The ERISA Edit: More Coverage Mandates and TiC Enforcement Ahead

Employee Benefits Alert
10.05.2023

Expanded Over-the-Counter Preventive Services Coverage Mandate Under Consideration

The Departments of the Treasury, Labor, and Health and Human Services (collectively, the Departments) issued a Request for Information (RFI) on Friday seeking public comments on application of the preventive services requirements under section 2713 of the Public Health Service (PHS) Act to over-the-counter (OTC) preventive items and services prescribed by a healthcare provider as part of a course of treatment. Current agency guidance interpreting statutory and regulatory requirements states that preventive products that are generally available without a prescription, such as folic acid, contraception sponges, and spermicides, must be covered without co-sharing only when such products are prescribed by a healthcare provider. The RFI signals that the Departments are considering future rulemaking or new guidance that would eliminate the prescription requirement.

The Departments refer to Biden administration executive orders aimed at increasing access to affordable healthcare and protecting access to reproductive healthcare in the wake of the overturning of *Roe v. Wade* and the Food and Drug Administration's (FDA) July 2023 approval of a progestin-only birth control pill available without a prescription as contributing to the impetus for the RFI. According to the Departments, "[R]equiring plans and issuers to cover, without cost sharing, OTC preventive products without a prescription by a healthcare provider under section 2713 of the PHS Act is an important option to consider for expanding access to contraceptive care." They also reference "interested parties' recent experiences operationalizing coverage requirements for OTC COVID-19 diagnostic tests without cost sharing and without a prescription by a healthcare provider" as "relevant to the considerations included in the RFI."

The RFI contains a long list of topics on which the Departments seek input, addressing, *inter alia*, "operational challenges to plans, issuers, third-party administrators, pharmacy benefit managers (PBMs), and retailers if plans and issuers are required to cover, without imposing cost-sharing requirements on the consumer, OTC preventive products purchased without a prescription." They also seek input on "lessons learned" from the coverage and provision of OTC COVID-19 diagnostic tests during the pandemic and on an array of questions related to the utilization and operational costs associated with the contemplated preventive services requirement.

Comments in response to the RFI are due on or before November 4, 2023.

Court Vacates HHS Prescription Drug Co-Pay Accumulator Regulation

The U.S. District Court for the District of Columbia issued a decision on September 29, 2023, vacating a rule issued by the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) in 2020 that permitted, but did not require, health insurance issuers and group health plans to decline to credit certain financial assistance provided by drug manufacturers when calculating cost-sharing obligations under the Affordable Care Act (ACA). *HIV and Hepatitis Policy Inst. v. U.S. Department of Health and Human Services*, No. 1:22-cv-2604 (JDB) (Sept. 29, 2023, D.D.C). The challenged rule allowed plans and issuers to exclude the amount of co-pay assistance paid by manufacturers as a "co-pay" for purposes of calculating out-of-pocket expenditures, but only "to the extent consistent with state law." Multiple states have enacted laws that prohibit or limit plans and issuers from implementing "co-payment accumulator" programs by which health plans and issuers track co-pay assistance to participants and beneficiaries to exclude those amounts from deductibles and annual out-of-pocket maximum calculations. The controversial 2020 rule is touted by the agencies and payors as helping to rein in rising prescription drug costs, claiming manufacturer co-pay assistance exacerbates increasing costs by steering patients toward higher priced, brand-name drugs. The rule is disfavored by drug manufacturers and patient advocates who claim it harms participants and beneficiaries who rely on the

co-pay coupons and other forms of financial assistance to lower overall out-of-pocket healthcare spending.

The plaintiffs in the case, the HIV and Hepatitis Policy Institute, the Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council, alleged that the rule, which allowed for co-pay accumulator programs, violated the Administrative Procedure Act (APA) and improperly provided "a windfall to [insurers], allowing [insurers] to collect full deductible and co-payment amounts from each patient for each prescription fill, but then disregard any portion of those payments that came from manufacturer assistance on future prescription fills." The federal government, supported by an *amicus* brief from trade association America's Health Insurance Plans (AHIP), argued, *inter alia*, that the statutory definition of "cost-sharing" in the ACA is ambiguous and that the agencies' decision to permit exclusion or inclusion of amounts paid by drug manufacturers in the definition of "cost-sharing" was reasonable even though it did not resolve the ambiguity. They further argued that the use of co-pay assistance coupons raises overall prescription drug expenditures by plans and issuers because they disincentivize market-driven consumer decision-making that would normally result in more generic prescription fills at lower costs.

The district court, ruling on the parties' cross-motions for summary judgment, sided with the plaintiffs, finding that the rule embodied a "contradictory textual interpretation." According to the court, the contradictory reading of the same statutory and regulatory language and "the fact that the agencies have yet to offer a definitive interpretation of ["cost-sharing"] that would support their authorization of co-pay accumulators" demonstrated that the rule was arbitrary and capricious. The court also ruled that the ACA's definition of "cost-sharing" "does not speak clearly as to the treatment of manufacturer assistance." The court vacated the rule and remanded the matter to the agencies to interpret the statutory definition in the first instance.

Following this ruling, it is unclear what rules will govern the use of co-pay accumulator programs. The prior agency rule, under which plans and issuers were allowed to exclude manufacturer co-pay assistance payments from deductible and out-of-pocket maximum calculations only if a generic drug was available and only to the extent permitted by state law, may be reinstated, but it suffers from the same issues that led the court to vacate the 2020 rule. The government may move for reconsideration of the court's ruling or for a stay of the ruling, pending an appeal and an appeal is expected. Further guidance from HHS and CMS is likely forthcoming in the interim. It should be noted that state laws prohibiting co-pay accumulator programs could be susceptible to ERISA pre-emption challenges and the related guidance may spawn collateral litigation.

Tri-Agencies Issue FAQs Rescinding Transparency in Coverage Enforcement Policies

On September 27, 2023, the Departments issued *Frequently Asked Questions About Affordable Care Act Implementation* Part 61 (FAQs), rescinding several temporary enforcement policies that gave plans and issuers some leeway in trying to comply with transparency and disclosure provisions contained in the 2020 Transparency in Coverage (TiC) Final Rule. According to Part 61, the Departments will no longer adhere to a deferred enforcement policy with respect to the TiC requirements that plans and issuers publish machine-readable files relating to prescription drug pricing, which was announced in Part 49 of the FAQs in August 2021 following enactment of the prescription drug reporting requirements in the Consolidated Appropriations Act, 2021 (CAA). That policy was intended to address concerns about potentially duplicative and overlapping reporting requirements for prescription drugs. The Departments state that they intend to develop technical requirements and an implementation timeline in future guidance to account for any reliance interests that plans and issuers may have developed with regard to Part 49. They do not, however, intend to undertake further rulemaking to implement the reporting requirements for prescription drug costs under the CAA, as originally contemplated, as the they have determined there is "no meaningful conflict" between the TiC and CAA reporting requirements.

In addition, the Departments state in Part 61 that they are rescinding the enforcement safe harbor provided in Part 53, which applied to circumstances where compliance with the TiC Final Rules was not possible "due to alternative reimbursement arrangements that do not permit the plans and issuers to derive with accuracy specific dollar amounts contracted for covered items and services in advance of the provision of that item or service." This type of limitation on advance determination of provider rates made it impossible for plans and issuers to comply with TiC requirements mandating disclosure of provider contracted rates. The Departments now state that whether a plan or issuer is able to comply with the requirement to disclose certain rates as dollar

amounts is a fact-specific determination and going forward they intend to exercise enforcement discretion with respect to this requirement on a case-by-case basis, without any categorical "safe harbor." The Departments note that in exercising their enforcement discretion, they are unlikely to pursue enforcement action if a plan or issuer can demonstrate that compliance with the relevant provisions of the TiC Final Rules would have been "extremely difficult or impossible," but provide no guidance as to what these conditions would be, other than referencing the difficulties stated in Part 53.

Upcoming Speaking Engagements and Events

On October 17, Joanne Roskey will present, " Headaches, Heartburn, and Anxiety - Mental Health Parity Policy Implications ," to members of the ERISA Industry Committee.

On October 31, Joanne Roskey and Dawn Murphy-Johnson will present, " State Legislative Activities Impacting Employee Benefits," an American Staffing Association webinar.
