* that employment discrimination based on of gender identity violates Title VII.
  - Plan sponsor impact: group health plans must provide any benefits already covered under the plan to all participants, regardless of a participant's gender identify.
- The 11th Circuit ruled in favor of a transgender employee who sued after her employer's health plan denied coverage based on the exclusion of "drugs for sex change surgery" and "services and supplies for a sex change and/or the reversal of a sex change." Employer was found to have violated Title VII, and employee was awarded $60,000 in damages.
- 4th Circuit ruled that state health plans' exclusion of gender-affirming care violated Title VII, as well as the Equal Protection Clause

Key Compliance Components of Gender-Affirming Care
Ingredient 2: Section 1557

- Section 1557 prohibits discrimination based on race, color, national origin, ***sex***, age, or disability in certain health programs and activities
  - "Sex" has been the subject of litigation and rulemaking that has adopted interpretations of varying expansiveness
  - Recent final rule confirms that discrimination on the basis of sexual orientation and gender identity is prohibited (as well as on sex stereotypes, sex characteristics, and pregnancy or related conditions)
- Clarifies that the rules apply to all operations of a covered entity, including an insurer's TPA's activities. Pharmacy Benefit Managers (PBMs) are also covered if they receive federal financial assistance or are part of another covered entity's operations
  - More TPAs owned by insurers will be directly subject to Section 1557 and prohibited from categorically excluding services such as gender-affirming care
- Employer sponsoring group health plans are covered entities if the health plan receives funding from HHS
- Recent litigation halted agency enforcement of these provisions

Key Compliance Components of Gender-Affirming Care
Ingredient 3: Executive Orders

- *Executive Order 14148* (Jan. 20, 2025): the term "sex" refers to "an individual's immutable biological classification as either male or female…and does not include the concept of 'gender identity."
  - Rescinded conflicting Executive Orders from the Biden administration, including application of *Bostock*
- *Executive Order 14187* (Jan. 28, 2025): aims to restrict the availability of gender-affirming care (defined to include the use of puberty-blockers, hormone therapy, and surgical procedures) to individuals under the age of 19.
  - Feb. 13 - Federal court issued national TRO that bars the administration from enforcing part of the EO that prohibits federal funding to hospitals/medical providers that provide gender-affirming care
  - Feb. 20 - HHS rescinds 2022 "Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy"

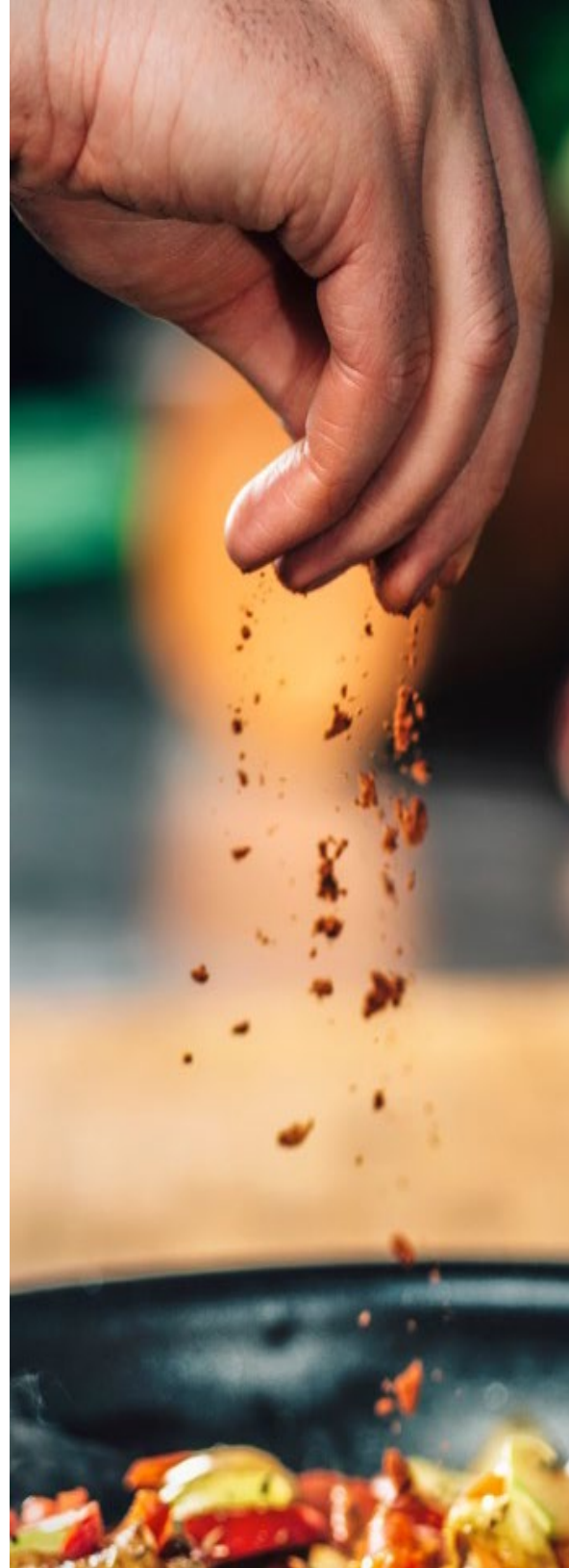
Whisking it All Together

- Title VII: Rescission of EO on *Bostock* will shift agency interpretation and that "sex" may no longer be considered to extend to gender identity
- Section 1557: Section 1557 will likely be revised without the gender affirming care provisions
- MHPAEA: Possible impacts on MHPAEA parity that may affect treatment for gender dysphoria
- State Law: Government is withdrawing opinions in cases where previous administration was supporting challenges to state law limitations on gender-affirming care (*Skrmetti* - TN)
- All roads lead to SCOTUS (Title VII, Section 1557 and MHPAEA rules for gender-affirming care)

It's Getting Spicy!
Wellness Program Litigation

It's Getting Spicy! Wellness Program Litigation

- Recent wave of class action lawsuits targeting wellness programs under self-funded group health plans
- Lawsuits allege violations of ERISA's fiduciary duty rules and HIPAA nondiscrimination rules
- HIPAA prohibits discrimination based on health outcomes:
  - Cannot require participants pay higher premium than similarly situated participants based on a health status related factor
- Wellness program exception allows different premiums for participants if program meets certain requirement, which vary based on type of program:
  - Participatory programs – provide no reward or reward eligibility not conditioned on satisfying health factor related standard
  - Health contingent programs – reward eligibility conditioned on satisfying health factor related standard
  - Activity only – must only perform certain activity to obtain reward
  - Outcomes based – must achieve or maintain specific health outcome to receive reward



It’s Getting Spicy! Wellness Program Litigation

- Key allegations common to most lawsuits:
  - No RAS - Since plan premium reductions only available on prospective basis, plan fails to offer RAS
  - RAS disclosure inadequate – Existence of RAS not disclosed in all plan materials
  - ERISA fiduciary duty breach – Collecting surcharge results in fiduciary breach
- No dispositive court ruling yet, but have had a case settle where employer agreed to pay back 62% of surcharges
- Practical steps for employers:
  - Can have rewards/premium surcharges but must properly administer and disclose them
  - Ensure full reward available - do not just apply premium reduction prospectively
  - Confirm RAS properly disclosed in ALL plan materials
  - Train staff and/or ensure vendor staff trained on RAS availability

The Right Ingredients: Employer Accountability in Fiduciary Duties

ERISA Fiduciary Litigation Update

Recent class actions brought attention to alleged fiduciary failures by health plan sponsors:

- *Lewandowski v. Johnson and Johnson* – alleges failure to prudently monitor and select the plan's pharmacy benefit manager (PBM) and to negotiate more favorable pricing, causing participants to pay excessive premiums and out-of-pocket expenses for Rx
  - Jan. – two fiduciary breach claims* dismissed with leave to amend, with the court finding the plaintiff had failed to established standing to file the lawsuit
  - Held that plaintiff's claims she paid higher premiums due to plan mismanagement were too speculative; failed to establish actual injury; and no ruling by the court could redress the harm she allegedly suffered
  - **A third claim that J&J failed to timely provide plan documents was not dismissed*
  - Could result differ if plaintiff hadn't her out-of-pocket maximum for the year?
  - Is this a big win for employers?
- *Navarro v. Wells Fargo* – alleges failure to exercise prudence and to act in the interest of participants by selecting a PBM and agreeing to make the plan and participants pay "unreasonable prices" for prescription drugs based on "unreasonable methodologies"
- *SMO v. Mayo Clinic* – alleges failure to act in the best interest of health plan participants, particularly concerning mental health care coverage for out-of-network services

Who is an ERISA Plan Fiduciary?

- An ERISA plan must have at least one named fiduciary – a person or entity - identified in the written plan as having control over the plan's operation
  - The named fiduciary can be identified by office or by name – for some plans, it may be an administrative committee or the entity's board of directors
  - A vendor may agree to serve as a named fiduciary in a certain capacity, such as a carrier managing the claims and appeals process … in that case, the insurer would be a fiduciary for purposes of benefit claims, but the plan sponsor (i.e., the employer) would be the fiduciary of the plan overall
- Fiduciary liability may extend beyond those named in the plan document, as fiduciary status is determined based on functions, not just title … **is the person or entity exercising discretion and control over the plan?**
- Who is *not* a fiduciary? Persons performing "ministerial functions," such as preparing employee communication materials, applying eligibility rules, and maintaining service records … as well as attorneys, accountants and actuaries

ERISA Fiduciary Duties

Duty of Loyalty

Acting for the exclusive purpose of providing benefits to participants and beneficiaries or for defraying reasonable expenses of administering the plan

Duty of Prudence

Acting with the care, skill, prudence and diligence of a prudent person

Duty of Diversification

Diversifying plan investments to minimize risk of large losses (welfare benefit plans with trusts)

Duty to Act in Accordance with Plan Documents

Establishing, maintaining and administering the plan in accordance with written terms

Fiduciary Duty of Prudence

- Prudence focuses on the *process* for making fiduciary decisions
  - Document plan decisions and the basis for those decisions through regular meetings and minutes
  - Hiring Service Providers: Get information from more than one provider; compare providers based on the same factors through formal RFP; consider each vendor's performance, policies and practices, the scope of services provided, experience with individual participants, and how much the vendor charges for services
  - Monitoring Service Providers: Consider performance guarantee requirements; Review performance on a regular basis; read all reports provided; check actual fees charged; ensure plan records are properly maintained; follow-up on participant complaints
  - Comply with all federal and state benefit regulations (e.g., ERISA, COBRA, ACA, HIPAA, MHPAEA, TiC/CAA of 2021, etc.)

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Fiduciary Duties: Key Takeaways

- Identify plan fiduciary(ies) and ensure they have a thorough understanding of roles, fiduciary duties, the plans, and plan administration
- Consider establishing a health and welfare benefits committee to handle plan administration and ERISA compliance
- Hold regular fiduciary training
- Institute a regular process to monitor and review all plan vendor and service provider activities, performance and fees
- Regularly review and revise all contracts with plan vendors and service providers, ensuring they include appropriate indemnification provisions
- Formalize plan processes and procedures and adhere to those to help demonstrate compliance
- Review plan – as well as all policies and procedures - for compliance with ERISA, ACA, COBRA HIPAA, etc.
  - Can delegate certain fiduciary duties, but cannot completely delegate all liability for compliance with applicable laws

The Recipe for Parity:
Equal Ingredients for Mental and Physical Health

Mental Health Parity and Equity Act (MHPAEA): Comparative Analysis Requirement

- MHPAEA prevents group health plans and issuers that provide mental health and substance use disorder (MH/SUD) benefits from imposing less favorable benefit limitations on those benefits than on medical and surgical (M/S) coverage
- MHPAEA's parity requirements apply to:
  - Financial requirements, such as deductibles, copayments and coinsurance
  - Quantitative treatment limitations, such as day or visit limits and
  - NQTLs, which generally limit scope or duration of benefits, such as prior authorization, step therapy and standards for provider admission to participate in a network

Mental Health Parity and Equity Act (MHPAEA): Comparative Analysis Requirement (cont.)

- As of Feb. 10, 2021, plan sponsors are required to document a comparative analysis of NQTLs that apply to MH/SUD claims and provide this written analysis to the Tri-Agencies (DOL, IRS and HHS) and/or state regulators, if requested:
  - Must contain a detailed, written and reasoned explanation of the specific plan terms and practices at issue and include the basis for the plan's or issuer's conclusion that the NQTLs comply with MHPAEA
- On Sept. 23, 2024, the Tri-Agencies issued a final rule to strengthen MHPAEA requirements and provide guidance to health plans and issuers on how to comply with the law's requirements

MHPAEA – Final Rules

Changes for 2025

- Fiduciary Certification
- Standardized Definitions
- Definition Sources Order

Fiduciary Certification from one or more fiduciaries that they have:

- Gone through a prudent process to choose an NQTL analysis provider; and
- Satisfied duty to monitor the provider during NQTL testing.

Fiduciary Certificates and Supplemental Materials may include:

- Vendor selection process, including questionnaires;
- Certification that analyses were reviewed and questions were asked by fiduciaries;
- Qualifications of service provider

MHPAEA – Final Rules

Changes for 2026

- MH/SUD - must get “meaningful” benefits in every category covered by the plan
- Relevant data evaluation required for NQTLs

- ERIC, the ERISA Industry Committee has filed a lawsuit over the September 2024 final MHPAEA regulations
- Allegations include claims that the rule is arbitrary and capricious, exceeds agency authority, and raises Due Process concerns;
- Goal of the suit is to set aside the final rules or obtain an injunction prohibiting enforcement
- Even if suit is successful, the requirement to have a comparative analysis is based in statute, so is likely here to stay
- MHPAEA has widespread, bipartisan support

MHPAEA 2024 Report to Congress

- Takeaways from this report released in January 2025:
  - Many plans aren't completing the required testing
  - Conclusory determinations in reports without supporting evidence still do not work
  - Goal is compliance - agency working with plans and insurers to correct deficiencies
- NQTL areas of focus:
  - Network adequacy and composition (EBSA secret shopper survey found many providers listed on network directories were not available for an appointment)
  - Impermissible exclusions, such as ABA therapy for Autism Spectrum Disorder, nutritional counseling for eating disorders, and medication-assisted treatment for opioid use disorder
- Federal enforcement and private actions by plan participants
  - ***Participants have a right to request these analyses, and plaintiffs' firms know this!***

Employer Plan Sponsor MHPAEA Compliance: Key Takeaways

- **Consult with Carrier (Fully-Insured)**: Fully-Insured plans share responsibility for MHPAEA compliance with and should request written confirmation of compliance from their carrier
- **Consult with TPA/PBM (Self-Funded)**: Self-funded plans are liable for compliance and should proactively consult with their TPA/PBM to:
  - Review DOL's self-compliance assessment tool, NQTL Warning Signs, MH/SUD Parity website and recent FAQs on the CAA's comparative analysis
  - Revise service provider contracts to address ongoing MHPAEA compliance and the respective responsibilities of the plan sponsor and the TPA/PBM
  - Request copy of any NQTL comparative analyses and supporting documentation and review with plan sponsor's benefit attorney
  - Develop internal controls, including training for individuals involved in plan administration, regular plan audits and a process for participants to file complaints

Is the Dish Done?:
HIPAA Security Proposed Rule

HIPAA Security Rule Proposed Regulations

- Proposed Rule would modify the HIPAA Security Rule
- Public comments due March 7
- If finalized have 240 days to document and implement the new rule
- Goal: strengthen cybersecurity protections for electronic protected health information
- Focus on health care providers, but “group health plans” will be affected
- Potential impact:
  - Plan amendment
  - Written contingency plan
  - Updated business associate agreements (with longer transition period available)

Finishing Touches:
Mid-Plan Year Amendment Reminders

Mid-Plan Year Amendment Reminders

- Ability to amend plan for desired change
- Feasibility to implement strategy
  - Categories of employees affected
  - Timely notification of service providers
  - Necessary lead time
- Impact of plan design changes
  - Change in pre-tax elections
  - ACA considerations
  - Nondiscrimination testing
  - Optics
- Notice to participants – legal and practical considerations
- Formalities matter
  - Follow the terms of the plan
  - Plan amendment and approval

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