

The background of the entire page is a photograph of the U.S. Capitol dome in Washington, D.C. The dome is white with a series of arched windows and is topped with a large, ornate dome. An American flag is visible on the right side of the dome. The sky is blue with some white clouds.

# 2025 Compliance *Year in Review*

---

HYLANT

[hylant.com/insights/blog](https://hylant.com/insights/blog)



## Table of Contents

2026 Benefit Plan Amounts .....	3
Federal Agencies Withdraw Proposed Rule to Expand ACA's Contraceptive Coverage Mandate .....	4
U.S. Supreme Court Will Rule on ACA's Mandate for Free Preventive Care .....	6
FAQs Provide New Guidance on Gag Clause Attestation Requirement .....	8
ERISA Fiduciary Breach Claims Dismissed in J&J Lawsuit.....	11
IRS Issues ACA Reporting Guidance That May Require Action.....	13
Navigating Employee Benefits Changes Under a New Administration.....	15
New Wave of Lawsuits Target Health Plan Tobacco Surcharges .....	18
New Executive Order Aims to Reduce Drug Costs by Aligning with Global Prices .....	21
Trump Administration Won't Enforce Portions of Final Rule on Mental Health Parity.....	23
Health Plans Must Expand Breast Cancer Screening and Navigation Coverage in 2026.....	26
Federal District Court Invalidates Process for Assessing ACA Penalties.....	28
Understanding the Latest on Mental Health Parity Compliance .....	30
Federal District Court Vacates HIPAA Privacy Protections for Reproductive Healthcare.....	31
Congress Permanently Extends Pre-deductible Telehealth Coverage for HDHPs/HSAs .....	33
The "One Big Beautiful Bill Act" Includes Changes for Employee Benefits.....	35
HHS Revises Cost-Sharing Limits for 2026 Plan Years.....	38
Federal Agencies Issue New Guidance on Offering Fertility Benefits.....	40
PCORI Fee Amount Adjusted for 2026.....	42
ERISA Fiduciary Breach Claims in J&J Lawsuit Dismissed Again .....	44
CMS Proposes Eliminating Creditable Coverage Disclosure Obligation for Account-Based Plans .....	46
IRS Provides Guidance on the OBBBA's Expansion of HSAs.....	48



## 2026 Benefit Plan Amounts

HDHP – Annual Out-of-Pocket Limit	
Single Coverage	\$8,500
Family Coverage	\$17,000
HDHP – Minimum Annual Deductible	
Single Coverage	\$1,700
Family Coverage	\$3,400
HSA – Annual Contribution Limit	
Single Coverage	\$4,400
Family Coverage	\$8,750
Catch-up Contributions (Age 55 or Older)	\$1,000
Excepted Benefit HRA – Annual Contribution Limit	
All Coverage Levels	\$2,200
Health FSA Limits	
Employee Salary Reduction Limit	\$3,400
Carryover Limit	\$680
PCORI Fee – Due 7/31/26	
Plan Years Ending 1/1/25 Through 9/30/25	\$3.47 (multiplied by the average number of covered lives)
Plan Years Ending 10/1/25 Through 12/31/25	\$3.84 (multiplied by the average number of covered lives)
ACA Employer Shared Responsibility – Affordability Percentage	
Single Coverage	9.96% of income
Family Coverage	9.96% of income (measured for family members only for purposes of Exchange availability; does not impact an employer's potential "pay or play" penalty)



## Federal Agencies Withdraw Proposed Rule to Expand ACA's Contraceptive Coverage Mandate

PUBLISHED: JANUARY 23, 2025

On January 14, 2025, the Departments of Health and Human Services, Labor and the Treasury (Departments) [rescinded](#) a proposed rule from October 2024 that would have expanded the Affordable Care Act's (ACA) coverage mandate for contraceptives. Most notably, the proposed rule would have required most health plans and health insurance issuers to cover over-the-counter (OTC) contraceptives without imposing cost-sharing (e.g., deductibles, copayments or coinsurance) or requiring a prescription.

The Departments noted that they are withdrawing the proposed rule to **focus on other matters at this time**, such as a new transparency requirement for advanced explanation of benefits. However, new rules may be released in the future to address coverage of OTC contraceptives.

### CONTRACEPTIVE COVERAGE MANDATE

The ACA requires non-grandfathered health plans and issuers to provide benefits for certain women's preventive health services without imposing cost-sharing requirements. These preventive health services include contraceptive services and products approved, cleared or granted by the U.S. Food and Drug Administration (FDA) that a woman's attending healthcare provider determines to be medically appropriate.

Currently, health plans and issuers are only required to cover OTC preventive products without cost sharing when they are prescribed by a healthcare provider. In July 2023, the FDA approved the first OTC daily oral contraceptive, which is now widely available across the country.



## PROPOSED CHANGES (RESCINDED)

The [proposed rule](#), which has been rescinded, would have required health plans and issuers to:

- cover recommended OTC contraceptive items without requiring a prescription and without imposing cost-sharing;
- cover every FDA-approved contraceptive drug or drug-led combination product without cost sharing, unless the plan also covers a therapeutic equivalent of the drug or drug-led combination product without cost-sharing; and
- disclose to plan participants that OTC contraception is covered without a prescription and without cost sharing.



## U.S. Supreme Court Will Rule on ACA's Mandate for Free Preventive Care

PUBLISHED: JANUARY 23, 2025

The U.S. Supreme Court has decided to review the constitutionality of a key component of the Affordable Care Act's (ACA) preventive care mandate. This decision impacts the requirement for health plans and health insurance issuers to cover, without cost sharing, a wide range of preventive care services, including screenings for colorectal, lung and cervical cancers; medications for chronic conditions, such as cardiovascular disease; screening for HPV; depression and anxiety screenings; and hepatitis B and C virus screenings.

In June 2024, the 5th U.S. Circuit Court of Appeals ruled that a key component of the ACA's preventive care mandate is unconstitutional. However, the 5th Circuit limited its ruling to the plaintiffs in the case, a small group of individuals and businesses from Texas. This means that health plans and issuers have been required to continue to provide first-dollar coverage for the full range of recommended preventive health services. However, the Supreme Court's decision could lead to a **nationwide shift in coverage** if the Court rules in the plaintiffs' favor.

### ACA'S PREVENTIVE CARE MANDATE

The ACA requires non-grandfathered health plans and issuers to cover a set of recommended preventive services without imposing cost-sharing requirements, such as deductibles, copayments or coinsurance, when the services are provided by in-network providers. The recommended preventive care services covered by these requirements are:



- evidence-based items or services with an A or B rating in recommendations of the U.S. Preventive Services Task Force (USPSTF);
- immunizations for routine use in children, adolescents and adults recommended by the Advisory Committee on Immunization Practices;
- evidence-informed preventive care and screenings in guidelines supported by the Health Resources and Services Administration (HRSA) for infants, children and adolescents; and
- other evidence-informed preventive care and screenings in HRSA-supported guidelines for women.

## COURT DECISIONS

In March 2023, the U.S. District Court for the Northern District of Texas [struck down](#) a key component of the ACA's preventive care mandate. The District Court ruled that the preventive care coverage requirements based on an A or B rating by the USPSTF on or after March 23, 2010, the ACA's enactment date, violate the U.S. Constitution. More specifically, the District Court concluded that members of the USPSTF had not been appointed in a manner consistent with the Constitution's Appointments Clause. The District Court also issued a nationwide injunction, prohibiting the Biden administration from enforcing the affected preventive care mandates against any health plans or issuers.

The Biden administration appealed the District Court's ruling to the 5th Circuit, which covers Texas, Louisiana and Mississippi. The 5th Circuit put the District Court's decision on hold pending its ruling, which means health plans and issuers have been required to fully comply with the ACA's preventive care mandate without interruption. The 5th Circuit [agreed](#) with the District Court that members of the USPSTF had not been validly appointed under the U.S. Constitution. However, the 5th Circuit limited its relief to the plaintiffs in the case and held that there was no basis for a nationwide injunction.

On January 10, 2025, the Supreme Court agreed to hear the challenge to the ACA's preventive care mandate during its 2024-25 term. Oral arguments are expected later this year, with a ruling likely in the first half of 2025.



## FAQs Provide New Guidance on Gag Clause Attestation Requirement

PUBLISHED: FEBRUARY 10, 2025

On January 14, 2025, the Departments of Health and Human Services, Labor and the Treasury (Departments) issued [frequently asked questions \(FAQs\)](#) on the implementation of several federal transparency requirements, including the prohibition on gag clauses.

### BACKGROUND

Federal law prohibits group health plans and health insurance issuers from entering into agreements with third-party administrators (TPAs) or other service providers offering access to a network of providers that contain gag clauses (i.e., provisions that restrict the plan or issuer from providing, accessing or sharing certain information about provider price and quality and de-identified claims).

Health plans and issuers must annually submit an attestation of their compliance with the prohibition of gag clauses to the Departments. These attestations are due on December 31 of each year. Health plans and issuers that do not submit their attestations by the deadline may be subject to enforcement action.

Employers with fully insured health plans do not need to provide an attestation if their plan's issuer provides the attestation. Employers with self-insured health plans can enter into written agreements with their TPAs to provide the attestation, but the legal responsibility remains with the health plan.

---

### Quick Facts

**Who:** All group health plans and insurers must attest annually

**Deadline:** December 31 each year

**What's prohibited:** Any agreement that blocks access to or sharing of provider or claims data

**New guidance:** Includes downstream contracts and limits on de-identified data sharing

**Reminder:** Even if noncompliant, plans must still attest and disclose issues—good-faith reporting matters

---



## NEW GUIDANCE

The Departments' FAQs provide the following clarifying guidance for health plans regarding the gag clause prohibition and attestation requirement.

## DOWNSTREAM AGREEMENTS

A health plan's TPA or other service provider may have separate agreements (downstream agreements) with other entities to provide or administer the plan's network. If such downstream agreements restrict the health plan from providing, accessing or sharing the relevant information or data, this would be a prohibited gag clause, even if the plan is not a party to the agreement. To comply with the gag clause prohibition, the Departments expect that, in their direct contracts with TPAs or other service providers, plans will include provisions that prohibit the TPA or other service provider from entering into a downstream agreement that restricts the plan from accessing or sharing relevant information or data.

## DE-IDENTIFIED CLAIMS DATA

To comply with the prohibition on gag clauses, health plans cannot enter into an agreement with a TPA or other service provider that restricts the plan from providing de-identified claims data to a business associate (consistent with applicable privacy rules), except at the discretion of the TPA or other service provider.

## ANNUAL ATTESTATION

Health plans are required to submit the annual gag clause attestation **even if they are aware that they have entered into an agreement that violates the gag clause prohibition**. Plans must identify the noncompliant provision as part of their attestation, using the text box labeled "Additional Information" in Step 3 of the online system for this purpose. Such additional information should include:

- any prohibited gag clauses that a service provider has refused to remove;
- the name of the TPA or service provider with which the plan has the agreement containing the prohibited gag clause;
- conduct by the service provider that shows the service provider interprets the agreement to contain a prohibited gag clause;



- information on the plan's requests that the prohibited gag clause be removed from such agreement; and
- any other steps the plan has taken to come into compliance with the provision.

Even if a health plan submits this additional information, the provision in question could still be considered a prohibited gag clause and may be subject to enforcement action by the Departments. However, the Departments will take into account good-faith efforts to self-report a prohibited gag clause in any such enforcement action.



## ERISA Fiduciary Breach Claims Dismissed in J&J Lawsuit

PUBLISHED: FEBRUARY 10, 2025

On January 24, 2025, a U.S. District Court for the District of New Jersey [dismissed two claims](#) in a class-action lawsuit filed against Johnson & Johnson (J&J). The suit alleged that the company breached its fiduciary duties under the Employee Retirement Income Security Act (ERISA) by mismanaging its prescription drug benefits plan, costing the plan and its participants millions of dollars due to higher out-of-pocket costs for prescription drugs and higher premiums, among other things.

### LEGAL LANDSCAPE

For employers, the J&J lawsuit highlights the importance of adhering to their fiduciary duties when managing their health plans. Under ERISA's strict fiduciary standards, employers must prudently select and monitor their third-party service providers, including pharmacy benefit managers (PBMs). After the J&J lawsuit was filed, similar fiduciary litigation involving the management of prescription drug benefits followed. These cases are still making their way through the court system as scrutiny of the PBM industry intensifies.

### COURT RULING

In dismissing the two fiduciary breach claims, the court ruled that the plaintiff (an employee of J&J) lacked standing to bring a lawsuit. To have standing, a plaintiff must show that:

- they suffered an injury in fact that is concrete, non-hypothetical, particularized, and actual or imminent; and
- the injury was likely caused by the defendant; and
- there is a substantial likelihood that the injury can be remedied by a judicial decision.



### COURT DISMISSAL

The court found the plaintiff's first claim, that she paid more in premiums due to the defendants' purported breach of fiduciary duty during the plans' negotiation process, did not sufficiently show evidence of an injury and was "at best, speculative and hypothetical." Further, the outcome of the lawsuit would not affect the plaintiff's future benefit payments, and the plaintiff failed to show that the defendants' specific conduct resulted in higher premiums.

Regarding the plaintiff's second claim that she paid higher prices for drugs under the plans and thus paid more out of pocket, the court acknowledged that she suffered an injury that was traceable to the defendants' alleged ERISA violations. Notwithstanding, the plaintiff lacked standing based on this injury because a favorable decision would not be able to compensate her for the money she already paid, given that she had reached her prescription drug cap for each year asserted in the complaint. The court reasoned that, even if the defendants were to reimburse her out-of-pocket costs on a given drug, that money "would be owed to her insurance carrier to reimburse it for its expenditures on other drugs that same year."

### CURRENT IMPACT

The court granted the plaintiff leave to file an amended complaint within 30 days to address the deficiencies identified in the court's order.

While the J&J ruling can be viewed favorably for employers in their roles as plan sponsors, the outcome of the fiduciary litigation that was filed after the J&J case remains to be seen. Factors such as plan design and the specific allegations regarding how the defendants breached their fiduciary duties could result in different outcomes.



## IRS Issues ACA Reporting Guidance That May Require Action

PUBLISHED: FEBRUARY 25, 2025

The IRS has issued [Notice 2025-15](#) providing guidance on the alternative manner of furnishing statements to covered individuals and full-time employees, using Forms 1095-B and 1095-C, in accordance with the Affordable Care Act's (ACA) reporting requirements.

### BACKGROUND

The Paperwork Burden Reduction Act, enacted at the end of 2024 and applicable to 2025 reporting deadlines, provides that reporting entities are **no longer required to send Forms 1095-B and 1095-C to covered individuals and full-time employees unless a form is requested**. The legislation codified an existing alternative manner of furnishing Forms 1095-B established by a 2022 final rule and extended it to Forms 1095-C.

### ALTERNATIVE MANNER OF FURNISHING

The legislation provides that reporting entities must notify individuals of their right to request a copy of the statement “at such time and in such manner as the [IRS] may provide” to take advantage of the alternative furnishing method. These requirements are now set forth in IRS Notice 2025-15, which also applies to 2024 calendar year reporting due in early 2025.

In addition, any request must be fulfilled by January 31 of the year following the calendar year to which the return relates or 30 days after the date of the request, whichever is later.



## TIMELY NOTICE TO INDIVIDUALS

For 2024 statements required to be furnished in 2025, reporting entities will be able to provide Forms 1095-B and 1095-C upon request if they:

1. **Post a clear and conspicuous notice on its website by March 3, 2025**, stating that covered individuals and full-time employees may receive a copy of their statement upon request. The notice must include:

- An email address;
- A physical address to which a request may be sent; and
- A telephone number to contact the reporting entity.

2. **Retain the notice in the same location on its website through October 15, 2025.**

## ACTION STEPS

Reporting entities wishing to take advantage of the alternative manner of furnishing Forms 1095-B and 1095-C should take steps to **post the appropriate notice on their websites by March 3, 2025**, and ensure it is retained through October 15, 2025. Otherwise, reporting entities must provide Forms 1095 to each covered individual and full-time employee (as applicable) by March 3, 2025.

In addition, reporting entities must continue to comply with applicable state reporting requirements. The alternative furnishing method set forth in IRS Notice 2025-15 applies to federal reporting requirements.



## Navigating Employee Benefits Changes Under a New Administration

PUBLISHED: MARCH 13, 2025

In the wake of the new administration's dynamic policy environment, organizations face the challenge of navigating substantial changes in employee benefits policies. A core takeaway from our webinar, "[Key Employee Benefits Trends to Watch in the Trump Era](#)," is the necessity to expect the unexpected. As we transition into this new political landscape, it's crucial to understand that rapid changes could redefine the framework of employee benefits.

### At a Glance:

- **The new administration brought rapid changes** to employee benefits policy in 2025.
- Efforts to extend the **2017 tax law** signaled major financial planning implications.
- Many employers **reviewed benefits and pay structures** to stay compliant and competitive.
- Agility and **data-driven decisions** proved key to adapting throughout the year.

Staying informed about potential legislative changes is key to preparing for these shifts. The administration's emphasis on revising existing policies means that updates could come swiftly and have significant benefits management implications. Organizations can better anticipate adjustments and align their strategies by keeping abreast of these developments.

### KEY LEGISLATIVE CHANGES AFFECTING FINANCIAL PLANNING

Several legislative changes could significantly impact organizations' financial planning. The House Republicans' recent progress toward extending the 2017 tax legislation marks the first major hurdle in potential financial policy shifts that could directly affect how businesses plan and execute their financial strategies.

These legislative changes are not just about tax rates but also involve broader implications for corporate financial planning, potentially affecting everything from investment strategies to employee compensation packages. Understanding these changes is critical to maintaining a competitive edge and ensuring compliance with new regulations.



## STRATEGIES FOR ADAPTING TO NEW TAX LEGISLATION

Adapting to new tax legislation requires a proactive approach. Businesses must evaluate their current financial frameworks and assess how potential tax changes could influence their operations. This involves not only understanding the specifics of new laws but also exploring strategic adjustments to optimize tax efficiencies.

One strategy is to comprehensively review current financial policies and benefits programs. By identifying areas that may be affected by new legislation, businesses can develop contingency plans to minimize disruptions. Additionally, engaging with tax professionals and legal experts can provide valuable insights into the implications of these changes, ensuring that organizations are well-prepared to navigate the evolving tax landscape.

## PREPARING FOR UNFORESEEN CHANGES IN BENEFITS

Another critical focus is preparing for unforeseen changes in employee benefits. With the current administration's propensity for rapid change, organizations must be agile in adapting their benefits offerings to meet new requirements and expectations.

Developing a resilient benefits strategy involves regular review and adjustment of existing programs. This may include exploring alternative benefits options, such as enhanced wellness programs or flexible work arrangements, to remain competitive and attractive to current and prospective employees. By fostering a culture of adaptability, organizations can better manage the uncertainties of the current political climate.

## NAVIGATING POLICY CHANGES

Collaboration and communication across departments will be crucial to effectively navigating policy changes. By fostering a unified approach to policy changes, organizations can ensure that all stakeholders are informed and aligned in their strategies.

Leveraging technology and data analytics will also be important for keeping pace with change. By using advanced tools, businesses can better understand how policy changes may impact their operations and employee benefits. This data-driven approach enables more informed decision-making and enhances the ability to respond swiftly to legislative shifts.



## FUTURE OUTLOOK FOR EMPLOYEE BENEFITS IN A DYNAMIC POLITICAL LANDSCAPE

Looking ahead, the future of employee benefits in this dynamic political landscape remains uncertain yet full of potential opportunities. The fluid nature of the current administration means that organizations must remain vigilant and adaptable, ready to seize opportunities that may arise from policy changes.

As we anticipate further developments, the focus should be on building robust and flexible benefits programs that can withstand the test of political volatility. By prioritizing strategic planning and fostering a culture of continuous improvement, organizations can not only navigate the challenges of today but also position themselves for success in the future.



## New Wave of Lawsuits Target Health Plan Tobacco Surcharges

PUBLISHED: MARCH 19, 2025

Numerous class-action lawsuits have recently been filed against employers alleging that health plan premium surcharges related to tobacco use violate federal compliance requirements. These lawsuits have been filed by current and former employees of major U.S. companies, such as PepsiCo, Walmart, Target and Whole Foods, who have paid more in premiums due to their tobacco use, often hundreds of dollars more per employee per year.

In general, the lawsuits assert that the health plans violated HIPAA's nondiscrimination rules by:

### What to Know

- Employers face **class actions** over health plan tobacco surcharges.
- Alleged violations include **HIPAA nondiscrimination** and **ERISA fiduciary** rules.
- Several cases have led to **costly settlements** and penalties.
- Review **wellness program standards** and employee notices for compliance.

- not offering a reasonable alternative standard to avoid the surcharge (or only applying the premium reduction on a prospective basis after completing the alternative standard); and
- not describing the availability of the alternative standard in all plan materials.

Some lawsuits also assert that the collection of the tobacco premium surcharge was a breach of fiduciary duty under ERISA. The lawsuits request various forms of relief, including reimbursing employees who paid the surcharges with interest, disgorging any benefits or profits, and paying all attorney fees and costs.

### ACTION ITEMS

Employers may impose premium surcharges related to tobacco use if certain compliance requirements are met, including HIPAA's nondiscrimination rules. Given the recent wave of litigation, employers that impose tobacco surcharges should review whether their wellness programs are administered in accordance with these



legal requirements, including making available a reasonable alternative standard to qualify for the full reward and communicating the surcharge to employees in all materials.

### ***HIPAA Requirements***

Employers commonly require tobacco users to pay an additional charge for health plan premiums, whether they use cigarettes, cigars, e-cigarettes or smokeless tobacco. To comply with federal law, tobacco surcharges must be offered through a wellness program that meets the Health Insurance Portability and Accountability Act's (HIPAA) nondiscrimination requirements. For compliance purposes, HIPAA divides wellness programs into two categories: participatory wellness programs and health-contingent wellness programs. A wellness program that includes a tobacco surcharge will fall under one of these categories, depending on how the program's surcharge is designed:

- Participatory programs remove the surcharge for employees who participate in an activity (for example, attending a smoking cessation class), regardless of whether they quit using tobacco.
- Health-contingent programs only remove the surcharge for employees who satisfy a health-related standard (for example, not using tobacco).

Participatory wellness programs comply with HIPAA's nondiscrimination requirements without having to satisfy any additional standards as long as participation in the program is available to all similarly situated individuals, regardless of health status. Final regulations under HIPAA require health-contingent wellness programs to adhere to the following five standards related to nondiscrimination:

1. Frequency of opportunity—Eligible individuals must be provided with an opportunity to qualify for the reward at least once per year.
2. Size of reward—The total reward offered to an individual cannot exceed 30% of the total cost of coverage under the plan. However, for wellness programs that are designed to prevent or reduce tobacco use, the total reward cannot exceed 50% of the total cost of coverage under the plan.
3. Reasonable alternative standard—Health-contingent wellness programs must provide a reasonable alternative standard (or waiver of the otherwise applicable standard) to qualify for the full reward for anyone who does not meet the initial standard (that is, those who use tobacco products). For example, the reasonable alternative standard could include attending a smoking cessation class.



4. Reasonable design—Health-contingent wellness programs must be reasonably designed to promote health or prevent disease. A wellness program is reasonably designed if it has a reasonable chance of improving the health of (or preventing disease in) participating individuals and is not overly burdensome, a subterfuge for discrimination based on a health factor, or highly suspect in the method chosen to promote health or prevent disease.
5. Employee notice—The availability of a reasonable alternative standard to avoid the surcharge (and, if applicable, the possibility of a waiver of the otherwise applicable standard) must be disclosed in all plan materials describing the tobacco surcharge. This disclosure must also be included in any notice that an individual did not satisfy the wellness program’s standard of not using tobacco products. The disclosure must include contact information for obtaining the alternative standard and a statement that recommendations of an individual’s personal physician will be accommodated.

### ***Enforcement and Penalties***

The U.S. Department of Labor (DOL) has enforced HIPAA’s nondiscrimination requirements for health-contingent wellness programs for years, with some costly outcomes for employers. For example:

- In 2018, an employer agreed to reimburse its employees \$145,635 for tobacco surcharges after a DOL investigation found that the employer did not provide a reasonable alternative standard for avoiding the surcharge. It also agreed to pay a penalty to the federal government of \$14,563 for the violation.
- In 2023, an employer agreed to reimburse its employees \$16,660 for tobacco surcharges after a DOL investigation found that the employer had not informed employees about a reasonable alternative standard for avoiding the surcharge. Before the settlement, the employer had already reimbursed its employees \$79,780 for tobacco surcharge payments. It also agreed to pay a penalty to the federal government of \$13,422 for violating HIPAA and other federal requirements.

Although the recent wave of class-action lawsuits is in its early stages, the litigation will likely result in costly outcomes for the employers involved. One such employer, Bass Pro Shops, already agreed to a \$4.95 million settlement in a lawsuit alleging its tobacco surcharge violated HIPAA’s reasonable alternative standard requirements.



## New Executive Order Aims to Reduce Drug Costs by Aligning with Global Prices

PUBLISHED: MAY 15, 2025

On May 12, 2025, President Donald Trump issued an [executive order \(EO\)](#) that aims to bring the prices Americans pay for prescription drugs in line with those paid by similar nations. According to a White House [fact sheet](#), the prices Americans pay for brand-name drugs are more than three times the price other nations pay.

In April, President Trump signed another EO aimed at lowering prescription drug prices, which included a variety of directives related to the Medicare program and the pharmaceutical industry. The directives may not have an immediate impact on drug costs, as they will take time to implement.

### KEY DIRECTIVES

The most recent EO outlines a number of actions intended to lower prescription drug prices in the United States. Among other things, the EO directs:

- the U.S. trade representative and secretary of commerce to take action to ensure foreign countries “... are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes” in the U.S.;
- the Trump administration to communicate price targets to pharmaceutical manufacturers; and
- the secretary of Health and Human Services (HHS) to establish a mechanism through which American patients can buy their drugs directly from manufacturers who sell to Americans at a “most-favored-nation” price.

---

### Links and Resources:

#### **Full Executive Order**

Read the complete text outlining the administration’s drug pricing strategy.

#### **White House Fact Sheet**

See how U.S. drug prices compare.

---



Notably, if drug manufacturers fail to offer most-favored-nation pricing, the EO directs the secretary of HHS to:

- propose rules that impose most-favored-nation pricing, and
- take “other aggressive measures to significantly reduce the cost of prescription drugs to the American consumer and end anticompetitive practices.” This includes, but is not limited to, enforcement action by the U.S. Federal Trade Commission.

### POTENTIAL LEGAL HURDLES

While the EO directs the secretary of HHS to communicate most-favored-nation price targets to pharmaceutical manufacturers within 30 days, it is expected to face legal challenges. Industry professionals reference a similar proposal from Trump’s first term, which aimed to link Medicare payments for certain medications to the lowest prices paid by other countries. This proposal was blocked by federal courts for not adhering to the notice and comment process required by the Administrative Procedure Act. Thus, the immediate impact on drug costs remains to be seen.



## Trump Administration Won't Enforce Portions of Final Rule on Mental Health Parity

PUBLISHED: MAY 16, 2025

On May 15, 2025, the U.S. Departments of Labor, Health and Human Services, and the Treasury (Departments) released a [statement](#) regarding the nonenforcement of the [2024 final rule](#) under the [Mental Health Parity and Addiction Equity Act \(MHPAEA\)](#). The statement relates to a lawsuit brought by an employer trade group seeking to invalidate the final rule. Critics have called the rule's requirements "unworkable," warning they could lead employers to drop mental health and substance use disorder coverage altogether. The litigation has been put on hold while the Departments reconsider the final rule, including whether to modify or rescind it altogether.

According to the Departments' statement, they will **not enforce the 2024 final rule** (or otherwise pursue enforcement actions) based on a failure to comply that occurs **prior to a final decision in the litigation, plus an additional 18 months**. This enforcement relief applies only with respect to those portions of the 2024 final rule that are new in relation to the [2013 final rule](#). The Departments are also reexamining their MHPAEA enforcement program more broadly.

### 2024 FINAL RULE

On September 9, 2024, the Departments released a final rule to strengthen MHPAEA's requirements. MHPAEA requires parity between a group health plan's medical/surgical (M/S) benefits and mental health/substance use disorder (MH/SUD) benefits.

---

### Key Terms:

#### **MHPAEA**

Requires parity between mental health and medical benefits.

#### **Final Rule (2024)**

Issued Sept. 9, 2024; expanded NQTL compliance standards.

#### **NQTLs**

Limits like prior authorization, step therapy, or network design.

#### **Non-Enforcement**

Announced **May 15, 2025**; agencies paused enforcement for 18 months pending litigation.

---



The final rule's changes are extensive and primarily focus on nonquantitative treatment limitations (NQTLs). NQTLs include a variety of strategies that generally limit the scope or duration of benefits, such as prior authorization requirements. Among other changes, the final rule requires health plans and health insurance issuers to:

- offer meaningful benefits (including a core treatment) for each covered MH condition or SUD in every classification in which M/S benefits (a core treatment) are offered;
- not use factors and evidentiary standards to design NQTLs that discriminate against MH conditions and SUDs;
- collect and evaluate relevant outcomes data and take reasonable action, as necessary, to address material differences in access to MH/SUD benefits as compared to M/S benefits; and
- include specific elements in documented comparative analyses of NQTLs and make them available to the Departments, an applicable state authority or individuals upon request.

The final rule generally applies for plan years beginning on or after January 1, 2025; however, certain key requirements, such as NQTL data evaluation requirements, apply for plan years beginning on or after January 1, 2026.

## IMPACT ON EMPLOYERS

Despite the nonenforcement policy, the Mental Health Parity and Addiction Equity Act (MHPAEA) remains in effect. This includes the original statutory requirements and the 2013 final rule, both of which continue to apply. The nonenforcement policy applies only to those portions of the 2024 final rule that go beyond the 2013 rule.

MHPAEA was later amended by the Consolidated Appropriations Act, 2021 (CAA 2021), which added a requirement for group health plans to prepare and make available written comparative analyses for nonquantitative treatment limitations (NQTLs). To implement this mandate, the Departments issued FAQs About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (FAQ Part 45). While FAQ Part 45 is not subject to the current nonenforcement policy, the Departments have announced they are reevaluating this guidance as part of a broader review of MHPAEA enforcement.



Given the significant compliance challenges posed by FAQ Part 45—and the government’s indication that revisions may be forthcoming—employers and plans may want to pause before making substantial investments in implementing its more complex requirements.

In the meantime, plans should:

- **maintain compliance** with the 2013 final rule and MHPAEA’s core statutory provisions;
- **preserve documentation** and analyses prepared to date in connection with the CAA amendments; and
- **monitor developments** from the Departments, particularly any changes to FAQ Part 45 or future enforcement priorities.



## Health Plans Must Expand Breast Cancer Screening and Navigation Coverage in 2026

PUBLISHED: MAY 29, 2025

On December 30, 2024, the [Health Resources and Services Administration \(HRSA\)](#) issued updated preventive care guidelines requiring **non-grandfathered group health plans** to expand their no-cost coverage for breast cancer screening and related services. As a result, **beginning with plan years that start on or after December 30, 2025**, affected plans must cover additional imaging or testing needed to complete the initial mammography screening process and patient navigation services for breast and cervical cancer screening—all without cost sharing.

### WHAT'S CHANGING?

Under the updated HRSA-supported guidelines:

- Plans must cover, without cost sharing, additional breast imaging (e.g., MRI, ultrasound or mammography) and pathology evaluation when needed to complete the screening process for malignancies following an initial mammogram.
- Plans must also provide individualized patient navigation services for breast and cervical cancer screening and follow-up. These services include person-centered assessment and planning, healthcare access and health system navigation, referrals to appropriate support services (e.g., language translation, transportation, social services), and patient education.

These requirements apply to non-grandfathered group health plans and health insurance issuers, starting with the plan year that begins



one year after the guideline's publication—in this case, for plan years beginning on or after December 30, 2025. Calendar year plans will need to comply beginning on January 1, 2026.

### BACKGROUND: PREVENTIVE CARE REQUIREMENTS UNDER THE ACA

The Affordable Care Act (ACA) requires non-grandfathered health plans to cover certain preventive services without imposing cost sharing as long as the services are delivered by in-network providers. These services include:

- Evidence-based items or services rated A or B by the U.S. Preventive Services Task Force
- Routine immunizations recommended by the Advisory Committee on Immunization Practices
- Preventive care and screenings for infants, children, and adolescents supported by HRSA
- HRSA-supported preventive care and screenings specifically for women

These guidelines are updated periodically to reflect current clinical recommendations. When HRSA or other applicable agencies issue a new or revised guideline, plans generally have until the first day of the plan year one year later to implement the change.

### WHAT EMPLOYERS SHOULD DO

Employers should review their plan's preventive care coverage before the 2026 plan year to determine whether updates are needed. In most cases:

- Coordinate with your insurance carrier or third-party administrator to confirm compliance with the new guidelines.
- Communicate any required changes to participants through an updated Summary Plan Description (SPD) or a Summary of Material Modifications (SMM).

If your organization sponsors a non-grandfathered group health plan, these changes will likely apply to you. Ensuring timely updates now can help prevent compliance issues later.



## Federal District Court Invalidates Process for Assessing ACA Penalties

PUBLISHED: JUNE 11, 2025

A [recent federal court decision](#) has created uncertainty regarding the process for assessing employer shared responsibility (or “pay-or-play”) penalties under the Affordable Care Act (ACA). On April 10, 2025, the U.S. District Court for the Northern District of Texas held that the IRS cannot assess pay-or-play penalties without the U.S. Department of Health and Human Services (HHS) first providing the employer with a certification. Currently, the IRS uses [Letter 226-J](#) to notify employers that they may be liable for a pay-or-play penalty without prior certification from HHS.

### Case Snapshot

**Case:** Texas District Court, April 10, 2025

**Issue:** The IRS cannot assess ACA “pay-or-play” penalties without **HHS certification**.

**Outcome:** The court ruled in favor of the employer and ordered a **refund of 2019 penalties**.

**Scope:** Applies only to the plaintiff but may influence future **penalty disputes**.

**Next:** The administration may **appeal** or adjust **enforcement practices**.

Significantly, the District Court’s ruling is limited to the plaintiff involved in the lawsuit and does not directly impact the overall enforcement of pay-or-play penalties. However, employers disputing these penalties may use this decision’s reasoning to support an argument that the current assessment process is invalid. Note that the general deadline for filing a refund claim is three years from the tax return filing date or two years after paying the tax, whichever is later. Also, it is uncertain if the Trump administration will appeal this decision and how vigorously it will enforce pay-or-play penalties going forward.

### PAY-OR-PLAY PENALTIES

The ACA requires applicable large employers (ALEs) to offer affordable, minimum-value health coverage to their full-time employees or potentially pay a penalty to the IRS. ALEs are employers that employ, on average, at least 50 full-time employees, including full-time equivalent employees, during the preceding calendar year.

An ALE will face a penalty if one or more full-time employees obtain a subsidy for health insurance coverage purchased through



an ACA Exchange (or Marketplace). An individual may be eligible for a subsidy either because the ALE does not offer coverage or offers coverage that is unaffordable or does not provide minimum value.

### DISTRICT COURT RULING

The plaintiff, a Texas-based company providing janitorial services to schools, sought a refund of the pay-or-play penalty it paid to the IRS for 2019. In doing so, the employer argued that the penalty collection process was flawed because the ACA's statutory text first requires HHS to provide ALEs with a certification as to their potential liability and a notice of appeal rights. Once HHS certifies that an ALE owes a pay-or-play penalty, the IRS has the obligation to assess and collect the penalty. To streamline the assessment process, HHS delegated authority to the IRS to provide the certification required to assess a pay-or-play penalty. The IRS uses Letter 226-J as the penalty certification.

The District Court ruled in the plaintiff's favor and ordered the IRS to refund the penalty assessed for 2019. The court also invalidated HHS' delegation of the certification authority to the IRS, holding that the ACA's statutory text does not permit such delegation.

### IMPACT TO EMPLOYERS

The court's decision is limited to the plaintiffs in the case and does not directly impact the overall penalty enforcement process. However, employers disputing pay-or-play penalties may use the court's reasoning to challenge the current assessment process.



---

**Stay current on mental health parity compliance.**

Watch “**Understanding the Latest on Mental Health Parity Compliance**” for expert insight on the new **non-enforcement guidance** and next steps for plan sponsors.

[Watch Now >>](#)

---

## Understanding the Latest on Mental Health Parity Compliance

PUBLISHED: JUNE 24, 2025

In a rapidly evolving regulatory landscape, staying current on mental health parity requirements is more important than ever. Our latest webinar offers a timely and practical overview of the Mental Health Parity and Addiction Equity Act (MHPAEA), including a refresher on longstanding obligations and a deep dive into the recent non-enforcement guidance issued in response to pending litigation. Whether you’re managing a self-funded or fully insured plan, this session is designed to help you understand what’s changed—and what hasn’t.

### WHAT THE NEW NON-ENFORCEMENT GUIDANCE REALLY MEANS

The recent non-enforcement policy has generated a lot of questions—and some confusion. In this webinar, our experts explain what the guidance does and does not cover, clarifying its limited scope and implications for compliance moving forward. You’ll hear how this policy ties into recent litigation, what it means for the 2026 implementation timeline, and why it’s not a green light to pause your compliance efforts. This is essential viewing for anyone responsible for plan oversight and fiduciary duties.

### ACTIONABLE INSIGHTS FOR PLAN SPONSORS AND FIDUCIARIES

Beyond the legal updates, we provide practical tips and next steps tailored to both self-funded and fully insured plans. Learn how to navigate the complexities of non-quantitative treatment limitation (NQTL) comparative analyses, understand what to expect from your vendors, and explore steps your plan can take to work toward compliance. With clear explanations and real-world examples, this webinar is a must-watch for benefits professionals looking to stay ahead of the curve.



## Federal District Court Vacates HIPAA Privacy Protections for Reproductive Healthcare

PUBLISHED: JULY 2, 2025

On June 18, 2025, the [U.S. District Court for the Northern District of Texas](#) struck down a final rule issued in April 2024 to strengthen HIPAA's privacy protections for reproductive healthcare. The final rule, which became effective **December 23, 2024**, prohibits health plans and other regulated entities from using or disclosing protected health information (PHI) related to lawful reproductive healthcare in certain situations. The Texas decision vacates these new protections in their entirety, and the court ruling is effective nationwide.

---

### Case Snapshot

**Date:** June 18, 2025

**Ruling:** Texas court vacated new HIPAA reproductive healthcare privacy protections nationwide.

**Still in effect:** General HIPAA rules and SUD notice requirements.

**Action:** Employers should review HIPAA policies and remove reproductive care provisions.

---

### PRIVACY PROTECTIONS

The HIPAA Privacy Rule sets strict limits on the use, disclosure and protection of PHI by healthcare providers, health plans, healthcare clearinghouses and their business associates (regulated entities). The Privacy Rule also allows regulated entities to use or disclose PHI for certain non-healthcare purposes, including certain criminal, civil and administrative investigations and proceedings.

The [U.S. Department of Health and Human Services](#) (HHS) issued the final rule to protect the privacy of reproductive healthcare following the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, which eliminated the constitutional right to abortion. The final rule prohibits regulated entities from using or disclosing PHI for the criminal, civil or administrative investigation of (or proceeding against) any person in connection with seeking, obtaining, providing or facilitating reproductive healthcare **where such healthcare is lawful under the circumstances in which it is provided**. In certain circumstances,



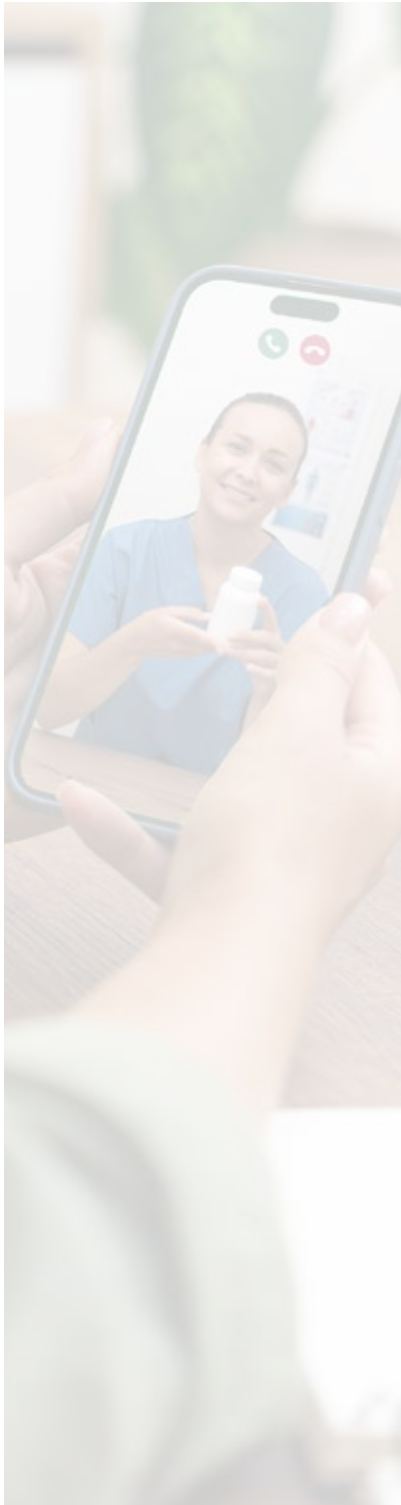
the final rule requires regulated entities that receive requests for PHI potentially related to reproductive healthcare to obtain a **signed attestation** that the use or disclosure is not for a prohibited purpose.

The final rule also requires covered entities to update their privacy notices by **February 16, 2026**, to describe the new privacy rights for reproductive healthcare. In addition, covered entities that handle certain substance use disorder (SUD) records must update their privacy notices to describe [new privacy protections](#) for these records by this deadline.

### DISTRICT COURT RULING

The Texas court ruled that the final rule's heightened protections for reproductive healthcare exceed HHS's statutory authority and unlawfully limit states' ability to enforce their own public health laws. Accordingly, the Texas court vacated the final rule nationwide. However, it did not vacate the new HIPAA privacy notice requirements for SUD records. Although this decision could be overturned or modified by a higher court, it seems unlikely that the Trump administration will appeal the court's ruling.

Going forward, regulated entities must still comply with HIPAA's general privacy requirements for PHI and any applicable state privacy laws. Employers should review the terms of their HIPAA policies to determine if updates should be made to remove the special rules for reproductive healthcare.



## Congress Permanently Extends Pre-deductible Telehealth Coverage for HDHPs/HSAs

PUBLISHED: JULY 10, 2025

On July 4, 2025, President Donald Trump signed a [major tax and spending bill](#) (commonly referred to as the “One Big Beautiful Bill Act”) into law. The legislation includes measures to expand the use of health savings accounts (HSAs). One of the new measures **permanently extends** the ability of high-deductible health plans (HDHPs) to provide benefits for telehealth and other remote-care services before plan deductibles have been met without jeopardizing HSA eligibility. This extension applies to plan years beginning after December 31, 2024.

### BACKGROUND

To be eligible for HSA contributions, individuals cannot be covered by a health plan that provides benefits, except preventive care benefits, before the minimum HDHP deductible is satisfied for the year. Historically, individuals who were covered by telehealth programs that provided free or reduced-cost medical benefits were not eligible for HSA contributions.

However, in response to the COVID-19 pandemic, the U.S. Congress enacted legislation that temporarily allowed HDHPs to provide benefits for telehealth or other remote-care services before plan deductibles were met. This relief became effective in 2020 and applied to plan years beginning before January 1, 2022. A federal spending bill extended this relief to telehealth services provided in months beginning after March 31, 2022, and before January 1, 2023. At the end of 2022, Congress further extended this first-dollar coverage for telehealth services to plan years beginning after December 31, 2022, and before January 1, 2025.



This exception for first-dollar telehealth services expired at the end of the 2024 plan year (i.e., December 31, 2024, for calendar-year HDHPs). However, the new legislation **permanently extends this relief, effective for plan years beginning on or after January 1, 2025.**

### IMPACT OF EXTENSION

Due to the permanent extension, HDHPs may waive the deductible for any telehealth or other remote-care services for plan years beginning in 2025 and beyond without causing participants to lose HSA eligibility. This provision is optional; HDHPs can apply any telehealth services, other than preventive care, toward the deductible.

Employers with HDHPs should review their health plan's coverage of telehealth services to determine if changes should be made. Any changes to telehealth coverage should be communicated to plan participants through an updated Summary Plan Description or a Summary of Material Modifications.



## The “One Big Beautiful Bill Act” Includes Changes for Employee Benefits

PUBLISHED: JULY 10, 2025

On July 4, 2025, President Donald Trump signed a major tax and spending bill, commonly referred to as the “[One Big Beautiful Bill Act](#)” (OBBA Act), into law. The OBBA Act includes changes for employee benefit plans, including provisions that:

- expand the availability of health savings accounts (HSAs);
- permanently extend the telehealth exception for high-deductible health plans (HDHPs);
- increase the maximum annual limit for dependent care flexible spending accounts (FSAs);
- allow employers to help pay employees’ student loans beyond 2025 and make cost-of-living adjustments to the tax exclusion for educational assistance programs; and
- allow employers to contribute up to \$2,500 per year to a new type of tax-advantaged account for children, called a “Trump Account.”

---

### Key Benefit Changes

**HSA expansion:** Eligible with low-cost direct primary care arrangements.

**Telehealth:** Permanent HDHP exception—coverage before deductible allowed.

**Dependent care FSAs:** Limit increases to \$7,500 (joint) and \$3,750 (separate).

**Student loans:** Permanent extension for employer repayment assistance.

**Trump Accounts:** New tax-advantaged savings accounts for children with optional employer contributions.

---

### HSA EXPANSION

Only eligible individuals can establish HSAs and make HSA contributions (or have them made on their behalf). To be HSA-eligible, an individual must:

- be covered by an HDHP;
- not be covered by any health plan that provides coverage below the minimum required HDHP deductible, with some limited exceptions;
- not be enrolled in Medicare; and
- not be eligible to be claimed as a dependent on another person’s tax return.



Effective January 1, 2026, the OBBB Act expands HSA eligibility by allowing individuals with **direct primary care (DPC) arrangements** to make HSA contributions if their **monthly fees are \$150 or less (\$300 or less for family coverage)**. These dollar limits will be adjusted annually for inflation. A DPC arrangement is a subscription-based healthcare delivery model where an individual is charged a fixed periodic fee for access to medical care consisting solely of primary care services. In addition, the OBBB Act treats DPC fees as a medical care expense that can be paid for using HSA funds.

Also, to expand the accessibility of HSAs in the individual market, the OBBB Act **categorizes as HDHPs all bronze plans** and catastrophic plans that are available through an Affordable Care Act (ACA) Exchange. This change is effective January 1, 2026. Bronze plans have the highest deductibles and lowest premiums among the four categories (or metal levels) of individual plans. Catastrophic plans have lower premiums than bronze plans and very high deductibles.

### HDHP TELEHEALTH EXCEPTION

To be eligible for HSA contributions, individuals cannot be covered by a health plan that provides benefits, except preventive care benefits, before the minimum HDHP deductible is satisfied for the year. Historically, individuals who were covered by telehealth programs that provided free or reduced-cost medical benefits were not eligible for HSA contributions.

A COVID pandemic-related relief measure temporarily allowed HDHPs to waive the deductible for telehealth services without impacting HSA eligibility. This relief expired at the end of the 2024 plan year. However, the OBBB Act **permanently extends the ability of HDHPs to provide benefits for telehealth and other remote care services** before plan deductibles have been met without jeopardizing HSA eligibility. This extension applies to plan years beginning after December 31, 2024. [Learn more here.](#)

### DEPENDENT CARE FSAS

Employers can provide dependent care assistance benefits for their employees on a tax-free basis, subject to a maximum annual limit. These benefit plans are referred to as dependent care FSAs (or dependent care assistance programs, DCAPs). Effective January 1, 2026, the OBBB Act increases the maximum annual limit for dependent care FSAs to **\$7,500** for single individuals and married couples filing jointly and **\$3,750** for married individuals filing separately (up from \$5,000 and \$2,500, respectively). The new limit is not adjusted for inflation.



## EDUCATIONAL ASSISTANCE PROGRAMS – STUDENT LOANS

Employers can offer programs to provide employees with undergraduate or graduate-level educational assistance. Educational assistance programs can pay for employees' books, equipment, supplies, tuition and other fees. Also, these programs can pay principal and interest on employees' student loans. The option to use educational assistance programs for student loans was set to expire on December 31, 2025. However, the OBBB Act **permanently extends this student loan payment option.**

Also, tax-free benefits under an educational assistance program are limited to **\$5,250 per employee per year**. Typically, educational assistance provided above this level is taxable as wages. Effective for taxable years beginning after 2026, the OBBB Act annually adjusts the \$5,250 limit for inflation.

## TRUMP ACCOUNTS

The OBBB Act creates a new type of tax-advantaged savings account for children under age 18, named a "Trump Account." Effective in 2026, Trump Accounts will operate similarly to individual retirement accounts, or IRAs, where earnings grow tax-deferred. In general, annual contributions are limited to **\$5,000 per child** (as adjusted annually for inflation beginning after 2027). The OBBB Act provides that children born in 2025-2028 may be eligible to receive a special \$1,000 contribution from the federal government.

Employers may make **tax-free contributions** to the Trump Account of an employee or an employee's dependent of up to **\$2,500 per year** (as adjusted annually for inflation beginning after 2027). These programs will require a written plan document and will be subject to some of the same tax rules that apply to dependent care FSAs, such as annual nondiscrimination testing and employee notifications.



## HHS Revises Cost-Sharing Limits for 2026 Plan Years

PUBLISHED: JULY 22, 2025

On June 25, 2025, the U.S. Department of Health and Human Services (HHS) published a final rule to implement new standards for the Affordable Care Act's (ACA) Marketplaces. This final rule also updates the methodology used for calculating the ACA's maximum annual limitation on cost sharing.

Based on this update, the **HHS** has revised the cost-sharing limits for plan years beginning in 2026. The maximum annual limitation on cost sharing is **\$10,600 for self-only coverage and \$21,200 for family coverage**. This represents an approximately 15.2% increase from the 2025 limits of \$9,200 for self-only coverage and \$18,400 for family coverage.

HHS previously released the maximum limits on cost sharing for 2026 based on a now-outdated methodology. Those limits (\$10,150 for self-only coverage and \$20,300 for family coverage) have been replaced with the revised limits.

### OUT-OF-POCKET MAXIMUM

The ACA requires most health plans to comply with annual limits on total enrollee cost sharing for essential health benefits (EHBs). The ACA's cost-sharing limits apply to all non-grandfathered health plans, including self-insured health plans, level-funded health plans and fully insured health plans of any size.

These cost-sharing limits are commonly referred to as an out-of-pocket maximum. Once the out-of-pocket maximum is reached for the year, the enrollee cannot be responsible for additional cost sharing for EHBs for the remainder of the year.



Under the ACA, EHBs must reflect the scope of benefits covered by a typical employer plan and include items and services in 10 general categories, including:

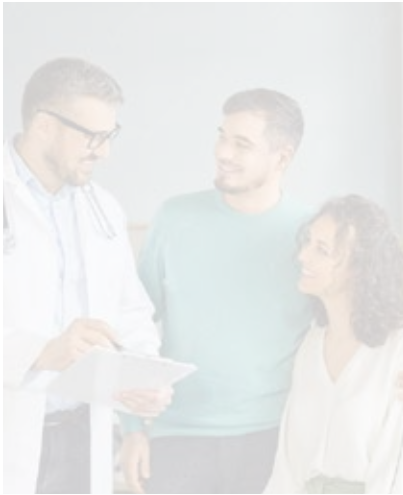
- Emergency services
- Hospitalization
- Prescription drugs
- Pediatric services
- Outpatient care
- Maternity and newborn care

Any out-of-pocket expenses required by or on behalf of an enrollee with respect to EHBs must count toward the cost-sharing limit. This includes deductibles, copayments, coinsurance and similar charges but excludes premiums and spending for non-covered services. Health plans that use provider networks are not required to count an enrollee's expenses for out-of-network benefits toward the cost-sharing limit.

Also, the ACA requires health plans to apply an embedded out-of-pocket limit for everyone enrolled in coverage. Each enrollee must have an individual out-of-pocket limit on EHBs that is not higher than the ACA's out-of-pocket maximum for self-only coverage.

### ANNUAL LIMITS

The ACA's cost-sharing limit is adjusted each year for inflation. For plan years beginning in 2025, the out-of-pocket maximum is \$9,200 for self-only coverage and \$18,400 for family coverage. The limits for plan years beginning in 2026 are \$10,600 and \$21,200, respectively. Employers should review the plan designs yearly to ensure they comply with the ACA's cost-sharing limits.



## Federal Agencies Issue New Guidance on Offering Fertility Benefits

PUBLISHED: OCTOBER 30, 2025

On October 16, 2025, the U.S. Departments of Labor, Health and Human Services, and the Treasury (the Departments) jointly issued [guidance](#) that clarifies existing categories of excepted benefits that employers can use to offer fertility benefits.

The guidance follows [Executive Order 14216](#), which directed the Domestic Policy Council (DPC) to submit a list of policy recommendations to protect in vitro fertilization (IVF) access and reduce out-of-pocket and health plan costs for IVF treatment. As part of those policy recommendations, the DPC recommended issuing regulations or guidance that would allow employers to expand access to coverage for fertility through the provision of an excepted benefit.

### WHAT ARE EXCEPTED BENEFITS?

Excepted benefits are certain types of employee benefits that are not subject to HIPAA's portability rules (like special enrollment rights and nondiscrimination rules) or the ACA's market reforms (such as annual limit bans and preventive care mandates). There are four categories of excepted benefits:

- Benefits that are generally not health coverage (e.g., automobile insurance)
- Limited excepted benefits (e.g., stand-alone vision and dental plans)
- Non-coordinated excepted benefits (e.g., cancer-only policies)
- Supplemental excepted benefits (e.g., Medigap or TRICARE)

---

### Fertility Benefits at a Glance

#### **Employers may now offer:**

- **Independent fertility coverage** as a non-coordinated excepted benefit
- **Excepted benefit HRAs** to reimburse fertility expenses
- **EAP support** for fertility coaching and navigation

*These options expand access to fertility benefits while preserving HSA eligibility.*

---



The benefits in the first category are always excepted; the others are excepted only if certain conditions are met.

### NEW GUIDANCE HIGHLIGHTS

The new guidance provides that employers may offer the following:

**Fertility benefits as an independent, non-coordinated excepted benefit**, if the applicable conditions are met. Individuals enrolled in such coverage may also contribute to a health savings account. A policy covering benefits related to infertility could qualify if it:

- is provided under a separate policy, certificate or contract of insurance (thus, the coverage cannot be offered as a self-funded arrangement);
- does not contain any coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and
- pays benefits regardless of coverage under other plans.

**An excepted benefit health reimbursement arrangement (HRA) that reimburses an employee's out-of-pocket costs with respect to fertility benefits**, as long as the HRA meets the applicable regulatory requirements.

**Benefits for coaching and navigator services to help employees and their dependents understand their fertility options under an employee assistance program (EAP) that qualifies as a limited excepted benefit.** To qualify as a limited excepted benefit, the EAP cannot be coordinated with benefits under another group health plan, no employee premiums or contributions can be required as a condition of participation, and there must be no cost-sharing under the EAP. The EAP would not constitute a limited excepted benefit if it offers any fertility benefits that are significant benefits for medical care.

### FUTURE RULEMAKING

In the guidance, the Departments stated that they intend to propose rulemaking aimed at providing additional ways for certain fertility benefits to be offered as a limited excepted benefit. They are also considering whether to modify the standards under which supplemental health insurance coverage provided by a group health plan, including a supplemental benefit for fertility coverage, will be considered to satisfy the conditions for being an excepted benefit.



## PCORI Fee Amount Adjusted for 2026

PUBLISHED: NOVEMBER 6, 2025

The Internal Revenue Service (IRS) has issued [Notice 2025-61](#) to increase the Patient-Centered Outcomes Research Institute (PCORI) fee amount for plan years ending on or after October 1, 2025, and before October 1, 2026. The updated PCORI fee amount is **\$3.84** multiplied by the average number of lives covered under the plan.

For plan years that ended on or after October 1, 2024, and before October 1, 2025, the PCORI fee amount is **\$3.47** multiplied by the average number of lives covered under the plan.

### IRS PCORI Fees Resources

- [PCORI Fee Overview Page](#)
- [PCORI Fee: Questions and Answers](#)
- [PCORI Fee Due Dates and Applicable Rates](#)
- [Chart: Application of the PCORI Fee to Common Types of Health Coverage or Arrangements](#)

### APPLICABILITY OF PCORI FEE

The PCORI fee was created by the Affordable Care Act (ACA) and first applied for plan or policy years ending on or after October 1, 2012. The fee is imposed on health insurance issuers and self-insured plan sponsors to fund comparative effectiveness research. The PCORI fee was originally scheduled to expire in 2019. However, a federal spending bill extended the PCORI fee for an additional 10 years. As a result, the PCORI fee will apply through the plan or policy year ending before October 1, 2029.

### PAYMENT DEADLINE

PCORI fees are reported and paid annually on IRS Form 720 (Quarterly Federal Excise Tax Return). These fees are due each year by July 31 of the year following the last day of the plan year. For plan years ending in 2025, the PCORI fee is due by **July 31, 2026**. Employers with self-insured health plans should have reported and paid PCORI fees for 2024 by July 31, 2025.



## CALCULATING PCORI FEE

The PCORI fees are calculated based on the average number of covered lives under the plan or policy. This generally includes employees and their enrolled spouses and dependents, unless the plan is an HRA. Final rules outline several alternatives for issuers and plan sponsors to determine the average number of covered lives, which include:

- Actual Count Method
- Snapshot Method
- Form 5500 Method



## ERISA Fiduciary Breach Claims in J&J Lawsuit Dismissed Again

PUBLISHED: DECEMBER 9, 2025

The U.S. District Court for the District of New Jersey has once again dismissed a class-action lawsuit filed against Johnson & Johnson (J&J), which alleged that the company breached its fiduciary duties under the Employee Retirement Income Security Act (ERISA) by mismanaging its prescription drug benefits plan, costing the plan and its participants millions of dollars due to higher out-of-pocket costs for prescription drugs and higher premiums, among other things.

The initial complaint was dismissed on January 24, 2025, where the court ruled that the plaintiff (an employee of J&J) lacked standing to bring a lawsuit and granted the plaintiff leave to file an amended complaint. In March 2025, the plaintiff filed an amended complaint where a new plaintiff was added to the case and new allegations pertaining to premiums were asserted (specifically, that higher drug costs because of defendants' fiduciary breaches inflated COBRA premiums). Despite these revisions, the court again granted the defendants' motion to dismiss.

### LEGAL LANDSCAPE

For employers, the J&J lawsuit highlights the importance of adhering to their fiduciary duties when managing their health plans. Under ERISA's strict fiduciary standards, employers must prudently select and monitor their third-party service providers, including pharmacy benefit managers (PBMs). After the J&J lawsuit was filed, similar fiduciary litigation involving the management of prescription drug benefits followed, such as the Navarro v. Wells Fargo & Co. case. Like the J&J lawsuit, this case is still making its way through the court system as scrutiny of the PBM industry intensifies.



## EMPLOYER TAKEAWAY

While the J&J ruling can be viewed favorably for employers in their roles as plan sponsors, its ultimate impact—and that of similar fiduciary litigation—remains to be seen. Factors such as plan design and the specific allegations regarding how the defendants breached their fiduciary duties could result in different outcomes. Although these dismissals were based on procedural issues like standing, they underscore the importance of employers upholding their fiduciary duties when managing their group health plans, including the prudent selection and monitoring of service providers such as PBMs.



## CMS Proposes Eliminating Creditable Coverage Disclosure Obligation for Account-Based Plans

PUBLISHED: DECEMBER 23, 2025

On November 28, 2025, the Centers for Medicare and Medicaid Services (CMS) released a [proposed rule](#) that would exempt account-based plans such as health reimbursement arrangements (HRAs), health flexible spending accounts (FSAs), and health savings accounts (HSAs) from creditable coverage disclosure requirements. Public comments on the proposal are due by January 26, 2026.

### BACKGROUND

Employers with group health plans that provide prescription drug coverage to individuals who are eligible for Medicare Part D must inform both those individuals and CMS whether that coverage is creditable. A group health plan's prescription drug coverage is considered creditable if its actuarial value equals or exceeds the actuarial value of standard Medicare Part D prescription drug coverage; coverage that does not meet this standard is deemed non-creditable.

For this purpose, the term "group health plan" includes account-based medical plans such as HRAs, health FSAs or HSAs, to the extent they are subject to the Employee Retirement Income Security Act (ERISA) as employee welfare benefit plans that provide medical care.

### PROPOSED EXEMPTION

The CMS proposal introduces changes aimed at reducing administrative burden by eliminating duplicative or outdated



requirements. As part of this effort, CMS proposes exempting account-based plans—such as HSAs, health FSAs and HRAs (including individual coverage HRAs)—from the creditable coverage disclosure requirements.

According to CMS, these account-based plans do not actually offer prescription drug coverage; rather, they are designed to provide savings on healthcare costs through pre-tax contributions and reimbursements to supplement other coverage, such as another group health plan. CMS explains that requiring these plans to determine if their coverage is creditable and report that status unduly increases administrative burden and could result in confusion for beneficiaries. For example, if an account-based plan discloses that it does not offer creditable coverage (because it does not directly offer prescription drug coverage) and the individual's plan that directly offers the prescription drug benefit coverage discloses that the benefit is creditable, the individual could receive potentially contradictory and confusing information. CMS notes that this contradiction may ultimately disadvantage Part D Medicare-eligible individuals in making informed choices about their prescription drug coverage. CMS's [fact sheet](#) on the proposal includes more information.

### EMPLOYER TAKEAWAY

Until the rule is finalized, **employers should continue to comply with existing creditable coverage disclosure requirements and monitor developments closely.** Even if the proposed exemption is finalized, it will only apply to account-based plans such as HRAs, health FSAs and HSAs. Group health plans that offer prescription drug coverage remain subject to the disclosure requirements, so employers should ensure that these notices continue to be provided.



## IRS Provides Guidance on the OBBBA's Expansion of HSAs

PUBLISHED: DECEMBER 23, 2025

On December 9, 2025, the IRS issued [Notice 2026-5](#), providing guidance on the expanded availability of health savings accounts (HSAs) under the [One Big Beautiful Bill Act \(OBBBA\)](#), which was signed into law by President Donald Trump on July 4, 2025. The OBBBA's changes expand the availability of HSAs by:

- permanently extending the ability to receive **telehealth and remote care services** before meeting the high-deductible health plan (HDHP) deductible while remaining HSA-eligible;
- allowing individuals enrolled in certain **direct primary care (DPC) arrangements** to contribute to HSAs and use their HSA funds tax-free to pay periodic DPC fees; and
- designating **bronze and catastrophic plans** available through an Affordable Care Act (ACA) Exchange as HSA-compatible, regardless of whether they satisfy the requirements for HDHPs.

This legal update summarizes these changes and highlights key guidance from Notice 2026-5.

### TELEHEALTH AND REMOTE CARE SERVICES

To be eligible for HSA contributions, individuals generally cannot be covered by a health plan that provides benefits, except preventive care benefits, before the minimum HDHP deductible is satisfied for the year. Historically, individuals who were covered by telehealth programs that provided free or reduced-cost medical benefits were not eligible for HSA contributions. A pandemic-related relief measure temporarily allowed HDHPs to waive the deductible for telehealth services without impacting HSA eligibility.



This relief expired at the end of the 2024 plan year. However, the OBBBA permanently extended the ability of HDHPs to provide benefits for telehealth and other remote care services before plan deductibles have been met without jeopardizing HSA eligibility. This extension applies to **plan years beginning after December 31, 2024.**

Notice 2026-5 confirms that otherwise eligible individuals may contribute to an HSA for 2025 if, before the OBBBA was enacted, the individual was enrolled in a health plan that provided coverage for telehealth or other remote care services before the minimum deductible was satisfied, if the health plan otherwise satisfied the requirements to be treated as an HDHP. This is true regardless of whether the HSA contribution is made before or after July 4, 2025.

Also, Notice 2026-5:

- addresses the **types of benefits** that are treated as telehealth or other remote care services that may be offered by an HDHP without a deductible; and
- clarifies that **in-person services, medical equipment or drugs** that are furnished in connection with a telehealth or other remote care service generally cannot be provided by an HDHP without a deductible under this exception.

### DPC ARRANGEMENTS

Effective **January 1, 2026**, the OBBBA expands HSA eligibility by allowing otherwise eligible individuals with DPC arrangements to make HSA contributions if their monthly fees are \$150 or less (\$300 or less for family coverage). These dollar limits will be adjusted annually for inflation. A DPC arrangement is a subscription-based healthcare delivery model in which an individual is charged a fixed periodic fee for access to medical care, consisting solely of primary care services provided by primary care practitioners. In addition, the OBBBA treats DPC fees as a medical care expense that can be paid for using HSA funds.

Notice 2026-5 addresses the types of arrangements that qualify as DPC arrangements for HSA eligibility purposes. For example, a DPC arrangement **does not include** an arrangement that:

- provides certain healthcare items and services to individuals on the condition that they are members in the arrangement and have paid a fixed periodic fee, **but bills separately for those items and services (through insurance or otherwise);** or
- provides services other than primary care services, regardless of whether members utilize those other services.



However, a DPC arrangement may include an arrangement that **has fees that are billed for periods of more than a month, but no more than a year**, provided the aggregate fees are fixed, periodic and do not exceed the monthly limit (on an annualized basis). For example, for 2026, the fee for a single individual could be \$1,800 for a year, \$900 for six months or \$450 for three months.

Notice 2026-5 also addresses how the tax rules for HDHPs intersect with DPC arrangements. For example, an HDHP cannot offer primary care benefits other than those specifically allowed (e.g., telehealth and preventive care) by paying fees for, or providing membership in, a DPC arrangement without a deductible (or before the minimum deductible has been satisfied). For individuals who are enrolled in both an HDHP and a DPC arrangement, the DPC arrangement's fees cannot count toward the HDHP's annual deductible and out-of-pocket maximum.

In addition, Notice 2026-5 provides the following guidance on the reimbursement of DPC arrangement fees from HSAs:

- The fees cannot be reimbursed by an HSA if they are paid by an individual's employer, including if they are paid through pre-tax salary reductions under a Section 125 cafeteria plan;
- The fees may be reimbursed from an HSA before the coverage period for the arrangement (for example, an HSA may immediately reimburse a substantiated fee for a DPC arrangement that begins on January 1 of that enrollment year, even if the enrolled individuals paid the fee prior to the first day of the enrollment year); and
- Fees that exceed the applicable dollar limit (i.e., \$150/\$300 per month for 2026) can be reimbursed from an HSA but will disqualify the covered individual from making HSA contributions while they are enrolled.

### BRONZE AND CATASTROPHIC PLANS

To expand the accessibility of HSAs in the individual market, the OBBBA categorizes as HDHPs all bronze plans and catastrophic plans that are available through an ACA Exchange. This change is effective **January 1, 2026**. Bronze plans have the highest deductibles and lowest premiums among the four categories (or metal levels) of individual plans. Catastrophic plans have lower premiums than bronze plans, but they also have very high deductibles. Notice 2026-5 provides that an employer-sponsored health reimbursement arrangement (HRA), such as an individual coverage HRA (ICHRA) or qualified small employer HRA (QSEHRA), can be used to purchase



individual coverage under a bronze or catastrophic plan without affecting the plan's status as an HSA-compatible HDHP. However, as a general rule, an HRA (including an ICHRA) is permitted to reimburse only premiums for the HRA to be a health plan that would not disqualify an employee from being an HSA-eligible individual.