Compliance Watch

April 2025 Roundup: Employer Mandate Challenged, Executive Orders Multiply, and HIPAA Enforcement Tightens

PROVANT

Breaking News:

APRIL 2025

Texas District Court Determines IRS 226-J Penalty Letters Cannot Be the First Notice of Exchange Tax Credits to Employers

On April 10, 2025, the Northern District Court of Fort Worth ruled in Faulk Co., Inc. v. Becerra that the Department of Health and Human Services (HHS) must be the one to inform employers when a full-time employee qualifies for a public health insurance Exchange Marketplace Premium Tax credit (PTC).

Applies To:

Applicable Large Employers (ALE), which are generally those employers with 50 or more full-time and equivalent employees (FTE) the previous calendar year (with employers in a controlled group or affiliated service group having to combine their employee counts).

Go Deeper:

The Affordable Care Act (ACA) was written to require that HHS provide this notice immediately upon an employee being approved for PTC so the employer has time to appeal the decision. However, that action has largely not occurred. Instead, HHS delegated authority to the IRS to include the required notification in the employer's ACA employer mandate penalty letter (which is often received two to three years after the employee's PTC is provided).

Faulk is an ALE that failed to offer minimum essential coverage to some of its employees. They filed this case after being penalized by the IRS for their violation of the employer mandate. They argued that Congress did not authorize HHS to delegate the notification requirement to the IRS.

WHAT'S NEW

Court Pushback on IRS Penalties
Texas court rules 226-J letters can't be the first notice of Exchange subsidies.

RxDC Reports Due June 1
Employers must prep 2024 drug and spending data now.

Executive Orders Target Drug Costs
New mandates focus on PBM transparency and generic drug access.

HIPAA Enforcement Ramps Up
Wellness vendor fined for failing to secure sensitive health data.

TAKEAWAY

A court ruling challenges IRS penalty process, but legal clarity remains elusive — meanwhile, employers face rising risk across HIPAA, PBMs, and plan oversight.

Practical Impact to Employers:
While it remains to be seen if the new administration appeals this decision, it is expected that many more companies will bring similar cases. There is likely a long legal road ahead before the matter is settled. Until the Supreme Court or the government addresses this concept, an employer likely should not rely upon this case to evade an otherwise justified employer mandate penalty. However, employers subjected to employer mandate penalties may consult their legal counsel to determine whether the holding in this case could provide some relief.

Hot Topics:

Next Round of RxDC Submissions Due by Sunday, June 1, 2025

Section 204 of the Consolidated Appropriations Act, 2021 (CAA) requires group health plans and issuers to report detailed prescription drug data and also requires information related to healthcare spending. The next round of reports for data during the 2024 "reference year" must be submitted directly to CMS by Sunday, June 1, 2025.

Applies To: All size employers sponsoring a group medical plan and prescription drug benefit.

Exempt: Excepted benefits such as standalone dental, vision, FSA, HSA, HRA and ICHRA.

Go Deeper:

To comply with this requirement, employers must rely heavily on their claims administrators because these service providers possess the required data for reporting.

Any gaps in submissions should be addressed by either the employer submitting themselves in the government's HIOS system or engaging with a third-party vendor to assist with coordinating submissions.

Typically, the claims administrator or carrier facilitates the full reporting, but two to three months before the June 1 annual deadline, they will ask the employer for key information needed to allow for complete reporting to CMS:

- They primarily need to know how much the employer paid vs. how much participants paid (including COBRA participants) for the previous calendar year's medical/Rx coverage (even if the plan does not operate on a calendar year).
- If self-funded, the premium "equivalent" is actual fixed costs plus actual claims (choose either incurred claims or paid claims for the calendar year, and maintain that choice every year), less stop loss rebates and pharmacy rebates retained by the plan.

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Employer plan sponsors, especially self-funded health plan sponsors, should continue to take necessary steps to prepare for the June 1 deadline. Visit the CMS RxDC webpage for helpful information and resources.

Other Hot Topics:

- The model CHIP notice was updated March 17 but there were no changes made to State information from the July 31, 2024 version.
- For an employer subject to the San Francisco Health Care Security Ordinance (HCSO), annual reporting is due by May 2.
- Employers subject to the Patient Centered Outcomes Research Institute (PCORI) fee due July 31 cannot begin compiling their submission until the second quarter Form 720 is released mid-June. Until then, employers can only work on compiling participant counts and determining which counting method to use this year.

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Federal Updates:

More Executive Orders

The President has signed many more executive orders in April, some of which could directly or indirectly impact employee benefits.

Applies To:

All employers sponsoring employee benefits.

Go Deeper:

April 9, 2025, the President issued an Executive Order directing the repeal of unlawful regulations:

The President is directing federal regulators to identify "unlawful and potentially unlawful regulations" and identify a path to repeal them over the next 60 days without the usual notice and public comment rulemaking process. This is a second step from the first order 14219 issued on February 19 "rescinding unlawful regulations and regulations that undermine the national interest".

The Executive Order specifically points to the Supreme Court's 2024 decision in Loper Bright as impactful to analyzing the lawfulness of a regulation. The holding in that case indicated that courts do not have to defer to the expertise and judgment of a federal agency in determining the appropriateness of regulations that the agency issues, but should instead evaluate the merits and appropriateness of a regulation under the full scope of current law.

It is not yet clear which regulations the Departments of Labor, Treasury and Health and Human Services would target for immediate repeal over the 60 days, but we will keep an eye on this development. So far, the IRS has taken a couple of actions:

- Eliminating Unnecessary Regulations does not appear to impact benefits.
- IRS Notice 25-22 withdraws nine prior guidance documents. Two related to the §4980I "Cadillac Tax". One, Notice 15-16, offered some ideas on how to price COBRA for HRAs. So, those ideas are all withdrawn and there is still not much guidance on how to properly price COBRA for HRAs beyond what is stated in Notice 2002-45.

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April 15, 2025, Executive Order 14273 focused on prescription drug costs and transparency:

This order addresses a number of goals, a few of which may directly or indirectly impact employee benefits:

- "Encouraging the development of generic and biosimilar alternatives";
- "Expand access to lower cost drugs imported from outside of the country";
- "Modify the Medicare Drug Price Negotiation Program to align the treatment of small molecule prescription drugs with that of biological products";
- "Conduct a survey under section 1833(t)(14)(D)(ii) of the Social Security Act to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments" and then make "adjustments that would align Medicare payment with the cost of acquisition";
- "Accelerate approval of generics, biosimilars, combination products and second-in-class brand name medications, and improve the process through which prescription drugs can be reclassified as over-the-counter medications";
- "Reduce anti-competitive behavior from pharmaceutical manufacturers";
- "Propose regulations pursuant to section 408(b)(2)(B) of [ERISA] to improve employer health plan fiduciary transparency into the direct and indirect compensation received by pharmacy benefit managers"

As a reminder, the CAA-21 requires ERISA group health plan brokers/consultants to provide compensation disclosures under ERISA §408(b)(2). At the time the CAA passed, PBMs were largely considered to be exempt from the requirement to provide compensation disclosures.

Interestingly, the new administration appears to believe PBMs should be subject to the compensation disclosure rules. A proposed rule is due within 180 days of the executive order.

Practical Implications to Employers:

No immediate changes have been instituted under these orders. However, the orders do provide more indication that the administration may make major changes. We will continue to monitor developments.

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CMS Updates Medicare Part D Benefit Parameters and Simplified Creditability Determination for 2026

The Centers for Medicare and Medicaid Services (CMS) published 2026 updates to Medicare's Part D benefits parameters. Each year, employers sponsoring a plan that provides or reimburses prescription drugs must disclose to employees and their beneficiaries, including those on COBRA or retiree coverage, whether their prescription drug coverage is creditable compared to Medicare Part D (i.e., whether it expects to pay as well as Part D pays on average). The Part D parameters are needed each year to help employers determine whether their plans are creditable or non-creditable so they can provide the correct notice.

Applies To:

All size employers sponsoring a plan that provides or reimburses prescription drugs.

Go Deeper:

CMS's announcement and two fact sheets (here and here) lay out the updates for 2026, including the following:

- Deductible increasing from $590 to $615
- Out-of-pocket maximum increasing from $2,000 to $2,100
- A revised simplified determination methodology that updates how much a creditable group health plan must be expected to pay toward prescription drug claims from the current 60% to 72% (to more accurately reflect enhancements brought by the Inflation Reduction Act)

Practical Implications to Employers:

Employers working on their 2026 benefit plans now have Part D benefit parameters and revised simplified determination methodology to help determine whether their prescription drug coverage is creditable or non-creditable. While the carrier or pharmacy benefit manager (PBM) will typically determine creditability for employer plans, there are times an employer must hire an actuary to certify creditable coverage status. So, the revised simplified determination methodology can help in submitting plan designs as compatible as possible rather than going back and forth making adjustments with the actuary.

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HIPAA Settlement Reached with Wellness Provider

HHS recently started a Risk Analysis Initiative to highlight the importance of covered entities and business associates needing to conduct a thorough Risk Analysis to identify and secure protected health information (PHI). Their fifth action under this enforcement initiative resulted in a settlement with Health Fitness Corporation (owned by Trustmark), a HIPAA business associate that provides wellness plans for employers.

By failing to conduct a risk analysis, Health Fitness failed to identify a system configuration that mistakenly left PHI accessible to web crawlers. As a result of this failure, they must pay a settlement fee of $227,816 and must commit to a corrective action plan to comply with HIPAA.

Practical Implications to Employers:

Most compliance checkups reveal that HIPAA privacy and security requirements are not properly completed (To this day, nationally, less than 20% of covered entities and business associates do the work necessary to comply with HIPAA requirements). HHS's new enforcement initiative aims to change that in 2025 by focusing on the foundational element upon which HIPAA compliance is built: the risk analysis that identifies what PHI exists and all the vulnerabilities to that PHI in operating the health plan throughout the years.

Employers sponsoring a level funded or self-insured health plan, health reimbursement arrangement (HRA), health flexible spending account (health FSA), limited purpose FSA, a carve-out or bolted on health plan that must integrate with their medical plan and/or a fully insured plan that provides the employer with claims analytics data will want to take note of this new enforcement initiative and determine whether it is time to start or update their risk analysis. Since this settlement was with a business associate providing employer wellness plans, this is also a good reminder for such employers to monitor their service providers for ongoing compliance with HIPAA (including the requirement to obtain a business associate agreement).

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Question of the Month:

What compliance obligations apply to Individual Coverage Health Reimbursement Arrangements (ICHRAs)?

Introduced in 2018 during President Trump's first term, ICHRAs have gained in popularity over the years. The basic premise of an ICHRA is the employer can provide employees tax-favored money to buy their own individual market health plan or Medicare.

Final ICHRA rules from 2019 and additional guidance/tools can be found here:

- General ICHRA Rules
- ALE and Nondiscrimination Rules
- Guidance and Tools (Including Model Notices and Premium Look-Up Table)

There are a number of ICHRA provisions which employers have become accustomed to over the last five years and, at this point, should be relatively well known:

- How ICHRAs work in a pass-through entity like an S-Corp. or LLC
- How ICHRAs can only provide a benefit to those able to substantiate they have Medicare or a qualified individual health plan (not group coverage through another employer, not a health sharing ministry, not TRICARE or VA, not student coverage through a university, etc.)
- How ICHRAs can satisfy applicable large employer (ALE) requirements under §4980H
- That employers must provide a model notice to employees at least 90 days before the ICHRA begins each year to ensure the employee has adequate time to explore the individual health plan market and allow for timely effective date of coverage
- How non-discrimination testing is not required under §105(h) if the ICHRA reimburses just individual insurance premiums but is required when the ICHRA also reimburses out-of-pocket medical expenses
- How ACA reporting (1094-B/1095-B for non-ALEs, 1094-C/1095-C for ALEs) is required for employers sponsoring ICHRAs
- Rules regarding contributions, classes, substantiation, salary reduction arrangements and more

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Following are other important considerations which are often misunderstood:

ICHRAs are group health plans, even when they only reimburse premiums. So, they must comply with several group health plan laws such as ACA, COBRA, ERISA, and HIPAA:

- **ACA:**
  - The ICHRA must be communicated on a Summary of Benefits and Coverage (SBC)
  - The employer cannot impose pre-existing condition limitations/exclusions
  - The employer cannot impose a waiting period longer than first of the month following 60 days (a 90-day waiting period is not feasible for an ICHRA)
  - Employer mandate ALE rules apply (such as waiving the waiting period for some rehires, or if the employer utilizes the lookback method, letting the ICHRA continue for the duration of any full-time stability period even if an employee's hours decrease below 30 hours per week)
- **COBRA:**
  - The premise is since the ICHRA is a group health plan, it is subject to COBRA and proper notices must be provided as applicable
  - There is extremely limited guidance on how to price the ICHRA COBRA premium, but employers should ideally calculate how much the plan is reasonably expected to cost (e.g., determine how much the employer actually pays out as a percentage of possible benefits, multiply every available ICHRA amount by that percentage, and add 2%)
  - Regulators expect some ICHRAs may allow employees to accumulate unused funds and carry them over to future years, making COBRA potentially more valuable when such funds can reimburse out-of-pocket medical expenses
- **ERISA:**
  - An ERISA plan document and SPD is required
  - The SPD should state that the employee's Medicare or individual health plan coverage is not part of the employer's ERISA group health plan
  - ERISA claims and appeal rights apply
  - An employer subject to 5500 reporting must include the ICHRA (using code 4A and typically noting it pays from general assets)
  - Even governmental or church plan employers should adopt a document to explain the plan's terms and appeal rights

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- **HIPAA:**
  - HIPAA special enrollment rights still must be honored by law
  - HIPAA also prohibits an actively at work clause delaying the start date of an ICHRA for a new hire who must take a leave of absence due to their health condition
  - Since the ICHRA is not a fully insured policy with an insurance carrier, the employer sponsoring the self-funded ICHRA must ensure it complies with the privacy & security requirements and provide a notice of privacy practices (NPP)

- ICHRAs are exempt from Medicare Part D creditability provisions **when they only reimburse premiums** but are subject to Part D creditability disclosures when they also reimburse out-of-pocket medical expenses.

  ICHRAs are a group health plan under the rules. However, the rules advise that an "entity that **offers prescription drug coverage**...must disclose to all Part D eligible individuals enrolled in, or seeking to enroll in, the coverage whether the coverage is creditable prescription drug coverage". So, ICHRAs that only reimburse premiums are not subject to Part D creditability disclosure requirements because they do not offer prescription drug coverage. However, ICHRAs that also reimburse out-of-pocket medical expenses would be subject to Part D creditability disclosure requirements.

- ICHRAs should be compliant with MHPAEA as long as they do not restrict the types of §213(d) medical expenses that can be reimbursed (if applicable).
- ICHRAs are not subject to RxDC reporting (HRAs are specifically excepted).
- ICHRAs are subject to PCORI reporting and fees (payable based on average enrolled employees and former employees without needing to count dependents).
- ICHRAs are not subject to the gag clause prohibition compliance attestation (GCPCA) because the ICHRA itself does not include any contract with a health care provider or network of providers.
- Hawaii does not allow employers to offer ICHRAs to employees protected under the Hawaii Prepaid Health Care Act (Hawaii employees working 20 or more hours per week).

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