

Health and Welfare Roundup – 4 Developments Plan Sponsors Should Be Aware of This Month

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1. Tri-Agencies Pause Enforcement of 2024 Final Mental Health Parity and Addiction Equity Act (MHPAEA) Regulations.

The U.S. Department of the Treasury, Department of Labor, and Department of Health and Human Services (the Departments) have announced that they will not enforce the September 9, 2024 final MHPAEA regulations (the “2024 Final Rule”), which expanded nonquantitative treatment limitation (NQTL) comparative analyses requirements under MHPAEA. The nonenforcement policy follows a lawsuit filed by the ERISA Industry Committee challenging the 2024 Final Rule as being arbitrary and capricious and contrary to law. The Departments secured a stay of the litigation while they reconsider the 2024 Final Rule. The nonenforcement policy will apply to any failure to comply with the 2024 Final Rule that occurs before a final decision in the lawsuit or within 18 months after the final decision.

The Departments note that MHPAEA (as amended by the Consolidated Appropriations Act, 2021) and the previous 2013 final rule still apply.

Winston Takeaway: While the Departments’ nonenforcement policy offers welcome relief from onerous new provisions of the 2024 Final Rule, including the fiduciary attestation and data requirements, it does not relieve plan fiduciaries and sponsors from their obligations under existing MHPAEA provisions and regulations. Plan sponsors and fiduciaries should continue to ensure compliance with those requirements.

2. House Ways and Means Committee Budget Reconciliation Bill – The “One Big Beautiful Bill”

The U.S. House of Representatives recently passed its long-anticipated tax bill. The bill makes the following changes affecting health and welfare plans:

- Allows individuals who are eligible for Medicare Part A but enrolled in a high-deductible health plan (HDHP) and still working to continue contributing to a health savings account (HSA).
- Allows individuals enrolled in HDHPs to concurrently enroll in direct primary care (DPC) service arrangements, maintain their HSA, and pay for the DPCs using HSA funds, up to a limit of \$150 per month (\$300 per month for family arrangements).

- Allows employees to utilize discounted health services at on-site clinics located at their worksites without losing HSA eligibility.
- Treats amounts paid for physical activity, fitness, and exercise as amounts paid for medical care. Thus, it allows individuals to use up to \$500 per year (\$1,000 for families) in HSA funds for reimbursement of these costs.
- Allows each spouse to make a \$1,000 catch up contribution to the same HSA, assuming they meet the age requirements.
- Allows employees who recently enrolled in an HDHP to rollover funds from a health flexible spending account (FSA) or health reimbursement arrangement (HRA) to an HSA, up to the FSA contribution limit.
- If an HSA is established within 60 days after HDHP coverage begins, allows use of HSA funds to pay qualified medical expenses incurred within that 60-day period.
- Removes the bar to HSA eligibility for an individual whose spouse is enrolled in an FSA.
- Increases the HSA contribution limits for lower-earning individuals and families.

The bill also makes the following changes to Individual Coverage HRAs (ICHRAs)—which became available following the issuance of regulations by the Departments in 2019:

- Codifies the Departments’ regulations into statute.
- Renames ICHRAs as “Custom Health Option and Individual Care Expense” or “CHOICE” arrangements.
- Allows an employee enrolled in a CHOICE arrangement to pay premiums for individual coverage purchased on the Healthcare Marketplace using pre-tax dollars set aside under an Internal Revenue Code section 125 cafeteria plan.
- Creates a two-year tax credit for employers with fewer than 50 employees offering CHOICE arrangements for the first time.
- Requires an employer to report the total amount of permitted benefits for an individual enrolled in a CHOICE arrangement on the individual’s W-2.

Winston Takeaway: The proposed legislation contains numerous changes that would affect the administration and utilization of health and welfare benefits. It also liberalizes certain provisions of existing law, providing employers with more flexibility in the design of their health and welfare benefits. The bill has been passed by the House and will be considered by the Senate. Stay tuned for further developments.

3. White House Issues Drug Pricing Executive Order

Last month, President Trump issued an executive order aimed at lowering prescription drug prices. The order instructs various federal agencies and officials to renew efforts begun in the previous Trump administration to lower drug prices and introduces new proposals. Specifically, the order:

- Instructs various officials to “provide recommendations to the President on how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices.”
- Instructs the Secretary of Labor to propose regulations to improve transparency into compensation received by pharmacy benefit managers (PBMs).
- Instructs the Food and Drug Administration to “streamline and improve” its existing drug importation program.
- Instructs the Secretary of Health and Human Services (HHS Secretary) to announce a plan to survey hospital acquisition cost for covered outpatient drugs at hospital outpatient departments to align Medicare payment with the cost of acquisition.
- Instructs the HHS Secretary to ensure federal grants to health centers are conditioned on those centers’ making insulin and injectable epinephrine available at low cost to certain low-income individuals.

- Instructs the HHS Secretary to propose guidance for the 2028 drug price negotiation cycle, which the Centers for Medicare & Medicaid Services published on May 12, 2025.
- Instructs the HHS Secretary to “work with the Congress to modify the Medicare Drug Price Negotiation Program to align the treatment of small molecule prescription drugs with that of biological products.”
- Instructs various officials to recommend changes to stabilize and reduce Medicare Part D premiums.

Winston Takeaway: Proposed regulations to promote PBM pricing transparency will be of particular interest to plan sponsors and fiduciaries in the design and administration of their prescription drug plans and negotiating agreements with plan service providers.

4. Federal Court Rules Health Insurer Violated ACA Section 1557 by Categorically Excluding Gender Affirming Care

In *L.B. v. Premera Blue Cross*, the U.S. District Court for the Western District of Washington held that a health insurer’s policy, which automatically denied coverage of mastectomy or breast-reduction surgery for “female to male” or “female to non-binary/gender-neutral” patients (collectively, transgender patients) under 18 years old, violated section 1557 of the Affordable Care Act because it facially discriminated on the basis of sex. Under the challenged policy, a transgender patient seeking gender-affirming chest surgery must have a diagnosis of gender dysphoria and be at least 18 years old, even if all other medical necessity criteria were met. But a different policy permitted the same surgery for cisgender boys with gynecomastia. Thus, a minor’s eligibility turned on whether the procedure was sought to alleviate gender dysphoria in someone assigned female at birth versus excess breast tissue in someone assigned male at birth.

The court concluded that this explicit differential treatment was “textbook sex discrimination,” regardless of whether sex is defined narrowly as sex assigned at birth or broadly to encompass gender identity. The court reasoned that if “sex” means sex assigned at birth, the policy favored adolescents assigned male at birth over those assigned female at birth, and if “sex” means gender identity, the policy disfavored transgender minors, using the diagnosis of gender dysphoria as a proxy. Either way, the court held that coverage hinged on a protected characteristic forbidden by section 1557, which incorporates Title IX’s prohibition on discrimination “on the basis of sex” by reference.

The court rejected the insurer’s justification that minors’ insufficient maturity and the lack of robust studies supported its determination that gender affirming breast reduction surgeries were medically unnecessary. The court cited the insurer’s unwritten “exceptions” to its own policy, noting that it had granted 28 of 63 prior requests for such surgeries because, for example, minors’ “binding” of their chests had led to injury. The court explained that these secret exceptions undermined the insurer’s assertion that minors’ immaturity and the lack of sound studies were driving the insurer’s determination that such surgeries were medically unnecessary.

Winston Takeaway: While section 1557 of the Affordable Care Act applies only to entities that receive federal funding, employers who sponsor self-funded health plans should evaluate whether exclusions for coverage of gender affirming care violate other applicable nondiscrimination rules.

Next Steps

The developments discussed above highlight the need for plan sponsors to be proactive to optimize benefits strategy, minimize risk, and anticipate compliance issues. Please contact a member of the Winston & Strawn Employee Benefits and Executive Compensation Practice or your Winston relationship attorney for further information.

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