



## **Court Orders Refund of Employer's ACA Penalty, Uppends IRS Assessment Process**

By: Matt Stiles

Last month, in *Faulk Company, Inc. v. Xavier Becerra, et al.* 4:24-CV-00609-P (April 10, 2025), the U.S. District Court for the Northern District of Texas granted an employer's challenge to employer shared responsibility penalties assessed by the Internal Revenue Service ("IRS") and ordered IRS to refund \$205,621.71 that Faulk Company, Inc. ("Faulk"), the lone plaintiff in the case, paid in 2019 penalties. As part of the court's order, it struck down the employer shared responsibility regulations at 45 C.F.R. § 155.310(i).

**IRS Assesses Faulk an ESRP Penalty.** Prior to 2019, Faulk, a Texas-based provider of janitorial services for schools, provided its full-time employees with minimum essential health insurance coverage as required under the Affordable Care Act ("ACA"). Beginning in 2019, Faulk discontinued providing such coverage. In December 2021, Faulk received from the IRS a Letter 226-J, assessing an employer shared responsibility ("ESRP") excise tax in the amount of \$205,621.71 due to Faulk's failure to offer its full-time employees minimum health insurance coverage under the ACA for 2019. Faulk paid the penalty to IRS but filed along with it a letter explaining that Faulk made such payment under protest. Faulk received no response, so it filed a refund claim with the IRS in 2022 and

then promptly filed suit in the Northern District of Texas.

**Faulk's Lawsuit.** In Faulk's lawsuit, it alleged that the IRS had violated the company's due process rights by issuing the Letter 226-J and assessing a penalty before the Department of Health and Human Services ("HHS") had first issued Faulk a "certification" as to Faulk's potential liability and provided Faulk a notice of right to appeal, a process Faulk asserted is rooted in the requirements of the ACA statute.

**The ACA's Employer Mandate.** Under ACA § 1411, applicable large employers (those employing at least 50 full time equivalent employees) must provide their employees minimum health insurance coverage, generally known as the "employer mandate." In the statute, Congress gave to HHS the exclusive authority to make that employer mandate effective. Employers who fail to satisfy the employer mandate may be statutorily liable for an ESRP penalty. However, Congress guaranteed due process rights to employers subject to the employer mandate and directed HHS to make the determination whether an employer has failed to satisfy it. Under the statute, if HHS determines an employer did not fulfill the employer mandate, HHS must notify the health insurance marketplace (the "Exchange") and then the Exchange must give the employer two notices. The first notice advises "that the employer may be liable" for an ESRP, and the second notifies the employer of its right to appeal. Once it has been determined that an ESRP penalty is owed, the ACA



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requires HHS to “certify” that finding to the employer. Nothing in the ACA authorizes HHS or the Exchange to delegate any part of this process to the IRS. Consistent with the ACA, once HHS has certified that an employer owes an ESRP payment, IRS has the obligation to assess and collect the ESRP penalty.

**HHS Attempts to Delegate Duties to IRS.** Three years after passage of the ACA, HHS promulgated regulations detailing the certification of an ESRP penalty under 45 C.F.R. § 155.310(i), in which HHS attempted to streamline that process, delegating to the IRS the duty to certify to an employer that an ESRP penalty is owed.

**The Court’s Ruling.** Upon review of Faulk’s challenge to the ESRP penalty assessment by IRS, the court ruled that nothing in the ACA authorized HHS to delegate to the IRS its duty to certify to an employer that an ESRP penalty is owed. In this respect, the court struck down the regulation at § 155.310(i), declaring it “void and unenforceable,” as inconsistent with the plain language of the ACA. The court went on to reason that because IRS relied on improperly delegated authority from HHS when it issued the ESRP penalty to Faulk, the penalty itself could not stand, and the IRS must refund the full penalty amount to Faulk.

**Practical Implications for Employers.** In what has become a somewhat rare occurrence of federal district courts exercising judicial restraint, the court’s ruling in *Faulk Company, Inc.* resulted in no nationwide injunction against HHS, IRS, or the ESRP assessment process. Rather, the court’s ruling provided limited relief to Faulk, alone. Still, the well-reasoned analysis of the court provides all employers in receipt of Letter 226-J a potential roadmap for challenging the authority of IRS to assess an ESRP penalty without HHS having first provided the employer with the required certification, intended to ensure the employer’s access to due process of law.

While employers experienced of flurry of Letter 226-Js during the Biden Administration, ESRP penalties were virtually unheard of during the first Trump Administration, and it remains to be seen how the second Trump Administration will handle IRS enforcement of ESRP penalties, if at all. The court’s ruling in *Faulk Company, Inc.*, may at least give the administration pause to re-evaluate the roles of HHS, the Exchange, and IRS in ensuring employer access to due process, consistent with the plain language of the ACA, itself. In the meantime, employers who find themselves challenging existing assessments of ESRP penalties have newfound legal support for attacking the shortcomings of the IRS process



## Trump Executive Order Seeks to Lower Prescription Drug Costs

By: Abby Blankenship

On April 15, 2025, President Donald Trump signed an executive order (the “Order”) titled “Lowering Drug Prices by Once Again Putting Americans First.” The Order directs multiple federal agencies to take actions intended to reduce the cost of prescription medications and biologic drugs, increase greater transparency among pharmaceutical manufacturers, and expand access to affordable treatments for patients—including Medicare beneficiaries and low-income individuals.

The Order includes reforms across several key policy areas, as explained in more detail below.

### **1. Addressing the IRA’s “Pill Penalty” and Lowering Medicare Drug Prices**

The Order directs the Department of Health and Human Services (“HHS”) to propose revisions to the Medicare Drug Price Negotiation Program established under the Inflation Reduction Act (“IRA”). Within 60 days, HHS is required to propose new guidance that will improve the transparency of the program. One proposed change would delay price negotiations for small-molecule drugs, such as pills, by four years, aligning their negotiation timelines more closely with biologic drugs like injections and infusions. This adjustment aims to address what critics have called the “pill penalty” and to encourage the development of lower-cost, more accessible treatments.

Additionally, the Order outlines several changes intended to reduce out-of-pocket costs for Medicare and Medicaid recipients. These include stabilizing Medicare Part D premiums, testing new payment models for expensive drugs, aligning hospital drug payments with actual acquisition costs, and discouraging the use of costlier hospital settings when a drug can be administered in a doctor’s office.

### **2. Accelerating FDA Approval for Lower-Cost Alternatives**

The Order directs the Food and Drug Administration (“FDA”) to accelerate the approval process for generic drugs, biosimilars, combination products, and second-in-class brand-name medications. Within 180 days, the FDA Commissioner is required to issue a report outlining administrative and legislative recommendations to expedite these approvals. Additionally, the order directs the FDA to improve the process by which certain prescription drugs can be reclassified as over-the-counter (OTC) medications. The report will include recommendations on how to identify drugs that can be safely and effectively made available to patients without a prescription.

### **3. Increasing Oversight of Pharmacy Benefit Managers (PBMs)**

The Order includes several directives aimed at “reevaluating the role of middlemen.” The Order instructs the Secretary of Labor to propose new transparency rules focusing on how much PBMS

-companies that manage drug benefits – are paid. Additionally, within 90 days of the Order, the Assistant to the President for Domestic Policy, in coordination with the Secretary of HHS, the Office of Management and Budget (OMB) Director, and the Assistant to the President for Economic Policy, shall provide joint recommendations to the President on “how best to promote a more competitive, efficient, transparent, and resilient pharmaceutical value chain that delivers lower drug prices for Americans.”

#### **4. Expanding Access to Insulin and Epinephrine for Low-Income Patients**

Within 90 days, the Order requires the Secretary of HHS to ensure that new community health center grants are conditioned on the health center establishing practices to make insulin and injectable epinephrine available at or below levels set by the federal 340B drug discount program to certain low-income individuals. This proposal echoes a directive issued during Trump’s first term.

#### **5. Supporting State-Led Prescription Drug Importation**

The Order directs the FDA Commissioner to take steps to simplify the Importation Program under Section 804 of the Federal Food, Drug, and Cosmetic Act. This directive is intended to “make it easier for [s]tates to obtain approval without sacrificing safety or quality.”

#### **Employer Takeaways**

Although the Order itself does not create immediate legal obligations for employers or group health plans, the ripple effects of these policy shifts—especially related to PBM transparency, drug importation, and formulary management—may impact plan design, contracting, and employee communication strategies. Employers and benefits advisors should monitor any legislative or agency actions related to the Order closely.



## **State PBM Laws And Audits: Things to Know and Next Steps**

*By Kate Belyayeva*

In recent years, many states, including Florida, have intensified their scrutiny of pharmacy benefit managers (“PBMs”). PBMs play a crucial role in managing prescription drug benefits for health plans; however, many critics have found the PBM state laws to be too far-reaching and in contravention of the U.S. Supreme Court’s ruling in *Rutledge v. Pharmaceutical Care Mgmt Assoc.* (2020), which initially allowed application of state laws to PBMs in certain circumstances while honoring the ERISA preemption doctrine—the doctrine that federal ERISA law preempts state law efforts to regulate the same subject. Given the magnified attention to PBMs lately, we have explored this topic in prior articles, which generally delved into the new transparency laws and PBM litigation. In the last few months, the Florida Office of Insurance Regulation (“FLOIR”) has brought PBM laws and preemption back into the spotlight with its somewhat stringent audit protocols aimed at increasing transparency and accountability within the pharmaceutical supply chain, a trend in state oversight of PBMs that may seem attractive to an increasing number of states.

### **Background**

The FLOIR has long mandated PBMs operating within the state to adhere to comprehensive reporting requirements. This year, the FLOIR commenced biennial examination of PBMs, focusing on compliance with specific PBM statutes. Most aspects of the audits do not raise as many concerns as the request by the FLOIR for the PBMs to disclose participant information, including the participants’ identity and health information. Despite the well-intentioned reasoning for the PBM audits, these efforts have sparked debates concerning their impact on employers, the potential preemption of state laws by federal law, and the privacy concerns related to the disclosure of participant information.

### **Preemption Concerns**

As a first line of defense, it is rather expected for ERISA preemption to be the center of discussion and a significant point of contention. ERISA includes a preemption clause that supersedes state laws relating to employee benefit plans subject to ERISA (generally self-insured employee benefit plans). Although the U.S. Supreme Court has previously permitted states to regulate insurance and PBMs, states cannot directly impose requirements upon self-insured employer plans. On one hand, the audit and disclosure requirements introduced by the FLOIR do not directly touch upon self-insured plans. On the other hand, the extent to which the FLOIR and the Florida statutes affect core aspects of self-insured plan administration, such as requiring detailed claims data and imposing compliance attestations, could be interpreted as encroaching upon areas generally protected by ERISA. This position is consistent with the letter written on behalf of The American Benefits Counsel (the “ABC Letter”) challenging the FLOIR regulation.

### **HIPAA Concerns**

As noted above, the audits require PBMs to submit detailed claims data, which includes sensitive patient information. Naturally, this raises privacy concerns and inflicts additional compliance burdens on employers who have to analyze the applicable law to determine whether to follow through with the disclosure. The FLOIR has previously attempted to address the privacy concerns in an Informational Memorandum issued on March 24, 2025 to all PBMs regarding the biennial examination. The FLOIR emphasized its belief that the request for potential protected health information ("PHI") is permitted under the health oversight activities exception of HIPAA, and reiterated its request for data and information in an unredacted and unaltered format. However, many practitioners are of the opinion that the FLOIR request does not rise to the level of a permitted or mandatory disclosure of PHI under HIPAA. The ABC Letter is in agreement with this position. Similarly, a proposed federal bill targeting PBM transparency explicitly noted that any disclosure "shall not include any information that would identify a patient or a provider that issued a prescription." In addition, even if the FLOIR had a compelling argument for why this information is requested, the "minimum necessary" standard under HIPAA is unlikely to be satisfied. Employers and third-party administrators are understandably wary of potential federal law violations and are stuck between a rock and a hard place attempting to comply with two (potentially conflicting) laws.

## Next Steps

While these measures by the FLOIR are designed to protect consumers and promote fair practices, the complexity of compliance for employers and third-party administrators necessitates the consideration of various factors, such as data privacy and contractual obligations. At this time, it is unclear so far how many PBMs and employers have complied with the disclosure requirements. Seeking legal advice to navigate the complex interplay between state and federal regulations is recommended. In particular, an employer should review the current terms of its PBM contract to pinpoint the employer's and the PBM's obligations with respect to state law compliance and HIPAA disclosures. The findings of the audits are yet to be made public. Nevertheless, such findings are expected to potentially affect the contractual relationships between employers and PBMs. Any discrepancies could lead to renegotiations of terms and legal disputes.

## Conclusion

The inclusion of PHI in the audit process by the FLOIR has raised alarms among employers. The federal HIPAA concerns add another layer of complexity to an already challenging topic of state PBM laws. Legal experts have largely highlighted the tension between state and federal authority on this topic and echoed the concerns voiced in the ABC Letter. As this tension is yet to be formally resolved, employers should remain vigilant of their next steps.



## Compliance Corner: Post-Mortem Distributions: Compliance Guidance For FSAs, DCAPs, and HSAs Upon Participant's Death

*By Kate Belyayeva*

Employers and third-party administrators face unique compliance challenges when a participant dies in both the retirement and health and welfare contexts. In particular, the treatment of unused funds from health flexible spending accounts ("FSAs"), dependent care assistance programs ("DCAPs"), and health savings accounts ("HSAs") varies significantly as a result of the structure and regulations surrounding these programs. The first two accounts are employer-owned as opposed to the participant-owned HSA, which does result in different sets of rules. Below is a breakdown of how each program and any distributions should be treated upon a participant's death, which should familiarize the employer with the applicable rules in place for different programs.

### Health FSAs

Pursuant to the Internal Revenue Code of 1986, as amended ("Code") Section 125, health FSAs are employer-sponsored arrangements that allow participants to cover qualified medical expenses on a pre-tax basis. Generally, upon a participant's death, the FSA contributions stop, and the unused funds are forfeited except as otherwise provided in the plan. Absent a COBRA coverage continuation right, a surviving spouse or dependent(s) can only submit the claims incurred prior to the date of the participant's death during the plan's run-out period (usually 30 to 90 days after the participant's death or the end of the plan year). The surviving spouse or dependent can submit for reimbursement of claims incurred after the participant's death only if they are covered individuals and eligible for COBRA. Qualifying health FSAs may limit COBRA continuation coverage only until the end of the year in which the participant dies. Alternatively, for non-qualifying health FSAs, the full COBRA period is applicable beyond the end-of-the-year mark.

### DCAPs

Code Section 129 governs DCAPs, which are employer-sponsored arrangements that allow for pre-tax contributions for dependent care expenses. Unlike health FSAs, the funds are not automatically forfeited in DCAPs upon a participant's death. The participant's spouse can file reimbursement claims for dependent care services incurred through the end of the plan year in which the participant dies so long as the surviving spouse is seeking employment or working during such time for which reimbursement is sought. For example, if Participant A dies in May 2025, Participant A's spouse can continue making reimbursement claims until the end of 2025 if the spouse is working or looking for work until then. There is no separate COBRA right to extend coverage beyond the year in which the participant dies.

### HSAs

Code Section 223 explains how the treatment of HSAs, individually owned accounts for qualified medical expenses, drastically differs from FSAs and DCAPs. For example, with HSAs, the contributions do not expire, and, thus, the remaining balance upon

participant's death is not forfeited. If a spouse is the designated beneficiary, then the HSA becomes the surviving spouse's HSA. However, if the spouse is not the beneficiary, the account ceases to be an HSA and is subject to income tax on the fair market value as of the date of the participant's death. Notably, if no beneficiary is designated, the HSA becomes a part of the participant's estate, to be reflected on the participant's last tax return. Regardless of which party obtains access to the HSA, the participant's qualified medical expenses can still be covered up to the date of death to reduce any tax burdens.

## Best Practices

Employers and administrators should review plan documents to ensure death-related claims and forfeiture provisions are clearly defined and effectively communicated to the surviving beneficiaries. Surviving spouses, dependents, and estate representatives should be timely informed about their rights and the terms applicable to claim submission. In addition, participants should be educated on the importance of designating beneficiaries for the HSA in particular. Given the significant tax consequences for HSAs, the participant and affected parties should consult with advisors about the ramifications, especially with respect to large HSA balances.

## Conclusion

Generally, health FSAs and DCAPs have much stricter rules as compared to HSAs in the event of a participant's death. Understanding the distinct rules is crucial for compliance and to support the deceased participant's surviving beneficiaries effectively.



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- CVS Health plans to close 23 pharmacy locations in Arkansas following the enactment of HB1150, which prohibits state permits for pharmacies owned by pharmacy benefit managers ("PBMs"), including CVS/Caremark. CVS/Caremark argues that the legislation will reduce healthcare access and result in over 500 job losses.
- On March 25, 2025, in *Tudor v. Whitehall Central School District*, the United States Court of Appeals for the Second Circuit clarified the standard for evaluating reasonable accommodation requests under the Americans with Disabilities Act (ADA). The court held that an employee may still be eligible for a reasonable accommodation even if the employee is capable of performing the essential functions of the job without the accommodation. The ruling underscores the employer's obligation to consider reasonable accommodations, even if such an accommodation is not necessary for the employee to perform essential job functions.
- This month, the U.S. Department of Labor ("DOL") published FAB 2025-1, which details its enforcement guidance on valid independent contractor relationships under the federal Fair Labor Standards Act. As part of this publication, DOL noted that it is considering rescinding the Biden DOL's stricter rule (the "2024 Rule") on valid independent contractor relationships and stated it would "no longer apply the 2024 Rule's analysis when determining employee versus independent contractor status in FLSA investigations," a measure which seems to signal that a rescission of the 2024 Rule is forthcoming if not imminent.

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