



Words Matter

What does your Plan Document say on
Today's Leading Trends?

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Agenda

What we are going to cover

- Importance of proper plan language
- Weight Loss Drugs
- Gene & Cell Therapy
- Abortion & IVF
- Grab Bag of Topics
- Questions

Why do we have a Plan Document

- ERISA requires. Participants can bring suite to enforce.
- To respond to Participants request for the document.
- Lawsuits may be based on past practices without one.
- “De Novo” standard would apply in absence of one.
- In order to amend or terminate.
- Fiduciary Duty

Benefits of Clear Language

- Plan Participants
 - Aids in understanding on plans coverage and exclusions
 - Improves decision making in use of benefits
 - Reduces misunderstanding
- Plan
 - Better compliance with plan regulations
 - Minimizes legal risk
 - Minimizes financial risk

Weight Loss Drugs

- Obesity Affects > 100 Million U.S. Adults & Costs Insurers \$150 Billion
 - U.S. prevalence of obesity increased from 30.5% during the period 1999 to 2000 to 41.9% during the 2017 to March 2020, according to the CDC.
 - New class of drugs → GLP-1 receptor agonists, appear to produce better, safer long-term results than earlier medications
 - KFF survey found that 80% of people believed that insurance should cover if there was an obesity diagnosis.
 - In some cases, side effects are extremely concerning (e.g., suicidal thoughts, stomach paralysis) and costly
- **7 Drugs Currently Approved for Weight Loss**
 - Bupropion-naltrexone (Contrave) \$516.56- \$698.57
 - Liraglutide (Saxenda) \$1309 - \$1498
 - Orlistat (Xenical) \$282.20 – \$722.13
 - Phentermine-topiramate (Qsymia) \$168.19- \$221.66
 - Semaglutide (Wegovy) \$1311- \$1619
 - Setmelanotide (Imcivree) \$34,253 – \$37,893
 - Tirzepatide (Zepbound) \$1029- \$1174

***Source: The Mayo Clinic **Drug Pricing GoodRX**
- There are 11 more in the pipeline.

Weight Loss Drugs

- A Mercer Study Cited a Huge Spike in Spending on Weight Loss Drugs as a Driver of Premium Increases for 2024
- Medicare spending on GLP-1s has skyrocketed even though current law prohibits Medicare from covered drugs for weight loss. Per a KFF study, spending on 3 GLP-1s has gone from \$57 million in 2018 to \$5.7 billion in 2022.
- What Are Employers Doing?
 - Survey → October 2023, 25% of employers covered weight loss drugs. 43% expected to cover them in 2024. 81% reported their EEs wanted them covered. ***Source** – Survey of 500 employers conducted by Accolade
- What Should Employers Do?
 - Perform cost/benefit analysis
 - Make a decision
 - Follow best practices

Weight Loss Drugs

- Plans Can Cover or Exclude Using Any of Various Descriptive Terms
 - Caution against being too specific or overbroad
 - Medical vs. prescription exclusions: cover all bases!
- Important Notes About the Exceptions Process
 - Fiduciary duties
 - Precedent & *de facto* plan amendment
 - Discrimination concerns
- VIPs Are Still Plan Members, After All
 - Different classes of participants can be subject to different benefits
 - Don't forget §105[h] requirements!

- **Nondiscrimination & Inclusion**

- **ADA** regulations include very specific language prohibiting plan designs from discriminating on the basis of an ADA-qualifying condition
- **GINA** protects employees from discrimination based on genetic information – which obesity may relate to
- **HIPAA** protects employees from discrimination on the basis of health factors. HIPAA states that any restrictions on benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or based on the health factor of any one individual
- **Mental Health Parity and Addiction Equity Act (“MHPAEA”)** may also play a role in certain instances → It may play a role if an individual is prescribed such a medication in connection with an eating disorder

Plan Language and Stop Loss

- Potential for Gaps, Gaps Everywhere!
- Explicit Policy Exclusions Are More & More Common
 - Weight loss / management / reduction
 - Anti-obesity
 - Medical necessity
 - Lifestyle medications
 - Cosmetic services
- New Lasers?
 - These treatments are indefinite and costly
 - In general, stop-loss coverage wasn't built to cover recurring therapy management over several years, especially when treating chronic conditions

- **Nondiscrimination & Inclusion**

- **ERISA** fiduciary responsibility to act in the interest of plan participants, pay only reasonable plan expenses, follow the plan document, and carry out these duties prudently.
- **ACA** regulations include OOPM requirements, MV calculations, and a prohibition of dollar limits for Essential Health Benefits which includes prescription drugs. How does the chosen state benchmark plan treat GCT?
- **ADA** regulations define a disability as an impairment that limits major life activities and includes major bodily functions (i.e., functions of immune system, normal cell growth, neurological, brain, respiratory, circulatory, endocrine, etc.).
- **GINA** protects employees from discrimination based on genetic information – which includes coverage decisions.
- **HIPAA** protects employees from discrimination on the basis of health factors. HIPAA states that any restrictions on benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or based on the health factor of any one individual.

Plan Document Considerations

- Include Discretionary Authority Provision
- No Annual or Lifetime Dollar Limits if EHB
- Non-clinical based exclusions may create EHB/ACA issues
- Timing – Avoid Mid-year Changes
- Reactionary exclusions may create HIPAA issues
- Review Existing Plan Language especially Definition of a Drug
- Examine Plan Provisions Relating to Experimental and/or Investigational Care
- Include Strong Medical Necessity Plan Language
- Review Plan's Medical Management Protocols
- Alternative Care Option
- Notice Requirements

Cost Containment Considerations

- Categorical exclusion permissible, but...
 - Include a caveat about preventive services
 - Consider DOL frowns upon excluding due to cost so look at data on safety and efficacy
 - Consider public relations and employee morale
 - Review for discrimination related issues (and implementation)
 - Impact to other agreements held by the Plan Sponsor (i.e., PPO contract, PBM agreement, other vendor agreements)

Cost Containment Considerations

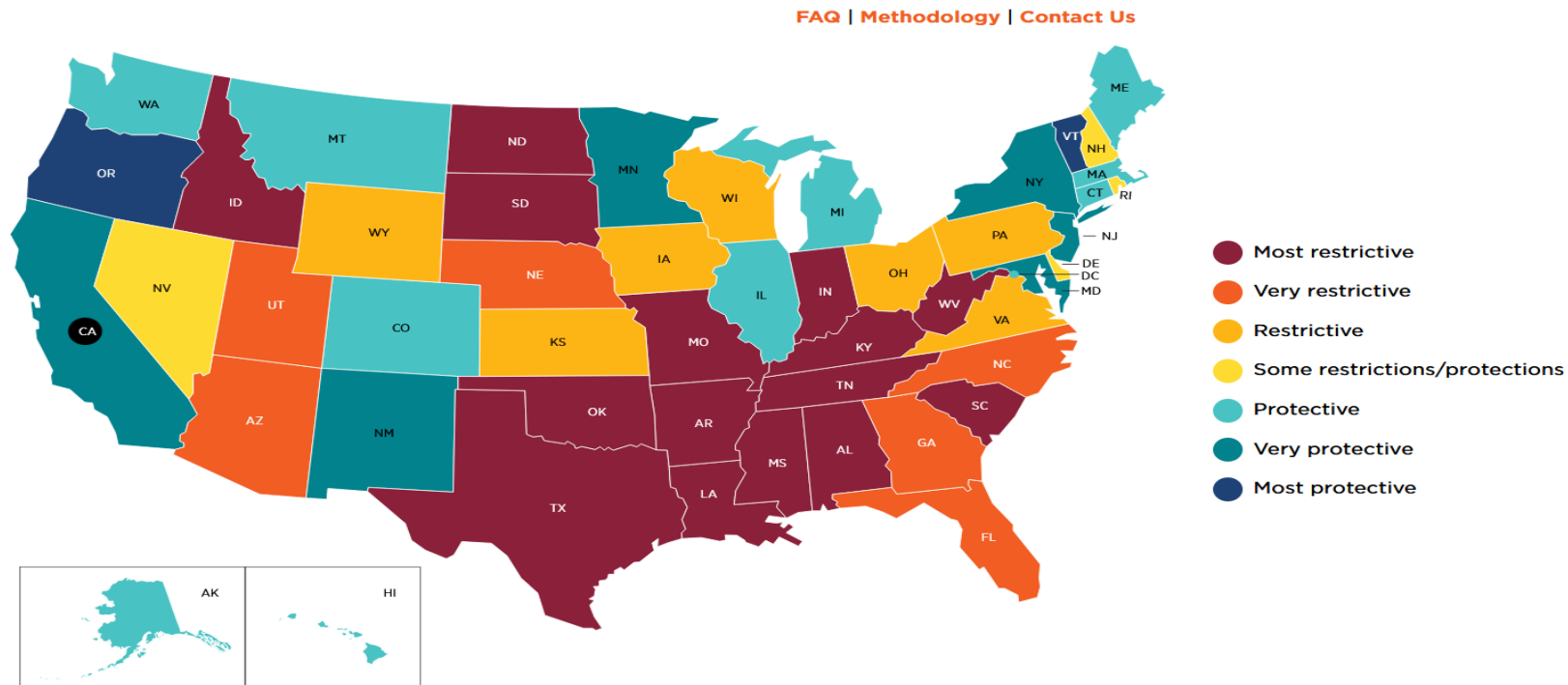
- Does the Plan include a foreign travel exclusion that meets the needs of group?
- Review existing plan design to ensure meet coverage intentions
- Efficacy of CGT Treatment
- Attractive and comprehensive benefit package
- Apply time limits before coverage under the plan
- Site of care limitations
- Direct contracting and/or special CGT
- Warranties
- Manufacturer Assistance/Copay Card/Alternative Sourcing Programs

Cost Containment Considerations

- Research programs offered by PBMs and carriers and other entities that may assist with coverage of some CGT, but
 - Look at the policies for conditions, treatments, and required coverage
 - Perform a gap analysis against existing documents (i.e., PD/SPD, stop loss policy)
- Investigate installment plan options (i.e., pay an amount in annual installments over a few years)
- Consider outcomes-based contracting (i.e., generally multi-year contract that could require upfront payment but puts skin in the game for the manufacturer to refund if clearly defined clinical performance metrics unmet)
- Potential trickle down from government initiatives – President Biden’s Executive Order “Lowering Drug Costs for Americans” and the three HHS models

Abortion & IVF

- Supreme Court Decision on Abortion
 - June 24, 2022 the SCOTUS released its opinion on the Dobbs v. Jackson Women’s Health case
 - Decision overturned Roe v. Wade
 - Dobbs case returned the decision to the States
 - Patchwork of laws around the country



Texas As Ground Zero

- Texas Heartbeat Abortion Law Permits Civil Suits Against Those Who “Aid & Abet” Abortions After Heartbeat Is Detected
- Texas Free Caucus Sends Warning Letter to International Law Firm
 - They “have been complicit in illegal abortions”
 - Firm had promised to reimburse employees for traveling out-of-state
 - Legislation would single out individual attorneys and disbar them
- This Is an Attempt to Indirectly Regulate Health Plans
- Many Other State Legislatures Are Drafting Similar Bills
 - Some target law/medical licenses

Don't Forget About Mental Health Parity & Tax Implications

- Mental Health Parity and Addiction Equity Act (MHPAEA) generally requires health plans to cover mental health and substance abuse services as generously as those plans cover medical and surgical services.
- A plan can meet MHPAEA requirements by providing travel benefits with respect to any service that is not legally available within a specified number of miles of a participant's home.
- Abortion travel benefits are considered eligible medical expenses under Section 213(d) of the Internal Revenue Code, with some limits
 - E.g., A plan can generally reimburse up to \$50 of lodging per night on a tax-free basis
 - E.g., If an employer offers a high-deductible health plan, it cannot reimburse abortion-travel expenses before application of the plan's deductible. That is true whether the reimbursement is provided directly through the high-deductible health plan or through an integrated HRA

Plan Document Considerations

- Fully-insured plans subject to state law
- ERISA Preemption?
 - Laws that relate to EE benefit plans
 - Laws with “general applicability” probably not
 - Bounty-style laws – unclear

What should you do

- Review plans to see how they address.
- If they chose to cover, make sure there is a caveat about “where not prohibited by law”
- If they chose not to cover but with exceptions like life of the mother is in danger or rape or incest will need to check state laws as they have varying rules/days/weeks for when these exceptions apply.

Abortion & IVF

- Alabama IVF Ruling
 - Brief Timeline
 - In February, Alabama Supreme Court decision held that embryos created through IVF are considered children based on an 1872 state law
 - Fertility clinics paused IVF services
 - On March 6, Governor Kay Ivey signed legislation shielding doctors and clinics from potential legal liability for providing IVF to patients in the state. As a result, IVF services have resumed in Alabama in at least two of the state's fertility clinics
 - What Employers Should Know
 - Alabama law was a criminal law of general applicability (so, ERISA would not likely preempt it), but it was not targeted at health plans
 - Plans might consider enhancing travel assistance benefits for EEs if IVF services become limited again

Grab Bag of Topics

- Annual ACA OOPM Limit
 - Self-only Coverage:
 - ❖ 2024: \$9,450
 - ❖ 2025: \$9,200
 - Other than Self-only Coverage:
 - ❖ 2024: \$18,900
 - ❖ 2025: \$18,400
- HSA-eligible HDHP Limits
 - Minimum Deductible for 2024
 - ❖ Self-only Coverage: \$1,600
 - ❖ Other than Self-Only Coverage: \$3,200
 - ❖ Embedded deductible: \$3,200
 - OOPM Limit for 2024
 - ❖ Self-only Coverage: \$8,050
 - ❖ Other than Self-Only Coverage: \$16,100
 - ❖ Embedded OOPM: \$9,450

Grab Bag of Topics

- COVID-19 Relief ending
 - National Emergency ended 4/10/23; Public Health Emergency ended 5/11/23; Outbreak Period ended 7/10/23. Last possible date for timeframe relief would end 7/10/24
 - HDHP were granted relief to provide first-dollar coverage for COVID testing. This relief is ending with plan years ending on or before December 31, 2024. For any plan years ending January 1, 2025 or after, COVID testing is subject to the applicable deductible for HDHP.
- ACA Affordability Threshold
 - Percentage of household income in 2023: 9.12%
 - Percentage of household income in 2024: 8.39%
- Change Healthcare Cyber Attack
 - Massive Cyber Attack which forced the shut off of systems for submitting medical claims, pharmacy claims, and processing payments.
 - Could result in claims being submitted outside of claim submission timeframes in PD, network contracts, and stop loss policies.

Questions & Answers

