BENEFITS INSIDER

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The ***Benefits Insider*** is a bimonthly member exclusive publication prepared for WEB members by the American Benefits Council ("the Council"), a premiere benefits advocacy organization based in Washington, DC. This newsletter provides the latest news and analysis on the most important benefits-related policy matters in Congress, executive branch agencies and the federal judiciary.

Please note: any views or opinions expressed in these stories represent the advocacy positions of the American Benefits Council and its membership. They do not necessarily reflect the views of WEB or its membership. To inquire about membership with the American Benefits Council, contact Deanna Johnson at (202) 289-6700 or djohnson@abcstaff.org.

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RECENT LEGISLATIVE ACTIVITY

Automatic IRA Plan Act Reintroduced

On February 7, Representative Richard Neal (D-MA), the ranking Democrat on the U.S. House of Representatives Ways and Means Committee, reintroduced a modified version of his automatic IRA/retirement plan bill, the Automatic IRA Act of 2024, requiring most employers to sponsor a retirement plan or provide an automatic payroll-reduction IRA to employees.

This measure is a revised version of bills Neal introduced in 2021, 2020 and 2017, with the requirements not taking effect until 2027.

Like previous iterations of this legislation, this bill would require virtually all employers to maintain a 401(k), 403(b) or SIMPLE IRA plan, or an automatic IRA arrangement. Governments, churches, small employers (ten or fewer employees) and new businesses (not in existence for two years) would be exempt from the requirement.

Under the proposal, if the employer adopts an auto IRA to satisfy this requirement, all employees must be eligible to participate in the auto-IRA program, except employees who are younger than age 18, have union status, have a nonresident alien status (with no US-source income) or have fewer than three months of service with the employer.

Notably, the bill provides that generally an employer that participates in a state auto IRA program is exempt from the federal requirement if the state auto IRA legislation was enacted before January 1, 2027. Prior versions of the bill required the state auto IRA legislation to have been enacted before the date of enactment of the bill.

During debate of the Build Back Better Act in 2021, when a prior version of Neal's automatic IRA legislation was being considered for inclusion, the Council urged Neal to revise the bill to protect employers from the growing a patchwork of state mandates, thereby ensuring uniformity in plan administration and addressing concerns about complexity and confusion for plan sponsors.

RECENT REGULATORY ACTIVITY

Agencies Issue FAQs on How Plans Can Ensure Contraceptive Coverage Compliance

The U.S. departments of Health and Human Services, Labor and Treasury (the "tri-agencies") recently issued new **Frequently Asked Questions (FAQs)** addressing coverage of contraceptives and contraceptive care without cost-sharing, as required under the Affordable Care Act (ACA). The FAQs provide a new method for compliance with this requirement but do not change the current, long-standing method for compliance.

According to the tri-agencies, the FAQ was issued in response to reports of plans and insurers imposing barriers to contraceptive coverage, such as step therapy protocols, administrative requirements and cost-sharing for services integral to the application of a preventive service.

The tri-agencies had previously issued FAQs in July 2022 listing these medical management techniques as potentially unreasonable under ACA preventive services requirements.

The new FAQs clarify that plans can use reasonable medical management techniques that comply with the requirement to cover the full-range of FDA-approved contraceptive drugs and drug-led devices without cost sharing by using a "therapeutic equivalence approach." (In this context, a drug-led device is a product that uses a device to deliver the contraceptive drug, for example a pre-filled syringe of contraceptive gel.)

Under a "therapeutic equivalence approach," the tri-agencies state that, in general, a plan will meet the ACA requirement if the plan covers all FDA-approved contraceptive drugs (and drug-led devices) in each category of contraception without cost sharing. However, a plan need not cover an FDA-approved contraceptive drug (or drug-led device) if at least one therapeutic equivalent of that drug (or drug-led device) is covered without cost sharing. However, this approach would generally only be considered reasonable if the plan also provides an exceptions process through which an individual could access the specific contraceptive where medically necessary as determined by the individual's attending provider.

The FAQs specify that the tri-agencies will consider a contraceptive drug or drug-leg device to be therapeutically equivalent to another drug or drug-led device if they are identified as therapeutic equivalents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

The tri-agencies also clarify in the FAQs that, although they expect plans that provide coverage consistent with the therapeutic equivalence approach to experience a significant reduction in the utilization of their exceptions process, they are still expected to have an exceptions process available to ensure that individuals can access coverage for medically necessary contraceptives.

The tri-agencies do stipulate that plans may continue to satisfy ACA requirements for preventive services with respect to contraceptive drugs and drug-led devices by following the tri-agencies' prior guidance. However, they do express concern that the exceptions processes used by many plans and insurers may not be properly following their guidance. Therefore, they reiterate the importance of plans having an exceptions process in place that ensures individuals can access medically necessary contraceptive coverage.

DOL Finalizes Application Procedures for PTE Exemptions

The U.S. Department of Labor (DOL) published **final regulations** on January 24, updating and amending its application procedures for prohibited transaction exemptions (PTEs). The final procedures will become effective on April 8, 2024. While the final procedures retain many of the changes from the proposed regulations that will make it more difficult to obtain exemptions going forward, the final procedures do, however, eliminate or modify some of the most troubling aspects of the initial proposal in response to the Council's previous comments and testimony.

In addition to the statutory PTEs that appear in the text of ERISA, DOL is authorized to grant administrative exemptions when the Secretary of Labor makes a finding on the record that relief is: (1) administratively feasible, (2) in the interests of the plan and its participants and beneficiaries and (3) protective of the rights of participants and beneficiaries of such plan. DOL

also has the authority to grant exemptions from the prohibited transaction rules that are described in the parallel sections of the Internal Revenue Code, which apply to IRAs.

Since the enactment of ERISA, DOL has developed procedures for reviewing PTE applications. The most recent version of these procedures was published in 2011. In March 2022, DOL proposed updates to its procedures for reviewing PTE applications. In two separate rounds of comments and at a public DOL hearing, the American Benefits Council urged DOL to reverse course and provide more opportunities for retirement plan sponsors to modernize their plans. In the Council's analysis, the proposed version of the procedures would "codify DOL's informal positions by discouraging retirement plan sponsors and service providers from requesting exemptions and approaching DOL with questions about the prohibited transaction rules." The Council also offered specific suggestions for improving the proposal if it could not be withdrawn.

The rules as finalized retain the provisions adding the Impartial Conduct Standards to every requested exemption and requiring requestors to provide significantly more information as part of their applications. However, in response to the Council's recommendations, the final regulations differ from the proposal in that they:

- Do not eliminate anonymous pre-submission conversations with DOL by potential applicants.
- Do not require declarations to be made under penalty of perjury.
- Do not categorically bar requests involving transactions or parties that are subject to investigation under any state or federal law.
- Do not include changes that would have narrowed the universe of investment professionals that are eligible to serve as qualified independent fiduciaries in support of an exemption transaction.

RECENT JUDICIAL ACTIVITY

Class-Action Lawsuit May Signal New Wave of Health Plan Fiduciary Allegations

On February 5, class action litigation was brought by a participant in the Johnson & Johnson (J&J) group health plan alleging that the fiduciaries of the plan violated their ERISA duties. *Lewandowski v. Johnson and Johnson, et al.*, filed in the U.S. District Court for the District of New Jersey, may signal a possible wave of similar litigation against employers in which participants allege a breach of fiduciary duty because the self-funded ERISA plan overpaid for services.

In *Lewandowski*, the complaint essentially alleges that the fiduciaries of the J&J group health plan overpaid for generic drugs offered on the plan's formulary, particularly specialty generic drugs. The complaint takes aim at the "spread pricing" model used by the plan's pharmacy benefit manager (PBM), in which the PBM charges the plan one amount for a specific drug and pays the pharmacy a different amount and retains the difference or "spread" between the two amounts.

The complaint alleges that certain generics offered on the formulary were many times higher than the cost of drugs obtained directly from a pharmacy outside of insurance or through a PBM "pass-through" pricing model (in which, in general, the PBM charges the plan what it pays the pharmacy for drugs, with no spread). The complaint raises numerous other issues, including allegations alleging that the J&J group health plan fiduciaries acted imprudently in contracting for drug benefit administration and concerns with the plan's use of a third-party broker and the broker's alleged receipt of revenue from the plan's PBM.

At its core, the complaint alleges that J&J breached the ERISA duty of prudence and the duty to act solely in the interest of the plan in selecting the PBM when other less costly arrangements were available (including pass-through options and specialty drug carve-out vendors). The alleged harm is the higher costs of drugs to the ERISA plan and to plan participants.

This case is expected to be the first in a possible wave of similar litigation against employers alleging a breach of fiduciary duty because the self-funded ERISA plan overpaid for services. At this point, the information contained in the complaint are just allegations and the legal process now gives the defendants an opportunity to respond, including on factual and legal issues.

Significantly and in general, employers may have numerous defenses to these claims. Additionally, plaintiffs in this case and similar cases will need to meet the newly clarified pleading standards set forth by the Supreme Court in 2022 in *Hughes v. Northwestern Univ.*, and if they do not, this could be grounds to dismiss the case(s). For example, with regard to the pleading standard, several circuit courts have held that mere allegations that "costs are too high, or returns are too low" do not give rise to plausible inference that a plan fiduciary has acted imprudently. Rather, plaintiffs must provide "a sound basis for a comparison" (or a "meaningful benchmark") for the services at issue (for example, as concluded by the 8th Circuit Court of Appeals in *Matousek v. MidAm. Energy Co.* in 2022).

Council staff will monitor this litigation closely and provide updates on any significant developments.