Compliance Watch

September 2025 Roundup: Transparency, Treatment & Deadlines

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SEPTEMBER 2025

In the News:

Price Transparency Rule

On September 2, 2025, the Department of Health and Human Services (HHS) published a final rule to enable better real-time cost-sharing of prescription drug benefits and speed up the process of securing prior authorizations for medications. The rules will modernize electronic prescribing, allow real-time prescription benefit checks (which show the drug cost for the insured patient at various pharmacies and what they could pay for alternative medications), and streamline prior authorization with modern API technology.

Applies To: Group health plans providing prescription drug coverage.

Go Deeper:

The Consolidated Appropriations Act, 2021 (CAA-21) introduced several price transparency requirements for group health plans. These include real-time cost-sharing so patients and providers can see the types of services or prescriptions the plan will cover, the cost, with considerations for deductibles, copays, and other cost-sharing requirements, and how much the person and family spent toward those requirements so far.

This final rule seeks to enhance the ability of patients and providers to electronically submit a proposed prescription to the plan for real-time verification of whether it is covered, obtain prior authorization quickly using an interactive real-time interface, and determine the various cost options for the desired drug and alternative drugs covered at various pharmacies.

The rule's requirements to adopt these new technology standards take effect October 1st, and the rule provides a transition period through 2027 for all plans and providers to utilize these new standards. Real-time verification, approval, and cost-sharing is a vital component of the CAA-21 requirements for health plans. In addition, a major milestone of accomplishing the CAA-21 goal is to facilitate prescription drug benefits so patients know their coverage approval, options, and costs before they leave the doctor's office.

Practical Impact to Employers

To comply with CAA-21 requirements, carriers and other claims payers for group health plans should implement these new technology standards promptly and over the next two years to provide real-time coverage verification and cost-sharing estimates. Once they integrate such technology into their systems, it is ideal and extremely beneficial to notify

WHAT'S NEW

HHS finalizes prescription transparency rule
Group health plans must adopt real-time drug cost checks and streamlined prior authorization APIs starting October 1, with a transition period through 2027.

ACA women's preventive care updates for 2026
Plans must cover expanded breast cancer imaging, intimate partner violence interventions, and individualized patient navigation with no cost-sharing.

Fall deadlines: MLR rebates & Medicare Part D notices
MLR rebate distributions are due within 90 days of receipt; Medicare Part D creditable coverage notices must be sent by October 15.

TAKEAWAY

Employers should act now to implement transparency rules, update preventive care, and meet fall deadlines to avoid costly penalties in 2026.

plan participants of the opportunity to utilize this new feature of the health plan when they see their health care provider and need a prescribed medication.

Court Decisions on Gender Dysphoria Treatment

Health plans imposing restrictions or Wexclusions on gender dysphoria treatment can run into several legal discrimination issues. From ACA §1557 to mental health parity and Title VII civil rights, the law remains unsettled on this topic. So, restricting or excluding gender dysphoria treatment that is otherwise covered by the plan for other reasons (such as for cancer or congenital deformities) remains risky.

Applies To: Employers wishing to impose restrictions or exclusions on services for gender dysphoria treatment that are covered by the plan for other conditions.

Go Deeper:

Recent court decisions continue to oscillate on whether gender dysphoria treatment restrictions or exclusions are discriminatory under various federal laws:

- A court recently ruled in L.B. v. Premera Blue Cross that Premera Blue Cross violated §1557 by excluding certain gender dysphoria treatment.
- A federal district court and a three-member panel of the Eleventh Circuit Court of Appeals ruled in Lange v. Houston County, Georgia, that an employer's group health plan discriminated on the basis of sex in violation of Title VII by excluding certain gender dysphoria treatment. However, the full Eleventh Circuit Court of Appeals recently reversed those rulings, holding that the plan did not violate Title VII and applying the Supreme Court's reasoning in its United States v. Skrmetti ruling to come to that conclusion.
- The Mental Health Parity and Addiction Equity Act (MHPAEA) would also seemingly impose restrictions on the exclusion of gender dysphoria treatment. However, enforcement of the law has fluctuated and its implications regarding gender dysphoria remain uncertain.

Any decisions courts issue are subject to appeal, and they tend to be focused on the facts and circumstances of the specific plan in question. Often a key point is that the plan covers a specific treatment for some conditions but not for gender dysphoria.

Practical Impact to Employers:

Since this is such an unsettled area of law, it is important that any restriction or exclusion of gender dysphoria treatment is evaluated with the help of legal counsel who will defend the employer should a government investigation or litigation arise.

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Federal Updates:

ACA Women's Preventive Service Updates for 2026

The Affordable Care Act (ACA) requires non-grandfathered health plans to cover a specific list of preventive health services in-network without cost-sharing to the plan participant. As ACA-required preventive service recommendations are updated, plan years starting one year after the new recommendation must cover those updated services in-network with no cost-sharing.

The insurance carrier or third party administrator (TPA) should keep up with these published updates to ensure inclusion in group health plans at the required time. Among the various updates coming for plan years beginning in 2026 are three updates specific to women's preventive services. One may require an update to employer's budgets and one requires care navigation services, which the carrier or TPA may not currently provide.

Applies To: Employers sponsoring non-grandfathered medical plans must ensure ACA-required preventive care services are covered in-network without cost-sharing.

Go Deeper:

In December 2024, the federal agency responsible for women's preventive service recommendations published three updates which non-grandfathered health plans must adjust to cover in-network without cost-sharing for plan years starting in 2026.

- Updated guidelines for domestic violence screening to:
  - Change the term "interpersonal violence" to "intimate partner violence," and
  - Change the potential need to provide or refer for "initial intervention services" to remove the word "initial" (so plans should be prepared to provide or refer for intervention services even beyond the initial provision or referral).
- Updated guidelines for breast cancer screening for women at average risk ages 40 to 74:
  - When the initial mammogram medically indicates a potential issue, the plan will be newly required to cover in-network without cost-sharing (a) extra imaging services such as MRI, ultrasound, or another mammogram, and (b) pathology evaluation to screen for and identify any potential concerns
  - "Women may require additional imaging to complete the screening process or to address findings on the initial screening mammography. If additional imaging (e.g., magnetic resonance imaging (MRI), ultrasound, mammography) and pathology evaluation are indicated, these services also are recommended to complete the screening process for malignancies."
- A new guideline requiring coverage of "patient navigation services for breast and cervical cancer screening and follow-up, as relevant, to increase utilization of screening recommendations based on an assessment of the patient's needs for navigation services."
  - Change the term "interpersonal violence" to "intimate partner violence," and
  - "Patient navigation services involve person-to-person (e.g., in-person, virtual, hybrid models) contact with the patient."
  - "Components of patient navigation services should be individualized."
  - "Services include, but are not limited to, person-centered assessment and planning, health care access and health system navigation, referrals to appropriate support services (e.g., language translation, transportation, and social services), and patient education."

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This is not an exhaustive list of all updates to ACA-required preventive services for 2026, but two of these women's preventive services may require extra attention from employers.

Penalties for Non-Compliance:

Non-grandfathered plans that fail to cover ACA-required preventive care services in-network without cost-sharing may be subject to a penalty of $100 per person per day plus a requirement to pay retroactively for services the plan should have covered.

Practical Impact to Employers:

While the carrier or TPA should keep the plan updated with ACA-required preventive services as they are published, the new requirements to cover additional imaging following an initial mammogram can add enough extra costs to the plan that self-funded employers may want to budget for those in advance. Employers will also want to ensure the carrier or TPA can accommodate the new individualized care navigation services to educate women and help them plan for breast and cervical cancer screenings.

HIPAA Security Risk Assessment Tool Updated

The Health Insurance Portability and Accountability Act (HIPAA) requires group health plans and their business associates to conduct a security risk assessment (SRA). The federal government provides an SRA tool to help facilitate this required assessment which was recently updated to version 3.6.

Applies To:

- Employers sponsoring a level-funded or self-insured group health plan.
- Employers sponsoring a health reimbursement arrangement (HRA), including an individual coverage HRA (ICHRA) that reimburses more than premiums (unless it is a self-administered HRA with fewer than 50 eligible employees, covered retirees, and COBRA qualified beneficiaries).
- Employers sponsoring a health flexible spending account (unless it is a self-administered FSA with fewer than 50 eligible employees, covered retirees, and COBRA qualified beneficiaries).
- Employers sponsoring a fully insured health plan which provides the employer with protected health information (PHI), such as through a claims analytics data feed.
- Business associates of fully insured, level-funded, and self-insured health plans.

Go Deeper:

When the health plan is fully insured, typically the carrier handles compliance with HIPAA's privacy and security rules. However, if PHI is shared with the employer (such as in a claims analytics data feed), the employer is also jointly liable to comply with HIPAA rules. Even without claims analytics, many employers with fully insured health plans also sponsor an HRA or health FSA which is not insured, and thus trigger the requirement to comply with HIPAA's privacy and security requirements.

When the health plan is self-funded, the plan itself is the covered entity that is subject to HIPAA's privacy and security rules. This generally means that the employer plan sponsor is obligated to meet HIPAA's requirements since they have access to PHI by virtue of the self-funded nature of the plan.

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An employer needing to run through the privacy and security requirements typically starts with designating a privacy official and a security official, and having that person or persons conduct an SRA. The results of that SRA then help the employer develop policies and procedures for handling and protecting PHI, implementing appropriate administrative, physical, and technical safeguards, and training employees handling PHI on all those policies, procedures, and safeguards.
The SRA Tool provided by the federal government is typically the starting place for an employer needing to conduct an SRA. While it is not guaranteed to fully address all requirements under HIPAA, federal, state, local, or international privacy laws, it serves as a solid starting place for addressing the HIPAA requirements.

Penalties for Non-Compliance:
When a potential breach of PHI occurs, the federal government may conduct an investigation.
When it finds an SRA was not conducted or was not updated when the employer's plan or operating environment significantly changed, the employer can be subject to fines and penalties. A violation can also trigger litigation risk.

Practical Impact to Employers:
One major improvement to the SRA Tool is the ability to mark each section independently of others with the last date and name of the approver of that section. This may help employers better track whether the SRA has been completed in its entirety and when each section was last reviewed.

Hot Topics:

MLR Rebates Reminder for Employers

Health insurance carriers are required to send out Medical Loss Ratio (MLR) payments to employers by September 30th when they did not spend enough of the premiums collected the previous calendar year on claims and allowable plan expenses. Most carriers are becoming better about not collecting more insurance premiums than MLR rules allow, so MLR rebates are not usually expected. However, occasionally they still occur, and the employer has 90 days to determine how much of the rebate must be shared back with participants and former participants.

Applies To: Any size employer with a fully-insured health plan the previous calendar year who receives an MLR rebate check this August or September.

Go Deeper:
When an employer receives a MLR rebate check from the insurer, they need to carefully consider how those funds are spent. They may not be able to keep the rebate unless their plan document specifies such rebates are retained by the employer. An employer with such language can simply retain the full rebate as taxable income to the organization.
Without such plan language, any portion of the rebate that is considered "plan assets" must be used in a very specific manner (described below). In other words, if employees paid any portion of the total premium, then that portion related to the MLR rebate may be considered plan assets which can only be used to benefit those participants, not the employer.

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For instance, if employees paid 20% of total premiums last year and the employer contributed 80%, then 20% of the MLR rebate may be considered "plan assets" and should only be used for the benefit of plan participants.
There are three basic methods an employer may use to spend the participants' portion of the MLR rebate:

1. Pay out a taxable cash refund
2. Offer a premium holiday for the amount of the rebate
3. Provide some type of benefit enhancement (keeping in mind participants must actually receive this within 90 days)

If the employer determines they need to share some of the rebate with former participants, a premium holiday or benefit enhancement might not work for them and sending a check may be more appropriate.
There is no de minimis exception to get out of distributing any portion that is considered plan assets (with a small exception regarding whether to include former participants). In other words, even if the rebate is a very small amount and dividing it among participants results in a few dollars, any portion related to plan assets still must be given back to current participants, and possibly to former employees (such as COBRA qualified beneficiaries and retirees).

Employers have express latitude under federal guidance to just divvy up the amount attributable to employees in an equal distribution. So, unless they choose, the employer does not need to further allocate the rebate for more equitable distributions reflective of the difference in what individuals paid. For example, if the employer provides single coverage at no cost to employees, the employer could issue an equal payment to all plan participants or could do further calculations to determine those in single coverage should not receive funds because they did not pay for coverage last year, sharing only with those who paid.
DOL Guidance for Handling MLR Rebatesas

Annual Medicare Part D Notices Due by October 15

Each year prior to October 15th, employers must provide coverage notices to all Medicare Part D eligible individuals who are covered under, or who apply for, the employer's prescription drug coverage indicating whether that coverage is creditable or not creditable (i.e., whether the plan pays as well as Part D pays on average). This includes individuals eligible for Medicare due to age, disability, or end stage renal disease (ESRD) whether they are eligible for the active employee medical plan or enrolled under COBRA or other continuation coverage (e.g. retiree coverage).

Applies To:

- All size employers with medical plans providing prescription drug coverage
- All size employers with an individual coverage health reimbursement arrangement (ICHRA) reimbursing not just insurance premiums but also prescription drug expenses

Go Deeper:
Determining Whether the Prescription Drug Coverage is Creditable
The notices required by October 15 are to disclose the creditable or non-creditable status of the employer's prescription drug plans. Employers should already know the status of each prescription drug plan's creditability, as notice would have been provided with open enrollment materials and a disclosure to the Centers for Medicare and Medicaid Services (CMS) is required shortly after renewal.

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Each prescription drug plan an employer sponsors must be evaluated separately, using actuarial principles subject to CMS rules, to determine whether it expects to pay, on average, as much for prescription drug claims as Medicare Part D expects to pay. The employer is not required to sponsor creditable plans, but is required to determine the creditable status of each plan it sponsors.
The employer will ideally secure a creditability determination from the carrier or TPA for each specific plan they offer. Often, the carrier provides a chart of off-the-shelf prescription drug plan options to show which plans for the upcoming calendar year are creditable or not creditable. As long as the employer is implementing an off-the-shelf, pre-designed plan without changes, they can rely on the creditability determination chart.
If the TPA or carrier will not make a creditability determination, the employer must either use CMS's design-based "simplified determination method" or obtain a determination using actuarial principles.

Simplified Determination Method

The simplified determination method is not always straightforward for an employer to use. Since last updated in 2009, it requires comparing the plan's deductible to the Medicare Part D deductible, ensuring adequate coverage of generics and brand drugs, adequate in-network retail pharmacy access for where participants are located, and determining the plan expects to pay at least 60% of prescription drug claim costs (so participants are expected on average to pay no more than 40% of prescription drug claim costs).

Revised Simplified Determination Method

A new option for 2026 (which becomes the sole simplified determination method in 2027) removes the need to evaluate the deductible but adds reasonable access to biological products to the list of requirements and increases the expectation for the plan to pay at least 72% of prescription drug claim costs rather than 60%. This revised simplified determination method is discussed starting at the bottom of page 27 of the Final CY 2026 Part D Redesign Program Instructions.
It is not always straightforward for an employer to determine whether a plan has "reasonable access" to generics, brands and biological products, has "reasonable access" to retail pharmacies where participants are located, and expects to pay at least 72% of prescription drug claims costs. When a simplified determination seems out of reach, the determination of creditable coverage status does not require an attestation by a qualified actuary unless the employer is electing the Medicare RDS (retiree drug subsidy), but the use of generally accepted actuarial principles in accordance with CMS guidelines is still required.

Providing the Creditable or Non-Creditable Notice

The employer must give a notice to Medicare-eligible individuals enrolled or seeking to enroll. Identifying these individuals can be difficult, particularly when eligibility for Medicare is based on a factor other than age, such as disability or end-stage renal disease. As a result, it is recommended employers provide Medicare Part D disclosures to everyone enrolled, or seeking to enroll in (i.e. eligible for) the group plan.
CMS provides a model notice with fields the employer must complete. Employers do not have to use the model notice, but do have to ensure required content elements are provided. The model notice has not changed since 2011.
The notice may be sent by mail, handed out at work, or sent electronically if the DOL's electronic disclosure requirements are met (i.e., employees have electronic access as a material part of their daily job or give consent to electronic delivery). If electronic delivery is chosen:

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- the employer must inform the plan participant that the participant is responsible for providing a copy of the electronic disclosure to their Medicare eligible dependents covered under the group health plan; and
- the notice must be posted on the employer's website, if applicable, with a link to the creditable coverage disclosure notice on the employer's home page.

If the Employer Knows a Creditable Plan will no Longer be Creditable January 1

If an employer knows before the October 15th notice deadline that a creditable plan option is going to lose creditability starting January 1, the employer would ideally include that detail in the notice they provide or in a cover letter. Some individuals already eligible for Part D may have been delaying enrollment due to having creditable coverage through their employer. Knowing in advance that their coverage will not be creditable in January may influence whether they want to elect Part D during the open enrollment period that begins October 15 (electing during the Part D open enrollment allows Part D coverage to start January 1).

Special Rules Allow Providing Notice in Open Enrollment Materials Instead of Sending by October 15

If an employer prefers, they could call special attention to the required notice in open enrollment materials and avoid the need to send a special mailing (or avoid the need to send an email and link on their website home page). The employer just needs to provide the notice anytime within the past twelve months before October 15th with language "prominent and conspicuous" enough in open enrollment materials to call attention to the importance of it and direct people where to find it in the materials.* This means that the disclosure notice portion of the document (or a reference to the section in the document being provided to the individual that contains the required notice) must be prominently referenced in at least 14-point font in a separate box, bolded, or offset on the first page of the information provided to the plan participant. This is typically accomplished by including a correctly sized text box in the table of contents pointing to the notices section or page of the open enrollment materials, such as this example:

> ***If you (and/or your dependents) have Medicare or will become eligible for Medicare in the next 12 months, a Federal law gives you more choices about your prescription drug coverage. Please see page xx for more details.***

*Note this approach is likely inappropriate when there is a change in the plan's creditable status since the last Medicare Part D Notice was distributed.

Penalties for Non-Compliance

While there is currently no direct penalty to an employer for failing to provide these notices, someone with non-creditable coverage who delays enrolling in Part D until after they are first eligible experiences a late enrollment penalty payable for life. Therefore, it is important that employers do their part to regularly educate employees when one or more plan options are not creditable so the individual knows when they or a dependent should weigh the pros and cons of delaying Part D or risking a late enrollment penalty if they stay in the non-creditable plan.

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Question of the Month

Q: What should we do when FSA limits are published after open enrollment starts?

A: The IRS usually publishes final 2026 indexing for benefits such as health FSA and qualified transportation limits pretty late in the year. It was October 22 in 2024 and November 9 in 2023. Many employers begin open enrollment around October 15 and wrap up by the time these numbers are published.

One option is to stick with the current limits, and when new limits are published, re-open the enrollment portal for an additional time period allowing employees to elect the new higher amounts. However, this effectively serves like a second open enrollment, and systems cannot always accommodate restricting a second window to only allow changes to FSA and commuter plan elections. Also, some employees who wish to elect more may miss the communication or the deadline.

An alternative option is to utilize projected indexing, which has been accurately predicted every year since the Tax Cuts and Jobs Act of 2017 switched federal indexing to "chained" inflation. Since the predictions are so reliable and are based on August inflation figures, the employer can inform employees in open enrollment communications that in the unlikely event the official limit ends up lower than projected, those who elected the maximum will be automatically reduced to the lower maximum. This alleviates confusion and potential mistakes, and removes the need to reopen the plans for adjustment.

Based on projected indexing, the health FSA limit is expected to increase by $100 to $3,400 for FSA plan years that begin in 2026. The carryover limit is always 20%, so that is projected to increase by $20 to $680.

The §132(f) qualified transportation fringe benefit limits are projected to increase by $15 in 2026 to $340 per month for qualified parking and $340 per month for qualified transit/vanpooling.

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