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HEALTH & WELFARE PLAN LUNCH GROUP

February 1, 2024

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INDEX

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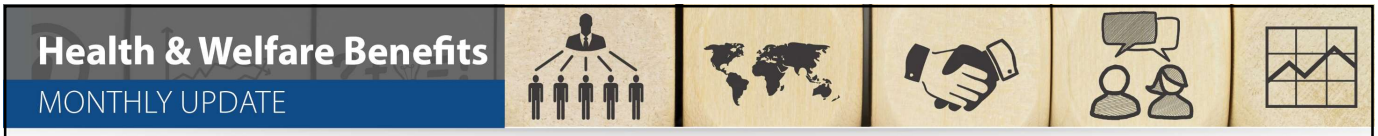
0



February 2024 Agenda

- 2023 Short-term Limited Duration and Fixed Indemnity Proposed Regulations – Impact on Abusive Wellness Program Arrangements
- Specialty Drug and Copay Assistance Program Compliance Issues
- Service Provider Agreement Compliance Issues
- Grab Bag Report and Reminders

1

Health & Welfare Benefits
MONTHLY UPDATE

2023 Proposed STLDI and Fixed Indemnity Regulations

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2

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Proposed Rule for STLDI and Fixed Indemnity Coverage

Core purpose of proposed rule is to reduce confusing STLDI and fixed indemnity coverage with ACA-compliant coverage. Proposed rule published by federal regulators on July 12, 2023 would:

- Cut back the current 36-month max renewal limit on STLDI to three months with one month extension (also includes an anti-stacking provision);
- Redefine "excepted benefits" status for hospital indemnity and other fixed indemnity supplement benefits;
- Impose new notice requirements;
- Change the tax treatment of all fixed indemnity health policies, including specified disease coverage.

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3

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Fixed Indemnity Coverage and "Excepted Benefits"

- Currently, certain benefits are "excepted" under HIPAA rules and excluded from the ACA requirements if:
  - the benefits are provided under a separate policy/certificate/contract;
  - no coordination of the benefits and exclusions under any plan maintained by same sponsor; and
  - benefits paid w/o regard to whether benefits are provided under plan maintained by same sponsor.
- If finalized, proposed rule would
  - reinterpret and expand the meaning of "noncoordinated" benefits in group and individual markets
    - If read too broadly, coverage that complements/fill in gaps of other coverage offered by same plan sponsor (or same insurer in the individual market) might no longer be an "excepted benefit."
  - eliminate variation in the amount of benefits by services/items, severity of illness/injury, or any other characteristics particular to a course of treatment, for individual and group coverage alike.
    - Currently, individual coverage allows benefits to vary on a per service and/or per period basis; group coverage can vary on a per-period basis and vary the amount of benefit based on the triggering event.
- General Effective Date: Applies to new policies sold or issued starting 75 days after a final rule is published.
  - Policies sold or issued before the General Effective Date: plan years (coverage periods in the individual market) beginning on or after Jan. 1, 2027.

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MONTHLY UPDATE

New Notice Requirements for Fixed Indemnity

- Proposed rule addresses the consumer confusion issue by adding a new notice requirement for fixed indemnity group coverage and amending the existing notice requirement for individual coverage.
- Notice states that coverage is not "comprehensive health insurance" and doesn't have to include Federal consumer health insurance protections.
  - Must be prominently displayed on first page of any marketing, application, and enrollment materials (paper or electronic) provided at or before enrollment or re-enrollment, and on first page of individual policies
  - Seeking comment on alternate language that would use the header "WARNING."
- Effective date for new notice requirement: 75 days after final rule is published.

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MONTHLY UPDATE

Tax Treatment for Hospital and Other Fixed Indemnity and Specified Disease

- Current understanding (see Rev. Rul. 69-154):
  - Premiums paid on after-tax basis: benefits received are tax-free.
  - Premiums paid on pre-tax basis (either employer contributions or employee pretax salary reduction): tax status depends on unreimbursed medical expenses.
    - Amounts not exceeding related unreimbursed medical expenses are tax-free.
    - Amounts exceeding related unreimbursed medical expenses are taxable.
- Proposed rule: If premiums are paid pre-tax (either employer-paid or pre-tax salary reduction), entire amount of benefit would be taxable income, regardless of the amount of the employee's unreimbursed medical expenses.
  - Benefits would also be subject to employment taxes.
- Effective Date: The later of the date of publication of the final rule or Jan. 1, 2024.

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MONTHLY UPDATE

What if New Reg is Finalized as is . . .

- Limits on types of fixed indemnity coverage
- All pre-tax health indemnity coverage creates taxable benefits
- Non-coordination and tax rules impact
  - Mini-MEC Coverage
  - Major-medical look-alike plans
  - Double dip wellness programs
  - HDHP indemnity combinations
- Requests comments on treatment of specified disease coverage
- Requests comments on level funded premium (LFP) plans

Wellness Program Abuse Scheme

- Employer provides comprehensive health and a fixed indemnity health insurance policy.
- Employees pay a monthly premium of $1,200 for the fixed indemnity policy through pre-tax salary reduction.
- The policy pays a monthly benefit of $1,000 triggered by certain health or wellness activities. The wellness benefit also offers full coverage of several triggering events, including wellness counseling, nutrition counseling, and telehealth benefits, at no additional cost.
- The wellness benefit "reimbursements" are paid by the insurance company to the employer. The employer then pays the "reimbursement" to the employee through their payroll system.
- The IRS concludes that the $1,000 wellness payments are taxable **and** subject to employment taxes (e.g., FICA, FUTA), because the payments are made automatically without regard to whether the employee has incurred any unreimbursed medical expenses. Rather, the "reimbursements" are tied to the amount of salary reduction and projected tax savings.

If it looks too good to be true . . .

- **Step 1: The employee makes a salary reduction election**.
- *If the promised tax benefits are realized*, the salary reduction election reduces employee and employer FICA and FUTA payroll taxes and employee income taxes.
- The pre-tax salary reduction election purportedly reduces the employee's taxable paycheck.

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MONTHLY UPDATE

If it looks too good to be true . . .

- **Step 2: Bring the employee's paycheck back up to the pre-salary reduction level**.
- The employee receives purportedly tax-free payments ("wellness payments") equal to most of the employee's salary reduction amount. The amount of salary reduction returned to the employee is generally reduced by a promoter's fee. Part of the monies returned, which aren't paid directly to the employee, may be used to pay for a traditional fixed indemnity plan.
- To receive the benefit payment, the employee is required to take certain actions, also referred to as "benefit triggers." These include: calling a health coach, signing up for a newsletter, getting a flu shot

Health & Welfare Benefits
MONTHLY UPDATE

If it looks too good to be true . . .

- The payments in Step 2 are taxable, which reduces the employee's take-home pay. For the payments in Step 2 to be tax-free, the payments must be reimbursements for an incurred medical expense. The benefit triggers, while perhaps health related, do not involve unreimbursed medical expenses as defined under federal tax rules. Thus, the purported tax savings evaporate.

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MONTHLY UPDATE

Specialty Drug and Copay Assistance Program Compliance Issues
(Copay Accumulators, Copay Maximizers, and Alternative Funding Programs)

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12

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Copay Accumulators, Copay Maximizers, and Alternative Funding Programs—What are they?

- All involve how a group health plan (GHP) treats drug manufacturer's assistance programs or charitable programs to either help with drug copays for those with GHP coverage or to pay for the drugs for those who are uninsured or without coverage for a specific drug. These programs typically involve specialty drugs.
- GHPs with copay accumulators do not count the manufacturer's assistance toward the GHP's deductible or maximum out of pocket.
- GHPs with copay maximizers typically set the copay for the drug at the amount of the manufacturer's assistance.
- GHPs with alternative funding programs typically exclude coverage for specialty drugs altogether and the participant or beneficiary seeks to have the drug paid with the manufacturer's assistance or charitable program.

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13

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MONTHLY UPDATE

Copay Accumulators, Copay Maximizers, and Alternative Funding Programs—What are they?

- For copay maximizers and alternative funding programs, vendors offering the program assist GHP participants and beneficiaries in enrolling in the manufacturer's program.
  - Can represent substantial GHP savings.
  - Manufacturer push-back and lawsuits.
- Copay Accumulators and Copay Maximizers affect benefits in the GHP itself, and, for ERISA-covered plans, those programs should be disclosed in the SPD.
  - Open questions on alternative funding programs and whether they are "outside" the GHP.

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MONTHLY UPDATE

Copay Accumulators

- Copay accumulators have been in existence for a number of years. They were addressed in the HHS Notice of Benefit and Payment Parameters (NBPP) in 2020 and 2021.
- We refer to the various forms of assistance, including coupons, as copay assistance.
- Issues arise under the ACA maximum out of pocket (MOOP) applicable to non-grandfathered GHPs for drugs that are essential health benefits as well as issues with the minimum deductible in an HSA-compatible high deductible health plans (HDHPs)
- 2020 NBPP stated that copay assistance did not have to count toward the ACA MOOP ***if there was a generic alternative available.***
  - Did this mean that copay assistance had to count if there was not a generic alternative?
- Concerns raised about a possible related effect on HDHPs and deductibles.
  - Q&A 9 of IRS Notice 2004-50 states that an individual is responsible for paying the costs of any drugs (taking into account the copay assistance) until the deductible of the HDHP is satisfied. In other words, you cannot credit the amount of the copay assistance toward the deductible.

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MONTHLY UPDATE

Copay Accumulators

- To count accumulators (HDHP deductible and ACA MOOP) separately where the copay assistance counted toward the ACA MOOP but not the HDHP deductible may prove challenging.
- Tri-agencies issued guidance in FAQs About Affordable Care Act Implementation Part 40 which contained a non-enforcement policy allowing GHPs to not count copay assistance in the ACA MOOP in all instances—even when there was not a generic equivalent.
- Formalized and adopted into HHS regulations in the 2021 NBPP.
- Advocacy groups challenged 2021 NBPP in a D.C. district court, arguing that not counting the copay assistance was inconsistent with the ACA definition of cost-sharing.
- In late September 2023, the D.C. district court agreed in *HIV and Hepatitis Policy Institute et al. v. HHS*, vacating 2021 NBPP and remanding the issue back to HHS. In December, after a request by HHS, the court clarified its ruling to state that by vacating the 2021 NBPP the 2020 NBPP was once again in effect.

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Copay Accumulators

- In briefing the request for clarification, HHS indicated that it would not enforce the district court's decision pending the issuance of new regulations.
- In that same briefing, the advocacy groups challenged HHS's non-enforcement position, but the D.C. district court decided that the non-enforcement issue was not properly before the court.
- The Biden administration initially appealed the D.C. district court decision but, after bi-partisan pressure from the Senate, dropped that appeal.

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Copay Accumulators

- Where are we now?
  - Under the district court's clarification, GHPs are not required to count copay assistance for essential health benefits toward the ACA MOOP if a generic drug is available.
  - Presumably the HHS non-enforcement position announced in briefing on the motion for clarification, ***for all copay assistance***, still stands even after the D.C. district court's decision on that motion. But a formal announcement by HHS on its enforcement position would be welcome.
  - A number of states, ***for fully insured plans***, have stated that the copay assistance must be counted toward the ACA MOOP and those laws are unaffected.
  - Many self-funded GHPs are continuing with copay accumulators pending proposed and then finalized regulations from HHS.
  - GHPs who continue with copay accumulators should begin studying ways to count the copay assistance toward the ACA MOOP while not counting it toward the HDHP minimum deductible.
  - There remains a real questions on whether the 2020 NBPP suffers from the same flaws that the D.C. district court perceived in the 2021 NBPP.

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Copay Maximizers

- Copay maximizers set the copay for the specialty drug under the GHP to the amount of the manufacturer's assistance. Simplified, if annual assistance is $36,000 there will be a monthly co-pay of $3,000.
- Participation in the programs are voluntary but participants or beneficiaries who do not sign up for manufacturer's assistance must pay the increased copay and cost share for such unenrolled participants does not count towards OOP max on basis that such drugs are not essential health benefits.
- The copay maximizer vendor helps the participant or beneficiary sign up for manufacturer's assistance.
- Participants and beneficiaries would likely reach the ACA MOOP quickly (if the cost share was applied to OOP max) if they did not sign up for manufacturer's assistance which would then leave the GHP with 100% of the cost after the MOOP.

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Copay Maximizers

- The ACA MOOP only applies to essential health benefits or EHBs. Rules under the ACA dictate the number of dugs which must be in a drug category and class for purposes of EHBs.
- Copay maximizer vendors interpret this rule to mean that if the minimum number of drugs in a classification or category is covered, the GHP can designate drugs above this specified number as non-EHBs and so the ACA MOOP does not apply to those copays.
  - The upshot is that participants and beneficiaries who opt out of the copay maximizer program will always have to pay the full amount of the increased co-pay without benefit of the ACA MOOP cap.

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MONTHLY UPDATE

Copay Maximizers

- HHS informally disagreed with this position in the preamble to the 2016 NBPP and stated that all drugs in the particular category or class would be EHBs.
- In the 2025 proposed NBPP HHS seeks to formally amend its EHB prescription drug regulation to incorporate this position stating that, "If a health plan covers prescription drugs in excess of the prescription drugs required to be covered … the additional prescription drugs are considered an essential health benefit and subject to the cost-sharing requirements [under the ACA]."
- The comment period on the 2025 proposed NBPP closed in January and a number of comments were received.
- In comments, some argued that the new rule, if formally adopted, should only apply to the insured small group and individual market. Others requested explicit clarification that it also applied to the large insured group market and self-funded plans.
- Further clarification is likely when the 2025 NBPP is finalized.

Alternative Funding Programs

- These programs can vary in design, but one iteration is that a drug is specifically eliminated from a GHP's formulary.
- The alternative funding program vendor then assists the participant or beneficiary in signing up for manufacturer's assistance.
- If that manufacturer's assistance is not available, then alternative means are explored to have the drug covered including possibly covering the drug under the GHP on an exception basis.
- In some of these instances, the vendors take the position that since the drug is not covered the alternative funding program is "outside" the GHP.
- Compliance questions arise as to whether the alternative funding program is, then, itself, a separate unwritten GHP with the tax and fiduciary implications of having an unwritten plan.

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MONTHLY UPDATE

Copay Maximizers, Alternative Funding Programs and Drug Manufacturer Reaction

- Drug manufacturers view their assistance programs as designed to assist the uninsured or those covered by GHPs where there are significant co-pays and deductibles that make a specialty drug unaffordable.
- The manufacturers take issue with copay maximizers that set the copay at the manufacturer's assistance amount or alternative funding programs that exclude a drug entirely.
- Certain drug manufacturers have sued copay maximizer and alternative funding vendors with regard to their programs.
- At least one alternative funding vendor has sued a drug manufacturer for defamation, deceptive business practices and tortious interference for comments it made about the vendor and refusing to allow those using that vendor to participate in manufacturer's assistance.

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MONTHLY UPDATE

Copay Maximizers, Alternative Funding Programs and Drug Manufacturer Reaction

- Applications for drug manufacturer assistance have become specific on these programs.
- Examples:
  - Require an attestation that the individual was uninsured.
  - Assistance may be terminated or modified for those in a copay maximizer program and providing that GHPs and PBMs are prohibited from assisting in enrollment. The enrollment form asks the potential enrollee to identify if they are in a copay maximizer program.
  - Providing copay assistance for up to $15,000 annually for those not enrolled in a copay maximizer program but limiting it to $5,000 for those enrolled in such a program.
  - Specifically, not covering those enrolled pursuant to an alternative funding program and actually calling out certain alternative funding programs by name.

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MONTHLY UPDATE

Copay Maximizers, Alternative Funding Programs, What To Do Now?

- Keep up to date on current litigation involving these programs.
- Understand that manufactures and healthcare providers are opposed to these programs.
- For copay maximizers analyze any effect that the final 2025 NBPP may have.
- Recognize that a copay maximizer or alternative funding vendor will be assisting participants and beneficiaries in obtaining manufacturer's assistance which could be viewed as a representation by the GHP itself. How does a GHP make sure these representations are accurate?
- PHI is likely involved in identifying participants and beneficiaries for the program and make sure appropriate HIPAA privacy and security protections are in place.
- Possible ADA and HIPAA nondiscrimination issues if changes in GHP formularies or increases in copays targeted to specific disabilities or health status.

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MONTHLY UPDATE

Regulatory Update

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26

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Regulations status update

Final rules issued in December 2023/January 2024:

- DOL **final rule** on **employee v. independent contractor** classification under the FLSA (January 10, 2024)
- Tri-Agency **final rule** on **Federal IDR Process Administrative Fee and Certified IDR Entity Fee Ranges** (December 21, 2023)

Proposed rules/Requests for information issued in 2023:

- DOL **Definition of "Employer"--Association Health Plan** Notice of Proposed Rulemaking to rescind 2018 AHP Rule (December 20, 2023); DOL proposes to rescind 2018 association health plan rule that would have expanded the definition of employer to allow more groups of unrelated entities to provide coverage to employees under ERISA's umbrella; ***comments due on or before February 20, 2024***
- HHS Proposed **Notice of Benefit and Payment Parameters 2025** (Nov. 24, 2023); *comment period ended Jan. 8, 2024*
- DOL Proposed **Retirement Security Rule** on Definition of an **Investment Advice Fiduciary** and Proposed Changes to Related PTEs (Nov. 3, 2023); comment period ended Jan. 2, 2024
- Tri-agency Proposed Rules on **Federal IDR Operations** (Nov. 3, 2023); ***comments originally due Jan. 2, 2024; extended until February 5, 2024***
- Tri-agency Request for Information on **Coverage of OTC Preventive Services** (Nov. 3, 2023); comment period ended Dec. 4, 2023
- Tri-Agency Proposed Rules on **MHPAEA** (Aug. 3, 2023); comment period ended Oct. 17, 2023
- Tri-Agency Proposed Rules on **STLDI, Independent, Non-Coordinated Excepted Benefits, Level Funded Arrangements** and Treasury Proposed Rule on **Tax Treatment of Certain Accident and Health Benefits** (July 12, 2023); comment period ended Sept. 11, 2023

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27

Regulations status update (cont.)

Currently under review by OMB

- HHS Office of Civil Rights (OCR) Proposed Rule on the **HIPAA Privacy Rule and Reproductive Health Care** (Apl. 17, 2023); comment period ended June 16, 2023 (since January 24, 2024)
- **Section 1557** proposed rule; comment period closed in October 2022 (since December 21, 2023)

And still waiting on:

- HHS Office of Civil Rights (OCR) Proposed Rule on **Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement** (Jan. 21, 2021); (comment period closed in May **2021**)

Section 1557 of the ACA: Nondiscrimination in Health Programs and Activities

Section 1557 of the ACA incorporates protections from existing civil rights laws:

- Title VI of the Civil Rights Act of 1964 (race, color, and national origin)
- Title IX of the Education Amendments of 1972 (sex)
- Age Discrimination Act of 1975
- Section 504 of the Rehabilitation Act of 1973 (disability).

Section 1557 does not apply to self-insured ERISA group health plans that do not receive funding from HHS, though current law is unsettled on how 1557 would apply to a TPA administering such a plan.

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Section 1557 Regulations—brief history

- 2016 Final Rule:
  - 1557 applies to any health program or activity, any part of which receives federal financial assistance (FFA) from HHS (presumably includes RDS); all HHS-administered programs; Health Insurance Marketplaces and participating issuers
  - Procedural Requirements: grievance procedure and compliance coordinator; notices of nondiscrimination and taglines for availability of language assistance services in top 15 non-English languages in state
  - Enforcement mechanisms under covered civil rights laws; suspension/termination/denial of federal financial assistance; referral to DOJ; recognizes a right for an individual to bring civil action challenge
- 2020 Final Rule repealed and revised several parts of the 2016 Final Rule:
  - Reduced the scope of the rule to exclude the TPA and ASO operations of insurers and covers HHS-administered operations only if established under Title I of ACA
  - Removed notice and tagline requirements; eliminates the compliance coordinator requirement and grievance procedure; modifies language assistance requirements
  - Removed the definition for "on the basis of sex", which included which included gender identity, sex stereotyping and termination of pregnancy under the 2016 rule
  - Enforcement: removed the right to bring a civil action under 1557; expressly states that 1557 shall be interpreted consistent with RFRA and federal conscience-protection laws

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1557: 2022 Proposed Rule

The 2022 Proposed Rule was published in the Federal Register on August 4, 2022 and sent to OMB on December 21, 2023. It proposes to reinstate/revise parts of the 2016 Final Rule and add new provisions:

- Reinstates scope of rule to include insurers' TPA/ASO activities and ALL HHS-administered programs. Also Interprets Medicare Part B as Federal Financial Assistance, which would be a reversal of HHS's position under the 2020 Final Rule.
- Refines application of 1557 to GHPs. Under the 2016 Final Rule, GHPs were included as entities that were categorically covered but are not included in the list in the 2022 Proposed Rule. Complaints against GHPs will be evaluated case-by-case to determine if the GHP is covered under 1557.
- Brings back notice requirements and revives tagline requirements in the form of "Notice of Availability" requirement; requires covered entities to have Section 1557 policies and staff training related to language assistant services and communication/modifications to policies & procedures for disabilities.
- Provides a notification process for objections under federal conscience or religious freedom laws (OCR will consider, investigate, and make a determination); preamble acknowledges a private right of action recognized by the SCOTUS in Cummings v. Premier Rehab Keller, P.L.L.C..
- Clarifies 1557's application to telehealth; Prohibits discrimination in the use of clinical algorithms to support decision-making in covered health programs and activities.
- Aligns regulatory requirements with Federal court opinions to prohibit discrimination on the basis of sex, including sexual orientation and gender identity, and adds discrimination on the basis of pregnancy or related conditions, including "pregnancy termination." Prohibits discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits.

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MONTHLY UPDATE

1557 and TPAs

- *Pritchard et al v. Blue Cross Blue Shield of Illinois*—TPA for a self-insured employer with sincerely held religious beliefs (Catholic Health Initiatives) denied claims for gender affirming care. Federal judge rejected TPA's defenses on summary judgment:
  - "Not a covered entity" Defense
    - Chevron deference did not apply; statutory language was not ambiguous, and 2020 rule is contrary to statute.
  - "No federal funds for TPA activities" Defense
    - Courts included activities as an issuer in the analysis (statute says "any part of which" receives FFA).
  - "Plan Design/ERISA" Defense
    - No deference to 2016, 2020, or 2022 rules; statutory text contains no exclusion for TPAs that did not design the plan.
    - Also, ERISA 1144(d) states that ERISA will not be construed to alter/invalidate/impair/supersede, etc. any other U.S. law.
  - Religious Freedom Restoration Act (RFRA) Defense
    - RFRA is inapplicable where the government is not a party
- On December 19, 2023 the court ordered BCBS to reprocess all claims that were denied based solely on the discriminatory provisions. On January 22, 2024, the court agreed to stay the order pending BCBSIL's Ninth Circuit appeal.

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ACA FAQs Part 64: Therapeutic Equivalence Approach

- On January 22, 2024 DOL, HHS and IRS issued FAQs Part 64, emphasizing prior guidance on compliance with coverage of contraceptives under HRSA-supported guidelines.
- Consistent with existing regs and guidance, reasonable medical management techniques are permitted. "Reasonable" techniques must include "an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or their provider" and must cover w/o cost sharing an FDA-approved/cleared/granted contraceptive product determined to be medically necessary by the provider.
- "Potentially unreasonable" techniques include:
  - Require step therapy/"fail first" protocols
  - Apply age-related restrictions
  - Impose unduly burdensome administrative requirements as part of an exceptions process
  - Require cost sharing for services integral to the preventive service provided even is billed separately (anesthesia, pregnancy test, other pre- and post-operative items)

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ACA FAQs Part 64: Therapeutic Equivalence Approach

- Q1: "Therapeutic equivalence approach" may be used to comply with requirement to cover full-range of FDA-approved contraceptive drugs/drug-led devices w/o cost sharing.
  - Plans that otherwise cover all FDA-approved contraceptives in a category can exclude a therapeutic equivalent…
  - BUT the exceptions process must allow access to the excluded product, w/o cost sharing, if determined to be medically necessary by the attending provider.
- Q2: Therapeutically equivalents are identified in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), designated with a code with the first letter "A".
  - Orange Book available at: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.
- Q3: TEA applies only to contraception that is an FDA-approved drug or drug-led device.
- Q4: ***Must still have a reasonable exceptions process***, even if the plan covers all FDA-approved contraceptive drugs/drug-led devices other than those for which there is a covered therapeutic equivalent.
- Q5: Plans and issuers already following prior guidance will continue to be in compliance. The Departments believe that under TEA, the exceptions process would apply less frequently.
- Q6: The Departments provide a chart of the appropriate contact information in Q6 for individuals with concerns about their plan's compliance with the ACA contraceptive coverage requirements.

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Florida's Prescription Drug Reform Act ("PDR Act")

- Signed into law in May 2023; effective January 1, 2024.
- Imposes several requirements on what must be included in the contract between a pharmacy benefit manager ("PBM") and a "pharmacy benefits plan or program".
- **Broad application:** A "pharmacy benefits plan or program" means "a plan or program that pays for, reimburses, covers the cost of, or provides access to discounts on pharmacist services provided by one or more pharmacies to covered persons who ***reside in, are employed by, or receive pharmacist services from this state***."
  - This appears to apply to any group health/prescription drug plan covering individuals residing in Florida and/or obtaining pharmacist services in Florida, regardless of plan or plan sponsor situs and whether the plan is fully insured or self-insured.
- Applies to contracts that are "executed, amended, adjusted, or renewed on or after July 1, 2023."
- Requires employer to attest compliance to the Florida Office of Insurance Regulation ("OIR"). Templates form and basic instructions are at https://www.floir.com/life-health/pbm.

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MONTHLY UPDATE

Florida's Prescription Drug Reform Act ("PDR Act")

Sampling of requirements for contract between PBM and plan:

- Must bar imposing mandatory mail-order requirements unless the drug cannot be acquired at any retail pharmacy in the PBM's network; opt-in mail order is allowed if, as compared to retail, there are no additional cost-sharing obligations or limitation on quantity through mail-order.
- PBM and plan must provide 60-day continuity of care period following midyear formulary changes.
- Must use pass-through pricing and prohibits the use of spread pricing.
- Must ensure funds received in relation to providing services for a plan or a pharmacy are used or distributed only pursuant to the contract with the plan or pharmacy or as required by applicable law.
- If the contract delegates the negotiation of rebates to PBM, PBM will pass through 100% of manufacturer rebates, and those rebates will be used for the sole purpose of offsetting defined cost sharing and reducing premiums of participants.
- Must include network adequacy requirements that meet or exceed Medicare Part D program standards for convenient access to network pharmacies, and extend the network beyond pharmacies affiliated with the PBM.

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10th Circuit PBM Litigation Update

10th Circuit: *Pharmaceutical Care v. Mulready*

- Supreme court stated in Rutledge that there are two types of state laws that are preempted:
  - Laws that require providers to structure benefit plans in particular ways
  - Laws that have an acute but indirect economic impact such that it forces providers to adopt a certain scheme of substantive coverage
- At issue in *Mulready*:
  - Geographic standards imposed on networks (Network Access Standards)
  - Prohibition against requirements or incentives for using a particular requirement (Discount Prohibition)
  - Any willing pharmacy requirement (AWP)
  - Prohibitions regarding terminations of pharmacists from network if on probation
- Brief Case History since August 2023:
  - In August 2023, 10th Circuit reversed lower court's decision, holding that parts of Oklahoma's "Patient's Right to Pharmacy Choice Act" was preempted by ERISA and Medicare Part D.
  - In September 2023 the state petitioned for a rehearing but was denied.
  - State filed a motion to stay the mandate pending the resolution of cert petition but was denied on January 2, 2024. The stay would have allowed the state to continue to enforce the law.
  - No cert petition yet filed with SCOTUS.

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Considerations for Group Health Plan Service Agreements

Looking at Agreements in light of Recent Legislation, Regulation and Litigation

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38

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Fundamental requirements for group health plan agreements

- Fiduciaries must not enter into agreements with service providers unless
  - The services must be "necessary"
  - The service provider receives no more than "reasonable compensation"
    - Direct compensation
      - Does this include amounts paid solely from the employer's general assets?
    - Indirection Compensation
      - General ERISA 408(b)(2) rules generally require disclosure by service providers of indirect compensation
      - New group health plan rules related to disclosures for "brokerage" and/or "consulting" services
      - Are disclosure rules applicable if service provider not providing brokerage or consulting services?
  - Termination on reasonably short notice w/o "termination penalty"
    - What is a termination penalty?

39

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39

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Practical Application-Claims Review and Payment Process

- ERISA Claims Review and Payment Process
  - Contents of claims review letters
    - ERISA requirements
    - Statute of limitations
  - Application of plan's anti-assignment clause
  - Use of Artificial Intelligence
  - Provider payment rules
  - Fiduciary status
- Independent Dispute Resolution of NSA claims
  - What is the amount initially paid to provider
  - Disclosures
  - Dispute process

Health & Welfare Benefits
MONTHLY UPDATE

Practical Application-Fees

- Review and analyze the types of fees/compensation in an agreement
  - PEPM
  - % Savings
  - % of Recovery
  - Payments FROM third parties (rebates, service fees, etc)
  - Payments TO third parties (subcontractor fees)

Practical Application-Compliance

- CAA Compliance
  - Machine Readable Files
  - Consumer pricing tools
  - Gag Clauses
  - ID Cards
  - NSA Disclosures
- MHPAEA analysis (beyond CAA)

Health & Welfare Benefits
MONTHLY UPDATE

Questions

ALSTON & BIRD