

COMPLIANCE CHRONICLE

REGULATIONS | POLICIES | STANDARDS | REQUIREMENTS | LAWS

THREE COMPLIANCE ISSUES TO KEEP ON YOUR RADAR THIS FALL

As employers move through open enrollment and begin looking ahead to 2027, several compliance issues deserve more than a routine annual check.

This month, we're focusing on three areas where employer responsibilities, plan design and vendor oversight intersect: Medicare Part D creditable coverage, continuing health coverage during employee leave, and the evolving compliance landscape for Self-Funded plans.

The common thread is simple: employers should know what applies to their plan, understand where responsibility sits, and avoid assuming that a carrier, TPA, or other vendor has handled the details.



THIS EDITION'S KEY TAKEAWAYS



MEDICARE PART D

Don't treat the Medicare Part D notice as a simple reissue of last year's document. The underlying creditable coverage determination may need a fresh look.



CONTINUING COVERAGE DURING LEAVE

Always check the carrier contract and plan terms. They often determine how long coverage may remain active during a leave.



LEG/REG UPDATES FOR SELF-EMPLOYED EMPLOYERS

Vendor administration does not eliminate plan-sponsor accountability. The direction of compliance is increasingly toward active oversight, documentation and fiduciary governance.



Medicare Part D

The biggest Medicare Part D creditable coverage development in 2026 isn't the notice itself — it's that the enhanced Part D benefit has raised the bar for what qualifies as creditable coverage, making 2026 a transition year before stricter standards effectively take hold.

The Big Story

Part D Got Richer, So Creditable Coverage Is Harder to Achieve

Historically, many employer plans comfortably passed the creditable coverage test using CMS' simplified determination method. However, the Inflation Reduction Act dramatically enhanced Medicare Part D benefits, including the annual out-of-pocket cap, making standard Part D coverage much more valuable than it used to be.

As a result, CMS created a **new simplified determination standard**.

Under the revised methodology, a plan generally must:

- Cover brand and generic drugs
- Provide reasonable access to retail pharmacies
- Be designed to pay, on average, at least **72%** of prescription drug expenses

The old, simplified method used a **60%** threshold.

What Employers Need To And Should Know:

- **For 2026**, plans can generally use either the prior simplified methodology or the revised methodology.
- **Beginning in 2027**, the revised approach is expected to become the operative simplified standard.
- **Plans with high deductibles, reduced employer drug subsidies, certain HRA/HDHP arrangements, or leaner prescription drug benefits** may need to revisit whether their coverage remains creditable without an actuarial determination.
- **The CMS online disclosure requirement** remains in place. Disclosure must generally be made within 60 days of the beginning of the plan year, with additional filings required after termination of prescription drug coverage and in certain other circumstances.

Transitional Relief

CMS recognized that Part D changed significantly, so for 2026 it is allowing many employers to continue using either the old, simplified methodology or the new methodology. But this is really a transition year.

For 2026, plans can generally use either methodology. Beginning in 2027, the revised approach is expected to become the operative simplified standard.

Compliance

The annual notice requirement isn't new, but more employers may need to pay attention to whether their determination remains accurate.

Many employers have treated the creditable coverage notice as a routine annual distribution. Going forward, some sponsors may need to revisit the underlying analysis rather than simply reissue last year's notice.

Don't Forget the CMS Filing

The CMS online disclosure requirement remains in place:

- Disclosure must be made within **60 days of the beginning of the plan year**.
- A filing is also required after termination of prescription drug coverage and in certain other situations.



Continuing Health Coverage During Leave: Employer Size Matters

When an employee takes a leave of absence, one of the first benefits questions is often: What happens to health coverage and who pays the premiums? The answer depends heavily on whether the employer is subject to the Family and Medical Leave Act (FMLA), along with applicable state law, plan terms and carrier requirements.

At a Glance

Employer Size	Law Applies	Must Maintain Coverage?	Employee Premium Rules	If Employee Doesn't Pay
50+ employees	FMLA	Yes, for up to 12 weeks	Prepay, pay as you go, or catch up	30-day grace + 15-day notice before termination
20-49 employees	No FMLA, COBRA applies	Depends on employer policy + carrier rules	Employer sets rules (usually pay as you go)	Coverage can terminate; COBRA offered
<20 employees	No FMLA, no COBRA	Depends on employer policy + carrier rules	Employer sets rules	Coverage can terminate; state continuation may apply

Does Your Plan Need Another Look?

Four Simple Checkmarks:

- ✓ **High deductibles**
- ✓ **Reduced employer drug subsidies**
- ✓ **Certain HRA/HDHP arrangements**
- ✓ **Leaner Rx benefits**

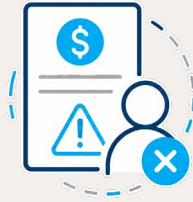
FMLA-Covered Employers with 50+ Employees

For employers subject to FMLA, the rules for premium payment during leave are federally defined. Employees must continue to pay their normal share of the premiums for employer-sponsored health coverage while on FMLA leave.



PERMITTED METHODS FOR COLLECTING EMPLOYEE PREMIUMS

- **Prepay:** The employee prepays premiums before leave begins.
- **Pay as you go:** The employee pays premiums on the same schedule as active employees.
- **Catch up:** The employer pays premiums during leave and collects the employee's share after the employee returns.



IF THE EMPLOYER FAILS TO PAY

- Coverage **must continue** during FMLA leave unless the employee is more than **30 days late** AND the employer gives **15 days' written notice** before terminating coverage.
- If coverage lapses due to nonpayment, the employer must **reinstate coverage** upon return from FMLA leave without waiting periods.



EMPLOYER REQUIREMENTS

- Must maintain coverage on the same terms as active employees.
- Cannot require employees to pay more than the active employee rate.
- Must provide written notice of premium payment requirements before leave begins.

FMLA-Covered Employers With Fewer than 50 Employees?



FMLA DOES NOT APPLY



CHECK THE RULES

- State leave laws
- Employer handbook or policy
- Plan document / carrier rules



CAN COVERAGE CONTINUE?

YES:

- Employee may be required to pay as they go
- Employer is not required to offer prepay or catch up

NO:

- Eligibility ends
- Move to continuation coverage



WHAT HAPPENS NEXT?

20-49 employees:

- COBRA may apply

Fewer than 20 employees:

- State continuation may apply



Carrier 'Active at Work' Rules

Most carriers require:

- Employee must be actively at work to remain eligible.
- Employers may continue coverage for a limited period (often 30–90 days) during employer-approved leave.
- After that, coverage must terminate and COBRA/state continuation applies.

COBRA Considerations (20+ Employer)

If the employer has 20+ employees, COBRA applies.

A leave of absence that causes loss of eligibility triggers COBRA if:

- The employee stops working enough hours to meet plan eligibility
- The employer terminates coverage due to nonpayment
- The employee must pay 102% of the premium under COBRA



Self-Funded Plans: 2026 Legislative/Regulatory Updates

2026 has emerged as the year when the focus shifted from simply complying with transparency rules to actively governing vendors, especially PBMs, under an ERISA fiduciary lens.

Janet Trautwein's

TOP 2026 Developments for Self-Funded Employers



- 1** ICAA 2026 PBM Reform
- 2** MHPAEA regulatory reset and parity enforcement
- 3** Expansion of health plan fiduciary-oversight expectations
- 4** RxDC reporting becoming an established compliance obligation
- 5** ACA preventive-services uncertainty



1 PBM Reform

The most consequential legislative action of 2026 was enactment of the Consolidated Appropriations Act, 2026, which includes sweeping pharmacy benefit manager (PBM) reforms affecting employer-sponsored health plans. The law requires significantly greater PBM transparency, mandatory reporting to plans, audit rights, participant disclosures, and generally requires 100% pass-through of rebates and other remuneration to plan clients. Most provisions become effective in 2028-2029, but plan sponsors need to start preparing now because PBM contracts will need substantial revisions.

For self-funded employers, the importance is not just the transparency itself. The reforms effectively raise expectations that plan fiduciaries understand PBM compensation, evaluate rebate practices, and actively oversee prescription drug arrangements rather than relying entirely on vendors.

WHY IT MATTERS

This is the most important structural change to employer pharmacy programs since the CAA transparency provisions first emerged in 2021.

2 MHPAEA Regulation Reset and Continuing Mental Health Parity Enforcement

The second major development is the ongoing upheaval surrounding the **Mental Health Parity** and **Addiction**.

Equity Act (MHPAEA)

In 2026, the Departments of Labor, Treasury, and HHS announced they would no longer defend key portions of the 2024 MHPAEA final rule and instead plan to develop replacement regulations by the end of 2026. However, the underlying statutory parity requirements and the requirement to prepare **NOTL comparative analyses** remain fully enforceable.

At the same time, regulators continue to prioritize MHPAEA audits and comparative-analysis reviews. Self-funded plans remain responsible for demonstrating parity even when TPAs or carriers perform operational functions.

WHY IT MATTERS

Large self-funded employers face significant compliance risk because the rules are in flux while enforcement continues.

3 Expanded Focus on ERISA Fiduciary Responsibility for Health Plans

A broader trend throughout 2026 has been increased emphasis on **ERISA fiduciary oversight of health plan vendors**, especially PBMs.



Both the new PBM legislation and proposed DOL initiatives signal that employers are expected to:

WHY IT MATTERS

Fiduciary governance of health plans has become a board-level and committee-level issue rather than simply an HR compliance issue.



UNDERSTAND
Vendor compensation



REVIEW
Conflicts of interest



MONITOR
Service-provider performance



DOCUMENT
Fiduciary decision-making

This reflects a continuing shift toward applying fiduciary standards to health plan purchasing decisions in ways that resemble retirement-plan governance.

4 RxDC Reporting Has Become a Permanent Compliance Requirement

Although not new in concept, 2026 marked the maturation of the **Prescription Drug Data Collection (RxDC)** reporting regime.

The June 1, 2026, filing for 2025 data proceeded with fewer transition accommodations and greater expectations that employers oversee reporting arrangements with TPAs and PBMs. Self-funded employers remain legally responsible even when vendors submit the files.

The data collected through RxDC reporting is increasingly being used to support federal prescription drug policy initiatives and transparency efforts.

WHY IT MATTERS

Many employers still view RxDC as a vendor responsibility, but regulators increasingly view it as a plan sponsor accountability issue.



5 Continued Uncertainty Around ACA Preventive Services

Another important issue for self-funded plans is the continuing legal and regulatory uncertainty surrounding **ACA preventive services coverage requirements** following ongoing litigation over the Affordable Care Act's preventive-services mandate.

While most plans continue covering preventive services without cost-sharing, employers have been closely monitoring federal agency actions and court developments because potential changes could materially affect plan design and coverage obligations.

WHY IT MATTERS

Preventive-services requirements affect virtually every self-funded group health plan and have significant financial and compliance implications.



Honorable Mentions

Other developments that benefits professionals have been watching include:

- State regulation of PBMs and increasing ERISA preemption litigation.
- Continued growth of GLP-1 drug utilization and corresponding plan-management strategies.
- Increased scrutiny of plan costs, transparency and vendor contracting.
- Ongoing implementation of CAA transparency rules and machine-readable file requirements.



Ask Janet!

Have compliance, regulatory, state or federal legislative questions? Submit them [here](#)!

Check out all of our compliance and legislative resources [here](#).