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Top 10 health, fringe and leave benefit compliance and policy issues in 2026

Law & Policy Group | GRIST

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Introduction: Health, fringe and leave benefit compliance and policy issues in 2026

Employers have greater compliance uncertainty stemming from the Trump administration's aggressive use of executive and regulatory authority, litigation and legislative activity. Pressure is also coming from a fast-approaching Jan. 1, 2026, effective date for many health and fringe benefit reforms enacted earlier this year in the One Big Beautiful Bill Act (OBBBA, Pub. L No. 119-21.). To help employers chart a course forward, this GRIST summarizes the relevant year-end 2025 and 2026 compliance and policy developments expected to affect health and fringe benefit plans and leave programs and suggests action steps for employers. Topics covered include the following:

- **Congressional outlook.** The July enactment of much of Republicans' policy agenda in the OBBBA, continuing partisan strife over the government shutdown and the looming year-end expiration of the expanded and enhanced Affordable Care Act (ACA) marketplace subsidies are contributing to the unpredictability of the moment. It remains to be seen if lawmakers can advance employer-backed bipartisan proposals that include pharmacy benefit manager (PBM) reforms, healthcare pricing transparency, restraints on drug price increases and new provider billing rules (for example, "site-neutral" policies). Any deal to end the shutdown is expected to involve a fix for the expiring ACA subsidies and may also include some of these bipartisan reforms, especially those that raise revenue. Unfinished legislative business this year will roll over to 2026, but the congressional calendar will be tight as lawmakers eye the November midterm elections.
- **Regulatory outlook.** A flurry of executive orders (EOs) and policy directives and an emphasis on deregulation mark a significant reshaping — and reversal, in some cases — of federal healthcare policy. Legal challenges to the administration, the ambiguity of some EOs and policy directives and the sheer volume of policy pronouncements from the president will make it critical for employers to keep a close eye on developments. In addition to issuing guidance on numerous OBBBA provisions effective in 2026, regulators are working to put the president's EOs and policy directives into effect. Those orders and the regulatory agenda feature issues such as PBM reform and broader price transparency, prescription drug costs, wellness and preventive services, electronic health plan disclosures, emerging uses of artificial intelligence (AI) in healthcare and ERISA fiduciary duties for health plan sponsors. Staff cuts and funding constraints may hinder regulatory action.
- **Litigation outlook.** Active litigation continues on several key health policy issues, including challenges to Trump administration actions, surprise billing, the ACA preventive services mandate, IRS enforcement of the ACA's employer shared-responsibility (ESR) provision, mental health parity rules, ERISA fiduciary issues for health plan sponsors, abortion-related services, gender-affirming care and ERISA preemption of state benefit laws, especially those affecting prescription drug benefits and PBM practices.

- **State outlook.** All but four state legislatures will be in session next year. Employers should be mindful of the increasing number of state laws affecting benefit design, especially those limiting prescription drug programs and PBM activities and imposing paid leave requirements. In addition, uncertainty around vaccine coverage exists as some states are likely to continue issuing guidelines that contradict HHS recommendations, which are currently in a state of flux.
- **Top 10 2026 health and leave benefit planning.** This list highlights 10 top compliance-related priorities for planning 2026 health, leave and fringe benefits and recommends general actions for each item.

Congressional outlook

Passage of the OBBBA in July by the Republican-led Congress, which delivered much of the party's agenda and several key wins for employer health plan sponsors — including preserving the tax-favored treatment of employer-provided healthcare coverage — was nonetheless difficult. Even under the budget "reconciliation" process that allowed the legislation to pass the Senate by a simple majority instead of the usual 60-vote threshold, Republicans' razor-thin majority allowed for almost no defections as the bill squeaked through.

Expiring ACA subsidies loom large

Republican interest earlier this year in moving a second party-line reconciliation measure, which would likely be even more difficult, has waned. But advancing legislation under "normal order" that requires 60 votes and thus some support from Senate Democrats is proving to be a major challenge, as evidenced by the government shutdown driven mainly by the partisan standoff over whether/how to extend the enhanced ACA subsidies that expire at year end. Although key lawmakers in both parties would like to pass a bipartisan healthcare package this year that may include employer-backed bipartisan policies contained in a failed December 2024 government spending bill, the fraught political environment makes the outlook uncertain.

Democrats, already feeling burned by the partisan reconciliation OBBBA process that included deep cuts to Medicaid spending and some ACA reforms expected to increase the number of uninsured, have demanded that Republicans negotiate on extending the enhanced subsidies as a condition for ending the shutdown. While some Republicans support an extension of current subsidies, and some conservative members staunchly oppose any extension, still others are open to extending them if major changes are made. Ideas under discussion include reinstating an income cap above which individuals could not receive subsidies, requiring some level of cost-sharing for all enrollees and further tightening sign-up procedures.

Since the expanded/enhanced ACA marketplace subsidies were put in place during the coronavirus pandemic, enrollment in marketplace plans has more than doubled from about 11 to over 24 million people, with the vast majority receiving the expanded/enhanced subsidies, according to the health policy research group KFF.

Projections by the non-partisan Congressional Budget Office (CBO) expect more than four million individuals to lose marketplace coverage over the next 10 years if the expanded/enhanced ACA subsidies expire. Provisions in the OBBBA that will shorten ACA marketplace

enrollment periods in 2027, eliminate auto-reenrollment for certain individuals receiving subsidies and end the monthly low-income special enrollment periods are likewise expected to dampen enrollment.

If Congress allows the expanded/enhanced ACA subsidies to expire or substantially pares them back for 2026, there could be ramifications for employer health plan sponsors. Employer plans may become more affordable and valuable in the eyes of current and potential employees and providers may attempt to make up lost revenue by charging higher rates to employer-sponsored plans.

PBM, transparency, provider billing reforms may be in play

As the government shutdown continues as of this writing, any congressional vote on extending the ACA subsidies in some form is not likely to happen until late this year, possibly as part of an end-of-year government funding measure. While the legislative path forward is unclear, a year-end bill could also be a vehicle for bipartisan priorities that raise offsetting revenue — like PBM reforms, site-neutral provider payment requirements, healthcare price transparency and curbs on anti-competitive provider contracts.

Bipartisan bills addressing these and other issues have passed committees in the House and Senate in recent years but have not cleared the finish line, partly due to external factors. A PBM overhaul that would have required regular PBM reports to employers detailing their direct and indirect compensation and providing extensive data on employers' prescription drug spending was part of a bipartisan spending bill that nearly passed in December 2024, but that was derailed by then President-elect Trump and his allies over broader concerns about the cost of the overall package.

Additional PBM reforms that could be in the mix for employer plans and/or public programs would delink list drug prices and PBM compensation; ban PBMs from engaging in "spread pricing" (i.e., charging a plan sponsor or insurer more than the amount reimbursed to the pharmacy dispensing the drug); and require PBMs to pass through all rebates, fees and discounts received from drug manufacturers directly to health plans.

Speeding generics to market and capping out-of-pocket costs for insulin in employer plans (similar to what has already been done for Medicare) are other bipartisan priorities that could make the cut.

Other potential add-ons include legislation to codify and strengthen current price transparency rules for health plans and hospitals and require new price transparency for services like diagnostic lab tests, imaging and ambulatory surgical centers owned by hospitals.

Democrats and Republicans have also eyed aligning Medicare payments for outpatient services across care settings (e.g., a hospital outpatient department or a freestanding physician office), to control costs and raise revenue. Plan sponsor groups hope lawmakers will extend the policy to the commercial market. Legislation under discussion would, for example, require each off-campus hospital outpatient department to include a unique provider identifier on payment claims to help Medicare and employers determine whether charges are appropriate.

Another possible bipartisan proposal would strengthen the No Surprises Act's (NSA) (Pub. L. No. 116-260) gag clause prohibition to ensure that employer plan sponsors are not

contractually restricted from obtaining their plans' cost or quality-of-care data from service providers. Other proposals would expand transparency and encourage more provider competition by barring anticompetitive contract provisions that prevent plans from directing employees to higher-value, lower-cost providers.

Negotiations on any year-end healthcare package would likely see Republicans also push for new health savings account (HSA) enhancements and codification of first-term Trump era rules that created individual-coverage health reimbursement arrangements (ICHRAs) and expanded association health plans (since rolled back by courts and the Biden administration).

After years of work on these bipartisan proposals, key lawmakers will be looking for opportunities to move them forward this year, but the outlook is uncertain in a legislative environment where mutual trust between Republicans and Democrats is at low ebb. Their fate this year may be determined by how Congress addresses the expiring ACA subsidies, as a compromise on that issue could pave the way for some of these longtime agenda items.

Provisions in a year-end healthcare package would likely defer many effective dates to 2027 or later, though some requirements could take effect next year.

Healthcare legislation that does not cross the finish line in 2025 will roll forward into the second session of the 119th Congress next year without having to be reintroduced. Although all eyes next year will be on November's midterm elections and mean a smaller legislative calendar, lawmakers may be motivated to showcase legislative accomplishments to their constituents and push for passage of bills that address pocketbook issues like healthcare.

Control of both chambers will be in play in the 2026 midterms, and the results could dramatically reshape congressional healthcare priorities after 2026.

Regulatory outlook

Since taking office in January, President Trump has moved quickly to outline his healthcare agenda, largely through numerous EOs, policy directives, deregulatory actions and a sweeping reorganization of federal health agencies. While there have been high-level expressions of policy priorities, specific regulatory actions are still taking shape with several political appointees just now being confirmed by the Senate. Staff reductions and budget cuts across many agencies may slow the pace of new rules, however.

The administration characterizes its agenda as focused on lowering drug prices; expanding healthcare price transparency; targeting "waste, fraud and abuse" in federal health programs; addressing chronic disease and prevention through the new "Make America Healthy Again" (MAHA) Commission; and reducing regulation and broadening consumer choice.

EOs and policy directives to date have laid out broad strategies aimed at, among other things:

- Lowering prescription drug prices, speeding regulatory approval of generic drugs and biosimilars and increasing PBM transparency, including disclosures of direct and indirect compensation to health plan fiduciaries
- Improving (and potentially expanding) existing hospital and health plan price transparency requirements

- Expanding access to fertility treatment, including in-vitro fertilization
- Prohibiting gender-affirming care for children aged 18 or younger
- Banning use of federal funds for elective abortions

Agencies are working on advancing related rulemaking on these issues, with more expected. Whether they can meet the deadlines for new rules specified in many of these EOs and policy directives is uncertain, as is what rules might ultimately take effect.

Regulators are also working on guidance to implement the OBBBA's health and fringe benefit provisions effective in 2026. These include the interplay of HSAs and direct primary care service arrangements (DPCSAs), the retroactive reinstatement and permanence of HSA-qualifying high-deductible health plans' (HDHPs') ability to cover (and otherwise HSA-eligible individuals to receive) telehealth and other remote care services on a pre- or no-deductible basis. The law also sets up new tax-preferred "Trump accounts" for children. It is unclear whether we will see guidance on the expansion of employer paid family and medical leave tax credits under § 45S of the Internal Revenue Code. (See *State-mandated paid leave and other state law trends* section.)

Other regulatory projects identified in the Spring 2025 Unified Agenda of Regulatory and Deregulatory Actions may bring new proposed and/or final rules in these areas:

- Default electronic delivery of health and welfare plan disclosures under ERISA
- PBM fee disclosures
- Healthcare and health plan transparency (e.g., air ambulance services reporting, agent/broker disclosures, provider enforcement, advanced explanations of benefits and amendment of 2020 Transparency in Coverage rules, etc.)
- No Surprises Act's independent dispute resolution process
- HIPAA Security rule, particularly cybersecurity
- Minimum essential coverage (MEC) reporting and employer shared-responsibility (ESR)
- Application of ESR and self-funded health plan nondiscrimination rules to individual-coverage health reimbursement arrangements
- Gender identity and dysphoria nondiscrimination under section 1557
- Tax treatment of funded welfare benefit plans under IRC §4976

The Trump administration did not include in its regulatory agenda published in September a Biden administration rule that would have addressed whether drug manufacturer cost assistance (e.g., coupons) must count towards (or can be excluded from) a plan member's annual cost-sharing limits. It still may be addressed, possibly in the next iteration of the Notice of Benefit and Payment Parameters, which should be issued later this year.

The administration is also rolling back several Biden-era initiatives, including expanded special enrollment periods, funding for ACA marketplace plans and restrictions on the duration of short-term limited duration insurance. It has also announced a nonenforcement

policy for the 2024 final mental health parity regulations pending the outcome of a legal challenge to the rules.

So far, we do not have details on the regulatory priorities of the Equal Employment Opportunity Commission (EEOC). However, with the EEOC now having a quorum following the recent confirmation of a second Republican commissioner, it is expected to advance Trump administration priorities, including challenging employers' diversity, equity and inclusion programs and scaling back protections for LGBTQ+ individuals.

Employers also need to monitor administration actions regarding tariffs. While key elements of the president's proposals are the subject of litigation, experts warn that tariffs on healthcare industry products and prescription drugs could increase costs, disrupt the medical supply chain, hamper pharmaceutical innovation and exacerbate ongoing shortages of certain medical equipment and products.

Litigation outlook

A monumental tariff case is pending before the US Supreme Court. Oral argument is slated for Nov. 5. The decision will have major implications for pharmaceuticals and other aspects of the healthcare ecosystem. Another case seeks US Supreme Court review of the parameters of ERISA fiduciary liability.

We are likely to see a sharp decline in the use of nationwide injunctions, as a result of the decision in *Trump v. CASA*. The degree of fiduciary responsibility will continue to warrant close attention, particularly related to three large employers facing legal challenges from participants in federal district court. (See *ERISA fiduciary issues* section.)

Behavioral health litigation should remain in the spotlight as participants continue to contest actions by insurers and third-party administrators on mental health parity grounds. (See *Mental health parity* section.)

Several lower court cases will likely progress, testing the limits of state PBM laws in light of ERISA preemption. (See *Prescription Drugs* section.)

Applicable large employers (ALEs) should also keep an eye on the *Faulk Company v. Kennedy* case, currently on appeal to the 5th Circuit. The District Court rejected the IRS Letter 226-J process used to assess tax penalties against ALEs for ESR violations. (See *Other ongoing ACA concerns* section.)

Finally, litigation on the validity of certain ACA-mandated preventive services (*Kennedy v. Braidwood Management*) continues at the lower courts, even after the US Supreme Court upheld the US Preventive Services Task Force recommendations as being constitutional. (See *ACA preventive services* section.)

State outlook

At the state level, employers can expect laws on paid leave, prescription drug pricing and PBM restrictions, telehealth access and health insurance coverage mandates. Also monitor state actions related to health plan coverage of vaccines.

Top 10 2026 health and leave benefit planning

The following list highlights 10 top compliance-related priorities for planning 2026 health, leave and fringe benefits and recommends general actions for each item. The links below take readers to more detailed information. The *Appendix* section provides resources related to each compliance topic.

1. **Prescription drugs (Rx).** Watch for potential PBM legislation, regulations, legal actions and other guidance in the coming months as state and federal lawmakers and agencies continue to consider PBM restrictions and prohibitions as a way to curb Rx costs. Address how any enacted Rx laws and regulations affect plan design with PBMs, actuaries and other vendors. Note Congressional hearings on PBM activities. Stay alert to substantive federal agency actions involving, in particular, EOs, vaccine access, the unified regulatory agenda and MAHA activity. Pay attention to tariffs. Follow state legislative activity and related litigation affecting plan design and costs for fully insured and self-funded ERISA plans. Track state bills restricting or eliminating customary PBM activities and assess efforts, which may result in erosion of ERISA preemption doctrine. Review PBM contracts and processes. Monitor ongoing Federal Trade Commission activities focused on PBMs, particularly the complaint about insulin pricing. Scrutinize PBM and Rx consultant compensation, given greater ERISA fiduciary sensitivity. Keep a constant eye on GLP-1 developments. Don't forget about the possibility of further triagency guidance on drug manufacturers' financial assistance and plan cost sharing. Look for federal guidance on — and state laws banning — copay accumulators and the possible expansion of federal policy on copay maximizers. Update RxDC processes as needed. Keep up on Medicare Rx price negotiations with manufacturers and any downstream financial impact on group health plan coverage.

2. **ERISA fiduciary issues.** Assess with legal counsel fiduciary roles, responsibilities, delegations and processes for ERISA benefit plans. Prudently select and regularly monitor service providers, ensuring they mitigate cybersecurity risks, don't have contractual gag clauses and make plan data available upon request when required, among other responsibilities. Regularly review compensation arrangements and service agreements with brokers, consultants and service providers. Use transparency data, claims data and quality metrics to analyze plan costs and consider effects on participants. Monitor litigation against group health plans and their service providers, including cases alleging failure to properly describe plan options, prescription drug prices, pharmaceutical rebates and service provider fees (including "shared savings"). Ensure claims and appeals processes are compliant, focusing on the use of AI and other automated processes at the center of some fiduciary litigations. Update plan documents and communications as needed. Comply in a timely manner with reporting and disclosure requirements and develop a response plan for document requests. Review other applicable fiduciary matters, such as those related to plan assets and bonding. Confirm that fiduciary insurance coverage is appropriate. Watch for Department of Labor (DOL) enforcement priorities under the Trump administration as they begin to take shape.

3. **Group health plan transparency.** Consider that group health plan transparency has bipartisan support and holds great promise for both consumers and group health plan sponsors in better understanding healthcare pricing and fees, but that comes with many compliance requirements that remain challenging, with new requirements in the pipeline. Continue complying with the final Transparency in Coverage (TiC) rule (including posting

machine-readable files (MRFs) for in-network and out-of-network allowed amounts and providing a self-service transparency tool for all covered items and services), and watch for related new guidance (for example, implementing the MRF requirement for prescription drugs). Confirm that vendors' data is accurate, complete and updated as required and that the MRFs and tools meet other requirements, including compliance with Schema 2.0 for MRFs by Feb. 2, 2026. Ensure plan-related contracts have no gag clauses on price or quality information and submit the gag-clause attestation by Dec. 31. Ensure timely submission of the required prescription drug data collection (RxDC) reports. (See *Prescription drugs* section.) Continue to comply with additional transparency requirements in the Consolidated Appropriations Act of 2021 (2021 CAA) and look for more guidance on several 2021 CAA transparency topics in 2026. Review proposed ERISA §408(b)(2) rules when issued. Review group health plan and hospital transparency data as well as third-party analyses of previously unavailable pricing information and consider how to use such information. Work with vendors on compliance with transparency requirements and make sure that they will provide the necessary assistance to employers to help them comply with those requirements. Watch for new transparency legislation.

4. **Data privacy and security.** Regularly review compliance with HIPAA security requirements and DOL cybersecurity measures for ERISA plans. Use compliance tools from regulators to identify and address security vulnerabilities. Evaluate vendors, new technologies and apps to determine whether HIPAA or other data protection and privacy laws apply and assess compliance. Pay special attention to mobile technologies and tracking technologies across all platforms. Assess how federal policy facilitating the exchange of health data may affect data privacy and security priorities of group health plans. Review HIPAA privacy policies and procedures for any revisions needed following the vacatur of the 2024 HIPAA privacy rule.

5. **Artificial intelligence (AI) in benefits.** Become familiar with — if not already — the use of AI in healthcare and employee benefits. Monitor the federal policy shift regarding the use of AI in healthcare and employment. Consider implications for design and administration of employee benefits, including group health plans and the effects on plan participants and beneficiaries. Consider setting guardrails encouraging the responsible use of AI internally and by employee benefit plan vendors, given the risks and opportunities of this fast-evolving technology. Remember that ERISA plan fiduciaries must act prudently in selecting and monitoring service providers, including with respect to their use of AI. Watch for federal legislation, state regulation and litigation to unfold, and apply any new requirements or best practices to plans.

6. **Health savings account (HSA), health reimbursement arrangement (HRA) and health and dependent care flexible spending arrangement (FSA) developments.** Consider adopting provisions to reinstate and/or permanently allow HSA-qualifying HDHPs to cover telehealth and other remote care services on a pre- or no-deductible basis. Study whether to add HSA-compatible direct primary care service arrangements (DPCSAs) into a benefit design strategy and monitor IRS guidance for clarification on various unresolved issues related to DPCSAs. Update HSA-qualifying HDHPs, HSAs, excepted-benefit HRAs (EBHRAs) and health FSAs for 2026 indexed dollar limits. Identify pre- or no-deductible health benefits, programs or point solutions that could jeopardize an individual's eligibility to make or receive HSA contributions and confirm strategy. Review IRS guidance that expands the list of preventive care benefits that HSA-

qualifying HDHPs may cover on a pre- or no-deductible basis. Evaluate whether to offer fertility benefits through an HRA — either an integrated HRA or an EBHRA (limited to $2,200 for 2026). Determine whether to raise the annual income exclusion for dependent care assistance programs (DCAPs), such as dependent care FSAs (DCFSAs), and monitor impact on nondiscrimination testing. Monitor legislation that would provide safeguards for pre-deductible coverage for chronic disease treatments under HSA-qualifying HDHPs. Follow pending proposed IRS regulations on individual-coverage HRAs that could influence benefit strategy and compliance efforts. Review future IRS guidance on the definition of a tax dependent for any impact on account-based health plans.

7. **ACA preventive services.** Update a nongrandfathered group health plan's preventive services covered without cost sharing for the latest ACA guidance and any new or revised recommendations from the US Preventive Services Task Force (USPSTF), the Health Resources & Services Administration (HRSA) and the Advisory Committee on Immunization Practices (ACIP). Review guidance addressing coverage of pre-exposure prophylaxis (PrEP) HIV medications and confirm that your third-party administrator (TPA) and/or PBMs have updated their claims processing systems to comply. Monitor ongoing litigation and administrative/regulatory actions that might modify or rescind some of the ACA-mandated preventive services and consider whether the group health plan might continue no-cost coverage of particular preventive services if current recommendations change. Update official plan documents, summary plan descriptions (SPDs), summaries of benefits and coverage (SBCs) and other materials as needed.

8. **Other ongoing ACA concerns.** Review planned 2026 benefits against employer shared-responsibility (ESR) standards, including minimum essential coverage (MEC) for ACA full-time employees and the affordability and minimum value of health coverage. Ensure the adequacy of ESR and MEC recordkeeping and reporting and consider revisions to take advantage of reporting relief legislation. Review plan design for compliance with ACA benefit mandates and market reforms. Consider whether to modify or implement benefits or update communications based on recent developments related to noncoordinated excepted benefits. Continue to monitor the impact of ACA Section 1557's prohibition on discrimination on the basis of race, color, national origin, sex, age or disability. Continue to calculate and pay the Patient-Centered Outcomes Research Institute (PCORI) fee for self-funded group health plans, including certain health reimbursement arrangements and retiree-only plans. Prepare for continued medical loss ratio (MLR) rebates if sponsoring a fully insured group health plan. Continue to provide SBCs and ACA claims and appeals notices in a culturally and linguistically appropriate manner, consistent with updated guidance. Monitor legislation and regulations expected to reduce ACA marketplace and Medicaid enrollment and consider potential impact on employer-sponsored group health plans.

9. **Mental health parity.** Continue to comply with the Mental Health Parity and Addiction Equity Act (MHPAEA) by ensuring that no financial or treatment limits on mental health/substance use disorder (MH/SUD) benefits apply only to MH/SUD benefits or are more restrictive than those applied to medical/surgical (M/S) benefits. Maintain a written analysis of all nonquantitative treatment limits (NQTLs) that is ready to disclose upon request to federal regulators, states or plan enrollees. Watch for developments related to the Trump administration's nonenforcement of new requirements in the 2024 final rule. Require that vendors provide adequate assistance with MHPAEA compliance. Consider

parity requirements when improving a plan's M/S benefits. Monitor parity and behavioral health coverage litigation. Watch for changes to MHPAEA enforcement, as well as additional guidance or legislation.

10. **State-mandated paid leave and other state law trends.** Look for bills affecting paid leave, PBMs, fully insured plan coverage mandates and telehealth access as 46 states (except Montana, Nevada, North Dakota and Texas) convene their regular sessions in 2026. Do not overlook ongoing regulatory activity, particularly in the three states where paid family and medical leave (PFML) programs will be in full effect in 2026: Delaware, Maine and Minnesota. Examine how state PFML, paid sick and safe leave (PSSL) and other paid and unpaid leave mandates fit with existing employer programs, and assemble the puzzle pieces into a rational leave mosaic. Keep an eye out for renewed debate on a federal PFML program, given heightened interest and several pending bills. Review changes to the § 45S employer tax credit for PFML benefits as a result of OBBBA. Monitor telehealth developments, particularly related to behavioral health. Discuss with insurers how new state coverage mandates affect fully insured plans and consider whether to mirror those mandates for self-funded coverage. Be aware of access issues related to abortion and gender-affirming care. Continue health-coverage reporting where required. Maintain compliance with state laws related to group health plan assessments (and related reporting). Pay attention to PBM developments and ERISA preemption issues in the courts and state legislatures.

Section 1

Prescription drugs (Rx)

Action

Watch for potential pharmacy benefit manager (PBM) legislation, regulations, legal actions and other guidance in the coming months as state and federal lawmakers and agencies continue to consider PBM restrictions and prohibitions as a way to curb Rx costs. Address how any enacted Rx laws and regulations affect plan design with PBMs, actuaries and other vendors. Note Congressional hearings on PBM activities. Stay alert to substantive federal agency actions involving, in particular, executive orders (EOs), vaccine access, the unified regulatory agenda and Make America Healthy Again (MAHA) activity. Pay attention to tariffs. Follow state legislative activity and related litigation affecting plan design and costs for fully insured and self-funded ERISA plans. Track state bills restricting or eliminating customary PBM activities and assess efforts, which may result in erosion of ERISA preemption doctrine. Review PBM contracts and processes. Monitor ongoing Federal Trade Commission (FTC) activities focused on PBMs, particularly the complaint about insulin pricing. Scrutinize PBM and Rx consultant compensation, given greater ERISA fiduciary sensitivity. Keep a constant eye on GLP-1 developments. Don't forget about the possibility of further triagency guidance on drug manufacturers' financial assistance and plan cost sharing. Look for federal guidance on — and state laws banning — copay accumulators and the possible expansion of federal policy on copay maximizers. Update RxDC processes as needed. Keep up on Medicare Rx price negotiations with manufacturers and any downstream financial impact on group health plan coverage.

Specific steps

Watch for potential federal PBM legislation in the coming months as part of a healthcare package.

- **Monitor legislation during the 2025 lame-duck session.** While Congress has been mostly quiet on pushing forward meaningful PBM reform this year, the possibility exists that one or more proposals may make their way into a year-end legislative package, given bipartisan support. Specific changes may include prohibitions on spread pricing and PBM compensation based on a drug price, 100% rebate pass-through to group health plans and increased transparency and disclosures. In the prior session of Congress, the Lower Costs, More Transparency Act (HB 5378) received much ballyhoo but ultimately lost steam. The PBM provisions in that bill are largely in two bills this session: the PBM Transparency Act (S 526) and Prescription Pricing for the People Act (S 527). As with insulin cost-sharing caps in the Inflation Reduction Act (Pub. L. No. 117-169) (IRA), which became law in 2022, these reforms may be limited to Medicare plans, as seen in the PBM Reform Act (HR 4317). (See *Congressional outlook* section.)
- **Pay attention to Congressional developments in 2026.** The above reforms may make their way into an omnibus healthcare package next year, especially if structured in a way to reduce the federal budget. In addition, we may see renewed interest in limiting or eliminating so-called "patent thickets," which some manufacturers use to delay entry for

competitors related to a certain drug. The ETHIC Act (HR 3269/S 2276) is an example of such legislation.

- **Focus on how any enacted Rx laws affect plan design with PBMs, actuaries and other vendors.** The effective dates of these laws are likely to vary, depending on the type of change and the plan year.
- **Keep track of Congressional hearings on PBM activities.** This year saw hearings in the Senate Judiciary and Finance committees and House Health subcommittee. Expect more of the same in 2026, which may create momentum.

Stay alert to substantive federal agency actions.

- **EOs.** Since January, President Trump has issued three major EOs, directing agencies to reduce drug costs. EO 14273 was an early strategic dictate to pursue changes in Medicare and Medicaid pricing policy, FDA approval pathways and oversight of cost-driving entities, including PBMs. See the fact sheet. Currently, agencies are involved in rulemaking, including guidance under ERISA § 408(b)(2) to achieve the EO's goal to "improve employer health plan fiduciary transparency into the direct and indirect compensation received by pharmacy benefit managers." EO 14297 builds on an idea espoused during the first Trump administration, establishing price targets beyond Medicare based on the lowest price in any country in the Organisation for Economic Co-operation and Development (OECD) with a gross domestic product per capita of at least 60% of the US. This concept is often referred to as "most-favored-nation" pricing. See the fact sheet. EO 14336, another holdover from 2020, aims to decrease reliance on foreign sources for essential medicines through mandated stockpiling. See the fact sheet. While some of the non-binding deadlines have already passed, they indicate the general priorities of the Executive Branch during President Trump's second term. Of course, more EOs are possible, with indications that PBMs and drug manufacturers may be future targets.
- **Vaccine access.** Several HHS agencies have applied greater scrutiny into the efficacy and safety of vaccines, including the COVID-19 shot. Agencies to watch include the FDA, CDC and ACIP. In particular, ACIP's recommendations are used to determine what constitutes preventive health services under the Affordable Care Act (ACA) coverage mandate. In addition, the US Supreme Court's *Kennedy v. Braidwood* decision acknowledged that members of the US Preventive Services Task Force (USPSTF) — whose recommendations also feed into the ACA preventive health services mandate — are appointed and removable at the will of the HHS secretary. USPSTF actions, state health department announcements (for example, the West Coast Health Alliance of California, Hawaii, Oregon and Washington) and insurer decisions (for example, the America's Health Insurance Plans statement) also bear monitoring. Plan sponsors will need to decide what, if any, changes they want to make to existing vaccine coverage, based on guidance from federal and state authorities and other entities. In October, the CDC adopted ACIP's individual-based decision-making approach for the COVID-19 and varicella (chickenpox) immunizations. (See *ACA preventive services* section.)
- **Direct-to-consumer (DTC) approach.** The Trump administration announced a DTC initiative through a new website called TrumpRx. Currently, details are unclear as to the timing and impact of this new Rx access point on employer-sponsored coverage. Developments bear watching, especially given the announcement that fertility

medications will be available through the website. (See *Health savings account (HSA), health reimbursement arrangement (HRA) and health and dependent care flexible spending arrangement (FSAs) developments* and *Other ongoing ACA concerns* sections.)

- **Unified regulatory agenda.** The most recently published unified agenda provides insight into what 2026 will look like. Particularly, DOL plans to issue a proposed rule under ERISA § 408(b)(2) (in response to EO 14273: Improving Transparency into PBM Fee Disclosure). In June, the triagencies sought input on revising the Rx machine-readable files requirements under the TiC regulations, with plans to issue a proposed rule. (See *Group Health Plan Transparency* section.) Depending on what changes, plan sponsors may be able to make greater use of the data and make better decisions related to Rx coverage in the next few years. Both sets of proposed rules are currently pending at the Office of Management and Budget, which updates the agenda semi-annually.
- **MAHA reports.** The Trump administrative is pursuing a series of health priorities under the general umbrella of "Make America Healthy Again." In September, HHS released a report called "Make Our Children Healthy Again," which outlined the administration's strategy with over 120 priorities to address childhood chronic disease. Expect more reports and related actions in the coming year. Rx and vaccine issues will likely be addressed.

Pay attention to tariffs. President Trump's tariff actions could have a significant impact on the pharmaceutical industry, in terms of access and cost. The primary authority is based on presidential powers under the International Emergency Economic Powers Act (IEEPA). So far most of the lower court decisions have struck down the IEEPA tariffs. The case of *Learning Resources v. Trump* (consolidated with *Trump v. V.O.S. Selections*) is pending before the US Supreme Court. Oral argument is set for Nov. 5. A decision should follow a few months thereafter. (See *Litigation outlook* section.) In addition, the Trump administration has shown a willingness to offer relief from tariffs to drug manufacturers that make pricing concessions.

Follow state legislative activity and related litigation affecting plan design and costs for fully insured and self-funded ERISA plans.

- **Track state bills restricting or eliminating customary PBM activities.** PBM reform is a bipartisan issue. Bills target typical practices like spread pricing, network design, mail-order and specialty pharmacy steering, fiduciary status, drug price delinking from fees and other price-saving programs for fully insured and self-funded plans. PBM transparency and disclosures are also popular. In 2025, many states — Alabama, California, Illinois, Iowa, Mississippi, Montana and North Carolina — passed significant restrictions on PBM practices. Plans may have to make plan design changes to comply in some states.
- **Assess state efforts to erode ERISA preemption.** While the *Mulready* decision is now a binding precedent in the 10th Circuit, it may influence legislation and litigation in other states. Two examples are the *McKee Foods v. BFP* decision (striking down parts of a Tennessee PBM statute) and the *Iowa Association of Business and Industry* preliminary injunction (stopping an Iowa PBM law from taking effect). Both actions are grounded in ERISA preemption concerns. Self-funded plans should evaluate any new law's impact with their PBMs and legal counsel.

- **Review PBM contracts and processes.** Examine PBMs' plans for adherence with applicable state laws and regulations, particularly those enacted in the past year. Periodic check-ins with PBMs should focus on the impact to Rx access and overall plan costs. Plan sponsors can use data from RxDC reporting for more detailed discussions with PBMs about their compensation, both as a business and fiduciary issue.

Keep an eye out for ongoing FTC activities. In September 2024, FTC filed an administrative complaint against major PBMs over insulin pricing; that proceeding continues. In January, a second FTC interim staff report concluded that the Big 3 PBMs significantly marked up specialty generic drugs at their affiliated pharmacies. These drugs treat serious health conditions, like cancer, multiple sclerosis, HIV and pulmonary hypertension. When a final decision is issued, the repercussions on the industry should extend beyond the PBMs mentioned in the report. Also, a July listening session — hosted by the FTC, HHS and the Departments of Justice and Commerce — focused on lowering drug prices through competition. That could yield further investigations and enforcement activity.

- **Discuss with PBMs.** Check in with your PBM about how the FTC's actions might potentially impact plan design and costs, including PBM reimbursement practices and network design.
- **Monitor similar state activity.** Stay informed about state investigations similar to the FTC inquiry, particularly in Arkansas and Florida where Rx data collection efforts appear to be in full swing.

Scrutinize PBM and Rx consultant compensation, given greater ERISA fiduciary sensitivity. Group health plans' fiduciary risk seems to be at an all-time high, with heightened concern over Rx costs and PBM fees. ERISA requires fiduciaries to act "solely in the interest of the participants and beneficiaries." This duty includes regular monitoring of service providers and paying them reasonable compensation. In addition, depending on what services a PBM or other Rx consultant provides, Section 202 of the No Surprises Act (NSA) portion of the 2021 Consolidated Appropriations Act (Pub. L. No. 116-260) could apply. This provision requires disclosure of direct and indirect compensation by certain service providers. New ERISA § 408(b)(2) regulations likely will impose additional disclosure requirements.

Keep a constant eye on GLP-1 developments. Employers continue to grapple with coverage of GLP-1s. While most plans cover these drugs (including Wegovy and Ozempic) for diabetes, the main issue is to what extent to cover them for weight loss. Last year, the FDA approved Wegovy to treat serious cardiovascular events like heart attacks and strokes. Generic versions still appear to be years away. So far, we have seen only a few states (most recently, Colorado) mandate their use to treat obesity in fully insured plans. A GLP-1-specific HRA may be a viable solution for some employers to consider next year.

Do not forget about the possibility of further triagency guidance on drug manufacturers' financial assistance and plan cost sharing. Two types of programs are in view. First, a typical copay accumulator program enables a plan to disregard third-party financial assistance rather than apply it to the deductible and out-of-pocket maximum (OOPM). Applying this assistance to the deductible creates a potential issue for HSA-qualifying high-deductible health plans. Second, a typical copay maximizer program has a similar cost-saving goal, treating some high-cost drugs as nonessential health benefits (non-EHBs) under the ACA. (The ACA's EHB rules specify the number of drugs required in each

category and class.) As a result, these non-EHB drugs are not subject to the OOPM and can have an annual or lifetime limit.

- **Look for possible HHS guidance on copay accumulators.** These programs are still permissible under federal law. In a now settled lawsuit (*HIV and Hepatitis Policy Inst. v. HHS*, No. 22-2604), HHS has provided nonenforcement relief with no stated expiration date.
- **Watch for state laws banning copay accumulators.** This year, Connecticut and Indiana joined other states in enacting legislation to require fully insured plans to apply third-party financial assistance toward cost sharing. These laws typically do not apply to self-funded ERISA plans.
- **Be mindful of the possible expansion of HHS policy on copay maximizers.** Under the final 2025 HHS Notice of Benefit and Payment Parameters (NBPP), fully insured individual and small-group plans cannot use copay maximizers (i.e., treat drugs as non-EHBs) starting in 2026. However, this prohibition exempts fully insured large-group plans and self-funded ERISA plans. ACA implementation FAQ Part 66 expressed an intent "to propose rulemaking that would align the standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans." The final 2026 Notice of Benefit and Payment Parameters (NBPP) did not address this issue. Publication of the proposed 2027 NBPP is set for November 2025. We may see clarification then.

Update RxDC processes as needed. June 1, 2026, is the next reporting deadline under NSA Section 204. CMS did not change the RxDC process in 2025. We don't expect any for 2026. In fact, CMS hosted no Q&A webinars this year. Plan sponsors should continue efforts to gain access to their plan-level Rx data from PBMs if they have the means to analyze the data and take action.

- **Review which entities will submit data.** The Health Insurance Oversight System (requiring login credentials) remains the reporting mechanism. Ensure each reporting entity timely complies, especially if more than one entity will be reporting or vendors have changed.
- **Look for updated instructions (last updated in January 2025 for the 2024 reference year), regulations or other guidance that may require changes.**
- **Examine insurer, third-party administrator (TPA), PBM and other vendor agreements.** Given that RxDC is now a mature obligation, agreements should address RxDC obligations and the right to obtain a copy of their plan's data submission.
- **Don't miss the next CMS report based on RxDC data.** The NSA requires HHS to produce a biannual report, based on the RxDC data. The first report — issued in November 2024 — provided only broad insights because of the lack of data quality. Expect a more robust report later next year.

Keep up on Medicare Rx price negotiations with manufacturers and any downstream financial impact on group health plan coverage.

- **Monitor CMS's Medicare Rx price negotiations.** Section 11001 of the IRA gives CMS the authority to negotiate maximum fair prices for selected Medicare Part D drugs,

starting with 10 drugs in 2026 and more in future years. The third cycle of negotiations, announced no later than Feb. 1, 2026, per recent guidance, will take effect in 2028. The first cycle, already announced, will take effect in 2026 and could be renegotiated. These price negotiations could indirectly influence costs for employer-provided coverage and will directly affect retiree health plans, Medicare Advantage plans with an Rx benefit, and employer group waiver plans (known as EGWPs).

Related resources

Section 2

ERISA fiduciary issues

Action

Assess with legal counsel fiduciary roles, responsibilities, delegations and processes for ERISA benefit plans. Prudently select and regularly monitor service providers, ensuring they mitigate cybersecurity risks, don't have contractual gag clauses and make plan data available upon request when required, among other responsibilities. Regularly review compensation arrangements and service agreements with brokers, consultants and service providers. Use transparency data, claims data and quality metrics to analyze plan costs and consider effects on participants. Monitor litigation against group health plans and their service providers, including cases alleging failure to properly describe plan options, prescription drug prices, pharmaceutical rebates and service provider fees (including "shared savings"). Ensure claims and appeals processes are compliant, focusing on the use of artificial intelligence (AI) and other automated processes at the center of some fiduciary litigations. Update plan documents and communications as needed. Timely comply with reporting and disclosure requirements and develop a response plan for document requests. Review other applicable fiduciary matters, such as those related to plan assets and bonding. Confirm that fiduciary insurance coverage is appropriate. Watch for Department of Labor (DOL) enforcement priorities under the Trump administration as they begin to take shape.

Specific steps

Assess with legal counsel fiduciary roles, responsibilities, delegations and processes for ERISA benefit plans; consider establishing a benefits committee. Pay particular attention to core fiduciary duties and avoid transactions that create a heightened risk of conflicts of interest or self-dealing.

- **Focus on core fiduciary duties:**
  - *Duty of loyalty.* Primary focus is to benefit participants and beneficiaries.
  - *Exclusive benefit rule.* Actions should focus exclusively on providing benefits and defraying reasonable plan administration expenses.
  - *Duty of care.* Conduct plan activities as a "prudent expert." Consult with other experts as needed.
  - *Plan operations in accordance with written plan documents.* Comply with plan document terms, to the extent they are consistent with ERISA.
  - *Duty to diversify plan assets to minimize risk of large losses.* This duty generally applies only to health and welfare plans with a trust or a voluntary employee beneficiary association (VEBA). The obligation does not apply when plan funds are held in the employer's general assets because of the long-standing DOL nonenforcement policy for cafeteria plans and other contributory welfare plans. The

ERISA obligation to treat funds as plan assets is triggered when participant contributions can reasonably be segregated from the employer's general assets.

- **Determine who is acting as a plan fiduciary and what each fiduciary's responsibilities are.** Every ERISA plan must have one or more *named fiduciaries* authorized to control and manage the plan's operation and administration. In addition, anyone with discretionary authority or control over the plan's management or administration may be a *functional fiduciary*.
  - Examples of persons *not acting as fiduciaries* include those engaging in ministerial activities and those acting solely on the plan sponsor's behalf in a "settlor capacity" (e.g., adopting, modifying or terminating a plan).
  - The same person may sometimes act as a fiduciary and as a settlor at other times, and those actions (e.g., setting plan contributions or premiums) should be clearly delineated.
  - Watch for DOL guidance next year on the definition of fiduciary investment advice under ERISA. Current rules finalized during the Biden administration — and on hold due to litigation — expand the scope of fiduciary investment advice and apply to retirement plans, individual retirement arrangements and health savings accounts. While most health and welfare benefits are excluded, the Biden rule extends to ERISA-covered health and welfare benefit plans with an investment component (like certain permanent life and long-term care insurance policies, as well as VEBAs). DOL expects to engage in further rulemaking.
- **Ensure any delegation of fiduciary responsibility is properly documented.** The plan document must include a procedure for a named fiduciary's delegation of responsibilities, which must be followed and documented. For example, delegation of claims and appeals administration to a third-party administrator (TPA) must be documented. Note that delegation does ***not*** end the delegating fiduciary's responsibilities — even for a benefits committee — which may still be liable as a co-fiduciary for a breach committed by the delegate.
- **Review all fiduciary processes, including recordkeeping.** All actions taken by plan fiduciaries should conform to plan documents and be properly recorded. Keep all plan records (including any performance assessments of plan service providers) for the legally required period of time (generally at least six years under ERISA). Work with legal counsel to respond to any lawsuits, investigations or inquiries (e.g. from the press) as quickly as possible.

Consider qualifications, quality of services, reasonableness of compensation and cybersecurity standards (among other factors) when selecting service providers. To ensure a meaningful comparison, give each prospective service provider complete and identical information about the plan and the services desired. Consider soliciting bids via requests for proposals (RFPs), including desired contract terms. Elicit information to assess qualifications, quality of services and reasonableness of fees that will be paid from plan assets. Keep records of this process.

- **Review and incorporate DOL best practices for selecting a service provider.** Plan fiduciaries should get information from more than one provider, including disclosures of direct and indirect compensation, and should evaluate information about the quality of the

providers' services, including the identity, experience and qualifications of professionals who will be handling the plan or providing medical services. Among other considerations, review and compare:

- The scope, adequacy and quality of provider networks
- Procedures to timely consider and resolve patient questions and complaints
- Cybersecurity measures
- Procedures to preserve the confidentiality of patient records

Regularly conduct formal reviews to monitor service providers. Ensure that service providers are performing agreed-to services. Review and incorporate DOL best practices for monitoring service providers. Modify or terminate service agreements as needed.

- **Pay special attention to direct and indirect fees paid to a provider against prevailing rates for similar services.** Check actual fees charged. If paying a provider from plan assets, ensure fees remain reasonable for the services received. This may require a market check. Consider periodic audits of claims payments and compliance with plan terms, applicable laws and regulations, as well as court decisions shaping ERISA claim standards.
- **Review service providers' qualifications and quality of services performed.** Ensure providers avoid self-dealing, conflicts of interest or other improper influence.

Regularly review compensation arrangements and service agreements with brokers, consultants and service providers. Work with legal counsel and other experts as needed to collect and review broker and consultant compensation disclosures, service provider agreements and documentation of cybersecurity measures. (See *Data privacy and security* section.)

- **Identify and understand service agreement terms related to fees (direct or indirect), and look carefully at the reasonableness of any terms, including shared-savings arrangements**. Pay special attention to pharmacy benefit manager agreements, including rebates, spread and other types of potential compensation.
- **Review service provider agreements to**:
  - Ensure there are no prohibited gag clauses and that plan data will be made available upon request.
  - Confirm assistance with meeting transparency and parity obligations. (See *Group health plan transparency* and *Mental health parity* sections.)
  - Verify allowance for ongoing monitoring (e.g., audits or market checks) and contract termination if needed.
  - Confirm the service provider agrees to follow fiduciary standards, including avoidance of self-dealing and conflicts of interest.
  - Confirm the service provider agrees to comply with claims-procedure requirements under ERISA and the Affordable Care Act (ACA), including acting as a fiduciary as needed.

- **Look for potential plan asset/prohibited-transaction concerns relating to any cross-plan offsetting provisions.** If retaining these provisions, make sure they are clearly disclosed in the plan document and summary plan description (SPD).
- **Review legal responsibilities assigned to service providers versus the plan sponsor for compliance with ACA, ERISA, HIPAA, the Mental Health Parity and Addiction Equity Act (MHPAEA) and other laws.**
- **Review indemnification provisions and liability limits.**

Use transparency data, claims data and quality metrics to assess plan operations and cost and potentially reduce litigation risk. Explore plan data as compared to industry data; evaluate companies or organizations that can validate and summarize the data. (See *Group health plan transparency* section.) Review data through the lens of recent cases about allegedly misallocated rebates, the price of drugs and service provider fees (including "shared savings").

- **Watch for excessive fee lawsuits targeting ERISA plans that may include prohibited transaction claims alongside allegations of fiduciary breach.** The US Supreme Court's unanimous ruling in *Cunningham v. Cornell Univ.* (No. 23-1007 (April 17, 2025)) will likely make it more difficult for fiduciaries in these cases to defeat a prohibited transaction allegation on a motion to dismiss. The decision sets a low bar for what plaintiffs must plead in these cases to avoid dismissal and proceed to the costly discovery phase of litigation.
- **Monitor cases where health plan fiduciaries allegedly failed to prudently manage the prescription drug benefit plan, causing the group health plan and members to overpay for benefits, including higher payments for prescription drugs, premiums and out-of-pocket costs.** Allegations include failure to conduct an open RFP and consider alternative pharmacy service providers. One case alleges a prohibited transaction for failing to pay reasonable compensation to a service provider. Each of the cases are nearing a decision on motion to dismiss: *Stern v. JPMorgan Chase & Co*., Docket No. 1:25-cv-02097 (SD NY, filed March 13, 2025); *Navarro v. Wells Fargo*, Docket No. 24-cv-3043 (D MN, filed July 30, 2024); and *Lewandowski v. Johnson & Johnson*, No. 3:24-cv-00671 (D NJ, filed Feb. 5, 2024).
- **Review plan terms regarding allocation of rebates.** Appropriately drafted plan terms served to defeat an action brought by beneficiaries alleging the employer sponsor breached its fiduciary duty by misallocating prescription drug rebates. The court dismissed the case, finding the plaintiffs weren't entitled to rebates under the plan terms and weren't injured since they received their benefits as due (*Knudsen v. MetLife Group*, No. 23-2420 (3rd Cir. Sept. 25, 2024)).
- **Scrutinize shared-savings programs.** At least two cases brought by plan members challenging shared-savings programs for out-of-network claims are working their way through the courts: *Popovchak v. UnitedHealth Group Inc.*, No. 22-CV-10756 (SDNY Dec. 7, 2023) and *Davis v. United Health Group Inc.*, No. C21-01220RSM (WD WA April 14, 2023). In each case, the plaintiffs allege that the TPA breached its fiduciary duty of loyalty by artificially reducing eligible out-of-network expenses with repricer data using algorithms. The TPA allegedly would profit from shared-savings fees, even though it never reached agreements with the out-of-network providers, and plan members

allegedly received balance bills from these providers who received lower plan reimbursement.

  - A separate action challenges the use of algorithms for determining out-of-network payments on antitrust grounds (*CHS/Cmty. Health Sys. v. MultiPlan*, No. 2019-0165-JRS (DE Chancery Court Aug. 21, 2020). This and similar cases filed by providers allege the algorithms — apparently used with shared-savings programs — are anticompetitive. A federal court recently refused to dismiss one of those cases after the Department of Justice filed a statement of interest sharing their view that use of an algorithm can be the basis for a lawsuit under antitrust laws*: In re: Multiplan Health Insurance Provider Litigation,* No. 1:2024cv06795 - Document 428 (N.D. Ill. 2025). A different federal court, however, dismissed similar antitrust litigation in *Long Island Anesthesiologists PLLC v. United Healthcare Ins. Co. of N.Y. Inc.*, No. 2:22-cv-04040, (ED NY, April 8, 2025).
  - Sen. Amy Klobuchar (D-MN) requested that the Justice Department and Federal Trade Commission (FTC) investigate MultiPlan to see if it subverts competition or otherwise harms consumers.

- **Ensure that plan options are adequately disclosed to participants.** Two recent cases allege that offering and failing to disclose that a low-deductible PPO option offers no financial benefit over a high-deductible option is a breach of fiduciary duty: *Green v. University of Rochester*, No. 6:25-cv-06499 (WD NY, filed Sept. 23, 2025) and *Barbich v. Northwestern University*, No. 1:25-cv-06849 (ND Il, filed June 20, 2025).

Review TPA services, including claims administration, through the lens of a flurry of cases alleging wide-ranging TPA breaches of fiduciary duty and then work with counsel to minimize their risks. For example, demand disclosure about the use of AI or other automated processes in claims administration. The use of AI or other automated processes to administer claims (and potentially override physician recommendations) may violate ERISA's full-and-fair-review requirement. (See *Artificial intelligence (AI) in benefits* section.)

- **Monitor the growing body of cases with an ERISA fiduciary suing a TPA.** These include a recently revived case, *Tiara Yachts v. Blue Cross Blue Shield of Michigan,* No. 1:22-cv-603 (WD MI, filed July 1, 2022), as well as a number of newly filed cases — *Wesco, Inc. v. Blue Cross Blue Shield of Michigan*, No. 2:25-cv-11712 (ED MI, filed June 9, 2025); *Owens & Minor, Inc. v Anthem Blue Cross Blue Shield of Virginia*, No. 3:24-cv-820 (ED VA, filed Nov. 18, 2024); *Huntsman Int'l v. Aetna*, No. 2:2024cv00404 (E.D. TX, filed June 3, 2024); *Aramark Servs. v. Aetna Life Ins. Co*., No. 24-40323 (5th Cir. May 6, 2024); and *WW Grainger v. Aetna Life Ins. Co*., No. 2:24-cv-00352 (ED TX May 10, 2024). Among the alleged misconduct are TPA breaches of fiduciary duty related to:
  - Approval of allegedly inflated, false, fraudulent, improper and duplicative claims, resulting in overpayments to providers
  - Refusal to turn over claims data for employer to audit
  - Reprocessing of claims to allegedly pay providers less than in-network contracted rates and keeping the difference between what the plan pays and what providers receive

  - Cross-plan offsetting and otherwise agreeing to less favorable terms, allegedly benefiting TPA and its insured plans at the expense of self-funded plans

Update plan documents, SPDS and other communications. Consult with counsel about desirability of clauses addressing matters like rebate allocation, cross-plan offsetting, antiassignment, forum selection and contractual statute of limitations. Include plan design changes related to Rx or other benefits. Review terms against case-law developments.

Meet all ERISA reporting and disclosure requirements for group health plans in a timely manner. Requirements include but are not limited to the following: SPD, summary of benefits and coverage (SBC), Form 5500, RxDC reports (see *Prescription drugs* section), gag-clause attestation, machine-readable files, consumer transparency tools (see *Group health plan transparency* section) and a written comparative analysis of nonquantitative treatment limits (NQTL) (see *Mental health parity* section). Watch for guidance on default electronic disclosures, expected before June 2026.

- **Prepare a response plan for addressing document requests.** Some documents, like the SPD, must be provided within legally required timelines, while other documents may be subject to a nondisclosure agreement. A recent 9th Circuit opinion confirmed that not all claims administration agreements and internal documents about plan administration must be disclosed on request (see *Zavislak v Netflix*, No. 5:21-cv-01811 (9th Cir., Sept. 16, 2025)). When responding to a general request for ERISA plan documents, confirm the written NQTL comparative analysis is included. Give special consideration to documents that may include protected health information (PHI). (See *Data privacy and security* section.)

Review other fiduciary compliance concerns. Other complex fiduciary issues could arise for group health plan fiduciaries (for example, ERISA's plan asset or bonding requirements), which should be considered with counsel.

Confirm insurance coverage is adequate. Plans cannot indemnify fiduciaries from liability for ERISA violations. ERISA fiduciaries who violate their duties may be subject to investigation and personally liable for any profits obtained or losses incurred through the use of plan assets. ERISA fiduciaries also can be subject to removal from their fiduciary positions, other court-ordered equitable relief and DOL civil penalties. Many plan sponsors obtain fiduciary insurance to cover these risks, often including a "nonrecourse" rider purchased with nonplan assets to provide additional coverage to the fiduciary.

Monitor how DOL enforcement priorities related to ERISA fiduciary requirements take shape under the Trump administration. Review full compensation — directly and indirectly — that vendor partners receive for managing health plans. This appears to be a top priority for the DOL under Trump, particularly "hidden fees." Guidance that will require disclosure of indirect and direct compensation paid to PBMs under ERISA section 408(b)(2)(B) is expected.

- Issues tackled under the Biden DOL worthy of continued attention by ERISA fiduciaries include proper administration of emergency medical claims, methodology for determining out-of-network provider reimbursement rates, self-funded multiple-employer welfare arrangement reserves and life insurance evidence of insurability processes.

Related resources

Section 3

Group health plan transparency

Action

Consider that group health plan transparency has bipartisan support and holds great promise for both consumers and group health plan sponsors in better understanding healthcare pricing and fees, but that comes with many compliance requirements that remain challenging, with new requirements in the pipeline. Continue complying with the final Transparency in Coverage (TiC) rule (including posting machine-readable files (MRFs) for in-network and out-of-network allowed amounts and providing a self-service transparency tool for all covered items and services), and watch for related new guidance (for example, implementing the MRF requirement for prescription drugs). Confirm that vendors' data is accurate, complete and updated as required and that the MRFs and tools meet other requirements, including compliance with Schema 2.0 for MRFs by Feb. 2, 2026. Ensure plan-related contracts have no gag clauses on price or quality information and submit the gag-clause attestation by Dec. 31. Ensure timely submission of the required prescription drug data collection (RxDC) reports. (See *Prescription drugs* section.) Continue to comply with additional transparency requirements in the Consolidated Appropriations Act of 2021 (2021 CAA) and look for more guidance on several 2021 CAA transparency topics in 2026. Review proposed ERISA §408(b)(2) rules when issued. Review group health plan and hospital transparency data as well as third-party analyses of previously unavailable pricing information and consider how to use such information. Work with vendors on compliance with transparency requirements and make sure that they will provide the necessary assistance to employers to help them comply with those requirements. Watch for new transparency legislation.

Specific steps

Continue complying with the final TiC rule for nongrandfathered group health plans and insurers, and watch for related new guidance from the Trump administration. President Trump issued an executive order (EO) instructing the Departments of Labor, Health and Human Services (HHS) and Treasury to "rapidly implement and enforce" the TiC rule, so compliance with the current rule as well as staying abreast of any new TiC guidance should be a high priority for plan sponsors. The TiC rule applies to group health plans, including self-funded plans and insurers, but doesn't apply to grandfathered plans, health reimbursement arrangements (HRAs), excepted benefits, expatriate plans exempt from Affordable Care Act (ACA) provisions, retiree-only plans or short-term limited-duration insurance.

- **Continue to make accurate and complete MRFs for in- and out-of-network allowed amounts available on a public website and ensure that the files are compliant with current compliance standards and Schema version 2.0 by Feb. 2, 2026.**
  - *Current standards for MRFs.* The final TiC rule requires standardized MRFs, updated monthly, containing the plan's negotiated rates for in-network providers and past allowed payments to out-of-network providers for all items and services and

prescription drug information. The MRFs should include all data elements for the negotiated rate and the allowed amounts. Plans and issuers must provide facility fee information in MRFs. Plans can no longer rely on a safe harbor originally available for certain alternative reimbursement arrangements, but regulators will exercise enforcement discretion on a case-by-case basis. If the plan or issuer can demonstrate that compliance would have been extremely difficult or impossible, enforcement is unlikely.

- *Ensure vendors' MRFs are compliant with Schema 2.0 by Feb. 2, 2026.* Regulators recently posted Schema 2.0 on GitHub, a development platform that is being used by the agencies to communicate technical requirements for the MRFs.
- *Public posting.* If a group health plan does not have a website, guidance allows the plan to enter into a written agreement to have the plan's insurance issuer or TPA post MRFs on its public website for participants, beneficiaries and enrollees. The plan satisfies the posting requirements only if the health insurance issuer or TPA makes the information available as required. This guidance applies when the plan sponsor (for example, an employer) maintains a public website, but the employer's group health plan does not.
- *Recordkeeping.* MRFs must be updated monthly (or in reasonably consistent periods of approximately 30 days) and clearly indicate the date of the most recent update. The TiC rule doesn't address record retention, but separate guidance recommends that group health plans and health insurers maintain prior months' MRFs to demonstrate compliance. In addition, other federal laws may affect MRF retention, such as laws governing information accessibility, privacy or security or requiring properly authorized representatives to have access to participant, beneficiary or enrollee information held by plans and insurers. States may have other recordkeeping and retention requirements for health insurance plans and insurers.

- **Watch for guidance and prepare to post MRFs for prescription drugs.** The departments rescinded their enforcement delay of the TiC rule's prescription drug MRF requirement in 2023. In June 2025, the triagencies sought input on revising the Rx MRF requirements. Proposed TiC regulations may provide Rx MRF implementation guidance as soon as 2025.
  - Regulators intend to develop technical requirements (i.e., on GitHub) and an implementation timeline that sufficiently accounts for plans' and issuers' reliance on the temporary enforcement delay. Plans and issuers should work with vendors to ensure they are ready to post MRFs with prescription drug prices when required.
- **Continue providing a self-service transparency tool for all plan-covered items and services, including prescription drugs.** Ensure that all applicable plan service providers will deliver required data, including point solutions (e.g., fertility vendors). If using a separate tool from each vendor is problematic or noncompliant, consider using a transparency vendor to develop the self-service tool or provide a consolidated tool. Decide whether to include optional quality metrics for all items and services in the self-service tool.
  - *Include all required information and disclosures.* The self-service tool for plan participants must provide a variety of information and:

    - Disclose personalized out-of-pocket costs for all covered healthcare items and services (with paper copies available on request), including facility fees (as discussed below).
    - State any applicable prerequisite.
    - Give an estimate of a participant's cost-sharing liability for any in- or out-of-network provider, allowing the participant to compare costs before receiving medical care.
    - Enable searching by billing code, descriptive terms, in-network provider name and other relevant factors (like geography).
    - Track a participant's accruals toward any cumulative treatment limitations (like day or visit limits), deductibles and out-of-pocket maximums.
  - — *Draft model notice.* The Department of Labor (DOL) has provided a draft model notice for the self-service tool.
  - — *Ensure tool responds to cost estimate requests for low utilization items and services in accordance with guidance.* If a particular item or service has fewer than 20 claims in total over the last three years, the self-service tool should indicate that the item or service is covered but a specific cost estimate is not available due to insufficient data. In this situation, the tool should encourage the participant to contact the plan or insurer for more information. A plan or an insurer receiving such a request should provide any available relevant information, like the summary of benefits and coverage or the participant's portion of the cost for the item or service. (DOL has stated that it is likely to exercise its nonenforcement discretion if this process is followed.)
- **Discuss with carriers for insured plans the impact on potential medical loss ratio (MLR) rebates (insured plans only).** To encourage consumers to shop for better prices, the rule allows insurers to reduce MLR rebates if insured plans share cost savings with enrollees who choose less-expensive providers.
- **Take steps to avoid potential penalties.** Group health plan sponsors failing to meet the TiC rule face penalties of $100 per day per participant. However, many group health plan sponsors don't have access to all negotiated prices and can't provide the transparency disclosures without input from the plan's insurer or TPA. The rule offers some relief to sponsors in that situation:
  - — A safe harbor spares a fully insured group health plan sponsor from providing the transparency disclosures to participants if a written agreement requires the insurer to do so. If the insurer fails to do so, it — not the group health plan sponsor — will face liability for the violation. Employers with insured plans should ensure that their insurers provide this written agreement.
  - — The rule also provides relief for group health plans that make an error or omission or cannot obtain complete or accurate information from another entity, despite acting in good faith and with reasonable diligence to do so. Group health plans likewise won't face penalties if the website hosting the transparency tool and files is temporarily inaccessible. In both cases, the plan must correct the problem as soon as practicable.

Ensure plan-related contracts have no gag clauses on price or quality information and submit the gag-clause attestation by Dec. 31. Group health plans and health insurers are banned from entering into an agreement that would directly or indirectly restrict a healthcare provider, a network or association of providers, a TPA or another network service provider from engaging in any of these activities:

- Furnishing provider-specific cost or quality-of-care information or data (e.g., via a consumer-engagement tool) to referring providers, the plan sponsor or covered members (or those eligible to become covered members)
- Electronically accessing covered members' deidentified claims and encounter information or data
- Sharing the above-described information or data with a covered business associate under the Health Insurance Portability and Accountability Act, consistent with federal privacy regulations.

- **Applicability.** The gag-clause prohibition and the attestation requirement apply broadly to fully insured and self-funded group health plans (including grandfathered plans, church plans and nonfederal governmental plans), individual health insurance policies and student health insurance coverage. Neither the gag-clause prohibition nor the attestation requirement applies to excepted benefits (e.g., accident plans, limited-scope dental or vision plans, on-site medical clinics, specified disease or illness coverage, or hospital indemnity coverage), retiree-only plans, HRAs or other account-based plans (like health flexible spending arrangements).
- **Downstream agreements.** A downstream agreement (e.g., a network agreement between a TPA and a healthcare provider) that keeps the plan from indirectly providing, electronically accessing or sharing the data or information restricts the plan in violation of the gag-clause prohibition, per FAQ Part 69. Plans should include provisions in contracts with TPAs and other service providers that prevent the vendor from entering into a downstream agreement that restricts the plan from obtaining or sharing information or data.
- **Gag clause examples.** FAQ Part 69 includes a non-exhaustive list of prohibited gag clauses that should be eliminated from agreements with TPAs and other service providers:
  - Terms that limit disclosures to a business associate
  - A limit on the scope, scale or frequency of electronic access to de-identified claims and encounter information or data, to the extent that it unreasonably limits access to such information or data "upon request" of the plan or issuer. Unless the information or data specified by statute is otherwise electronically accessible to the plan or issuer, the following examples of restrictions on an audit or claims review would be considered impermissible gag clauses:
    - Limiting access to a statistically significant or the "minimum necessary" number of de-identified claims
    - Limiting the scope of access to the data to specific, narrow purposes (such as limiting access to the context of an audit)

  - Unreasonably limiting the frequency of claims reviews (e.g., no more than once per year)
  - Limiting the number and types of de-identified claims that a plan or issuer may access
  - Restricting the data elements of a de-identified claim that a plan or issuer may access
  - Providing access to de-identified claims data only on the TPA's or service provider's physical premises

- **Gag-clause attestation.** Group health plan sponsors and health insurers must annually attest the plan is in compliance with the prohibition on gag clauses — the third attestation is due Dec. 31, 2025.
  - Attestations cover the period beginning with the submission date of the last attestation and ending on the date of the current submission.
  - The annual attestation must be submitted through the CMS Health Insurance Oversight System portal. CMS maintains a website with compliance FAQs, updated instructions, a user manual and a reporting template.
  - Fully insured plan sponsors are deemed to have satisfied this requirement when their health insurer submits the attestation on the plan's behalf. Self-funded plan sponsors can contractually obligate the plan's TPA to submit the attestation on the plan's behalf, but the plan will remain legally liable.
  - FAQ Part 69 explains how to file the gag-clause attestation for a plan with an agreement that violates the gag-clause prohibition. The plan sponsor should work with the vendor to remove the gag-clause provision, and if unsuccessful, identify the noncompliant provision as part of the attestation by using the text box labelled "Additional Information" in Step 3.

Continue to comply with other 2021 CAA transparency requirements and related enforcement relief. Look for more guidance on several 2021 CAA transparency topics in 2026. The 2021 CAA's requirements, unless otherwise noted, generally took effect for the 2022 plan year and include the following:

- **Price comparison tool.** Since the 2023 plan year, plans and insurers have been required to provide a price comparison tool similar to the self-service price transparency tool required by the final TiC rule (discussed above). The tool must be available by telephone and on the plan's or insurer's website. To the extent practicable, the tool must allow participants to compare the cost sharing that they will owe for a specific item or service obtained from a participating provider in a particular plan year and geographic region. (Regulators plan to align compliance with the TiC self-service tool but have yet to issue guidance doing so.)
- **Air ambulance reporting (data collection delayed).** The 2021 CAA requires group health plans and insurers to report claims data for air ambulance services. HHS and the Department of Transportation must use that data to produce a comprehensive, publicly available report on air ambulance services. This report is expected to help shed light on what's driving the high costs of these services. Proposed rules came out in September

2021, but CMS has delayed data collection until final rules are issued. Employers should watch for final rules with more information on air ambulance reporting.

- **Advanced EOBs (enforcement delayed)**. Healthcare providers and facilities will have to provide group health plans with a good-faith estimate of expected charges when an enrollee schedules a specific item or service. A group health plan that receives such a notification or request has to meet tight time frames to provide an advanced EOB with detailed information about the plan's coverage of the scheduled item or service. Regulators have asked for comments about implementing this requirement and are delaying enforcement, pending publication of a proposed rule. A CMS progress report notes that industrywide standards are necessary, the new requirement will be hard to implement without interoperability and a pilot or demonstration project is likely before the requirement takes effect. (See *Data privacy and security* section.)
- **Disclosures on health plan ID cards.** Physical or electronic health plan ID cards must include any applicable deductible or out-of-pocket maximum, along with a telephone number and website address for obtaining consumer assistance. Consumer assistance may include information on hospitals and urgent care facilities that have a contractual relationship for furnishing items and services under the plan. Regulators expect good-faith compliance until regulations are issued.
- **Up-to-date provider directories.** Group health plans' public websites must provide an accurate, verified database that contains a list of — and directory information on — each healthcare provider and facility that has a direct or indirect contractual relationship with the plan. Group health plans also must prepare to respond to participant questions about the provider directory. If this database incorrectly lists an out-of-network provider as in-network and a participant or beneficiary obtains items or services from that provider, the plan must limit cost sharing to the in-network amount and credit that amount toward the in-network deductible or out-of-pocket maximum. Until regulations come out, regulators expect group health plans to show good-faith compliance by limiting charges for out-of-network care (as described above) when an enrollee receives inaccurate information about a provider's network status. CMS has asked for comments about establishing a National Directory of Healthcare Providers & Services that could serve as a "centralized data hub" for healthcare provider, facility and entity information nationwide. Apparently, CMS has begun building a Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interface (API) to enable apps to find provider networks, participants and relevant endpoints, while also improving data quality and mapping complex provider hierarchies.
  - A growing body of lawsuits against insurers and plan administrators (and in at least one case, the employer sponsoring the plan) challenge inaccurate provider directories, basing claims on the CAA, ERISA and other legal theories. A district court recently held that allegations that a provider directory failed to list all in-network providers was sufficient to show a violation of the CAA and an ERISA breach of fiduciary duty. The California Attorney General, in partnership with the San Diego City Attorney's Office, recently announced a $40 million settlement with a carrier resolving allegations of inaccurate mental health and medical provider directories. Finally, another class action lawsuit has been filed by plan members and the employers that purchased certain Connecticut health insurance policies alleging that mental health provider directories contain "ghost networks."

- **Broker and consultant disclosures.** Brokers and consultants expecting to receive at least $1,000 for their services must disclose to group health plans all direct and indirect compensation for those services. Regulators have issued an enforcement policy regarding broker and consultant disclosures: Pending proposed rules, covered service providers and plan fiduciaries generally are expected to use a good-faith, reasonable interpretation of the law. DOL considers that a good-faith and reasonable step is for a group health plan's service provider to take into account the department's July 16, 2010, and Feb. 3, 2012, pension plan guidance on this topic.

Review proposed ERISA §408(b)(2) rules when issued. The DOL is expected to propose rules later this year to improve employer health plan transparency into the direct and indirect compensation received by PBMs, as instructed by the President in Executive Order 14273.

Understand hospital price disclosures, and watch for improvement in compliance and CMS's efforts to improve the data supplied. Although hospitals have been required to post price information since 2021, the files have not been easy to use, and noncompliance has been widely reported. CMS has taken 27 enforcement actions imposing civil monetary penalties against hospitals that failed to comply with the rule (10 in 2025), and President Trump's EO prioritizes continued agency efforts to ensure hospitals disclose required price information. To make the data more useful and make it easier for hospitals to comply, HHS finalized hospital price transparency (HPT) rules to strengthen hospital transparency by requiring standardization of MRFs, certification of file accuracy if required by CMS and publication of other enforcement activities, in addition to civil monetary penalties, on a CMS website. This GAO report, which describes CMS enforcement (good aggregate figures), recommends stakeholder feedback and a CMS study for file accuracy. Look for additional hospital disclosures as enforcement against noncompliant hospitals increases. CMS has issued proposed amendments to the HPT rules to make a number of changes that would enhance clarity and standardization in hospital disclosure of standard charges and an RFI seeking public input on whether and how CMS can improve compliance and enforcement processes to ensure that the hospital pricing data in the MRF are accurate and complete. The RFI also sought information from payers (including employers who may use the data for contract negotiations) about how to improve hospital price transparency. Additionally, updated hospital guidance eliminates a previously available workaround hospitals could use to avoid posting a dollar where limited historical claims were available.

Here are the hospital disclosures currently required, which must be updated annually:

- **Consumer-friendly disclosure.** Hospitals must provide payer-specific negotiated charges, discounted cash prices, and deidentified minimum and maximum negotiated charges — the hospital's lowest and highest negotiated average prices — for 300 shoppable services. This information must be displayed and packaged in a "consumer-friendly" manner — for example, by using a price-estimator tool. CMS selected 70 of the 300 shoppable services, and hospitals could choose the remainder.
- **Publicly available MRFs.** Each hospital must make available to the public MRFs that contain gross charges, payer-specific negotiated charges, discounted cash prices, and deidentified minimum and maximum negotiated charges for each item and service provided. The payer-specific negotiated charge is the charge for an item or service that a hospital has negotiated with an insurer or a TPA — or in some cases, directly with a plan or a plan sponsor. Under the final rules, hospitals should display the required standard charges data using a template similar to the samples currently available on the CMS

hospital price transparency website, with a standard set of required data elements. These changes should bring more consistency to the MRFs of different hospitals.

Review group health plan and hospital transparency data as well as third-party analyses of previously unavailable pricing information and consider how to use such information. The hospital data and the MRFs (as well as the RxDC data described in the *Prescription drugs* section) should provide unprecedented insights into the rates that participants and plans pay for medical services and items like prescription drugs at hospitals. Consider comparing the data to claims data under the group health plan, as well as quality metrics, for a more robust analysis. Work with relevant experts — e.g., data specialists — to understand the data.

- **Monitor third-party analyses. Recent analyses include:**
  - A report by Purchaser Business Group on Health with purchaser-driven analysis combining hospital and payer pricing data with claims data and quality metrics
  - A white paper by Turquoise Health analyzing commercially negotiated rates at over 200 hospitals in 10 metropolitan areas, focusing on 37 common healthcare services
  - A brief by Peterson-KFF Health System Tracker examining some of the issues and challenges researchers and other data users may encounter when using the price data reported pursuant to the TiC rule
- **Ask your vendors/insurers how they are analyzing the data.**
- **Explore emerging opportunities** to use newly available data in selecting vendors, auditing and monitoring current vendors, reviewing networks, encouraging employees to use high value providers and/or negotiate or directly contract rates with individual hospitals or hospital systems if a particular plan currently pays higher rates than what other entities pay.

Work with vendors on compliance with transparency requirements and make sure that they will provide the necessary assistance to employers to help them comply with those requirements. Most plan sponsors don't have the required information for these disclosures. Make sure that vendor contracts are updated and reviewed by counsel and consider requesting vendors provide reporting and performance guarantees related to transparency compliance.

Watch for potential new transparency legislation (like the Patients Deserve Price Tags Act). (See *Congressional outlook* section.)

Related resources

Section 4

Data privacy and security

Action

Regularly review compliance with HIPAA security requirements and Department of Labor (DOL) cybersecurity measures for ERISA plans. Use compliance tools from regulators to identify and address security vulnerabilities. Evaluate vendors, new technologies and apps to determine whether HIPAA or other data protection and privacy laws apply and assess compliance. Pay special attention to mobile technologies and tracking technologies across all platforms. Assess how federal policy facilitating the exchange of health data may affect data privacy and security priorities of group health plans. Review HIPAA privacy policies and procedures for any revisions needed following the vacatur of the 2024 HIPAA privacy rule.

Specific steps

Regularly review compliance with HIPAA security requirements and DOL cybersecurity measures for ERISA plans. The HIPAA security rule requires covered entities and business associates to ensure the confidentiality, integrity and availability of all electronic protected health information (ePHI). HIPAA regulations prescribe how health plans should secure ePHI and provide notice and remedial action after a breach. ERISA fiduciary duties may require plan sponsors to implement cybersecurity measures for health plans that go beyond HIPAA security requirements. (See *ERISA fiduciary issues* section.)

- **Review — and update if needed — HIPAA policies and procedures to prevent, detect, contain and correct security incidents.** The FBI reports that healthcare and public health organizations experienced more data breaches from cyber threats in 2024 than any other critical infrastructure sector, and in 2025, large healthcare data breaches continue to be reported to HHS in high numbers. As of Oct. 1, the Office for Civil Rights (OCR) breach portal shows 442 data breaches of 500 or more records reported in 2025 and still under investigation, 29 of which are health plan breaches.
  - Conduct a risk analysis using the updated security risk assessment tool (version 3.6), after reviewing HIPAA security resources, including HHS's risk analysis guidance or the cybersecurity resource guide created by the National Institute of Standards and Technology (NIST) in collaboration with HHS. Consider adopting a cybersecurity framework from NIST or the HITRUST Alliance, for example.
  - Confirm the processes for mitigating the harmful effects of a breach and for documenting incidents and their outcomes. Review NIST's recommendations for responding to security incidents. Consider forming a security incident response team. Confirm the security breach terms are in each business associate agreement, clearly identifying each party's responsibilities. If there is a separate data-sharing agreement, confirm it's consistent with the Business Associate Agreement (BAA).
  - Watch for a final HIPAA cybersecurity rule, expected next year. The Biden administration proposed a rule that prescribes what health plans and business

associates must do to protect the security of electronic PHI and align with modern best practices for cybersecurity. For example, if adopted as proposed, greater specificity would be required for risk analyses, planning for contingencies and responding to security incidents, including swifter breach notifications. In addition, annual compliance audits and BAA verifications would be required.

- **Review the need for additional cybersecurity measures under ERISA's fiduciary duty requirement.** The DOL previously confirmed that its cybersecurity guidance generally applies to all employee benefit plans, including health and welfare plans. Review cybersecurity measures for all ERISA-covered plans, including health, accident, disability and life, as well as on-site clinics against the DOL cybersecurity best practices.
  - Review the tips for hiring a service provider. ERISA requires plan fiduciaries to prudently select service providers with strong cybersecurity practices and to monitor providers' activities.
  - Ask service providers about their cybersecurity practices, past breaches and insurance policies. Review vendor contracts against BAA terms detailing requirements in the event of a HIPAA breach and reconcile any conflicts between data security provisions and HIPAA breach requirements.
  - Consider including other terms to enhance protection for the plan and its participants and avoid provisions limiting the service provider's liability.
- **Verify that business associates and other vendors are implementing audit controls and sharing audit results and risk-mitigation measures.** The HIPAA security rule requires covered entities and business associates to implement hardware, software and/or procedural mechanisms that record and examine activity in information systems that contain or use ePHI. DOL cybersecurity best practices includes a reliable annual third-party audit of security controls.
  - Confirm that service agreements allow for periodic examination of the strength and effectiveness of cybersecurity practices, giving the plan sponsor the right to review audit results. Avoid pro forma security reviews. Instead, obtain third-party audits of cybersecurity practices and ensure reviews are tailored to the plan's particular risk profile. Request audit reports (and supporting documents) prepared and conducted in accordance with appropriate standards, with documentation of identified weaknesses and corrections. Confirm security awareness and training programs are ongoing for all workers supporting the plan.
  - Evaluate vendors supplying wellness and transparency tools, mobile apps and artificial intelligence. Partnerships with app developers, data warehouses or mobile-technology vendors to provide group health plan benefits and information could trigger HIPAA obligations.
  - Evaluate security challenges in telehealth tools. Confirm vendors ensure data security with telehealth tools. Evaluate if a BAA is needed with the telehealth technology vendor (often a separate entity) and that the technology meets HIPAA specifications. Ensure regular security risk assessments of the telecommunications platform, including encryption of ePHI, login standards and authentication requirements.

Review mobile technologies for cybersecurity measures required by the Federal Trade Commission (FTC). The FTC Act prohibits unfair or deceptive trade practices and applies to HIPAA-covered entities and business associates, as well as other companies that collect, use or share health information but aren't HIPAA-covered entities. This could include websites, mobile health apps and other technologies used to track diseases, diagnoses, treatments, medications, fitness, fertility, sleep, mental health and diet, among other health concerns.

- **Protect against impermissible disclosures of personal health information.** Whether digital solutions are made available through a health plan or offered separately by the employer, the privacy and security risks to personal health information should be assessed.
  - Make sure employees know how any vendor uses or discloses their data. Consider obtaining employee consent to the information use or disclosure. Among other actions, the FTC uses its enforcement authority against companies that violate their own privacy policies or make false statements about information security.
- **Review for applicable breach notification rules.** The FTC's health breach notification rule (HBNR) applies specifically to entities (and their third-party service providers) that are not subject to HIPAA (for example, health apps and direct-to-consumer technologies like fitness trackers, remote blood pressure cuffs and blood glucose monitors). Under the HBNR, a breach is not limited to cyberattacks but includes any use or disclosure of personal health information without that person's authorization. The HBNR requires notice to individuals and the FTC (and the media in some cases) within a specified time after a breach becomes known.

Pay special attention to tracking technologies. Screen plan websites, tools, vendor solutions and other health and wellness apps offered to plan participants and/or employees for tracking technologies that collect and analyze information about users and may contain personal health information. Disclosure of personal health information without authorization can violate HIPAA, trigger the HBNR and create litigation risk.

- **Monitor data flows of health information to third parties via technologies integrated into plan websites, apps and other health-related technologies (e.g., cookies, fingerprinting, web beacons and tracking pixels).** Review OCR's bulletin about online tracking technologies used by HIPAA-covered entities and business associates and the joint OCR and FTC warning about the privacy and security risks of online tracking technologies integrated into websites and mobile apps. Confirm these technologies, if in use with the plan or by vendors supporting the plan, do not result in impermissible disclosures of PHI, even inadvertently (for example, for marketing purposes). Confirm the HIPAA security risk assessment addresses tracking technologies, and consider auditing health apps, online tools and webpages to limit or eliminate third-party tracking. If tracking technologies can't be limited or eliminated, ensure they are disclosed and consider adopting a process for participants to opt out.
- **Monitor litigation alleging disclosure of PHI to online tracking technologies violates federal and state law.** Numerous cases alleging improper use and disclosure of information collected through tracking technologies on websites and patient portals were initiated this year against carriers, health information technology providers and healthcare providers. In most cases, violations of federal and state privacy laws are asserted.

Monitor federal enforcement. OCR continues to enforce the HIPAA security rule, as demonstrated by recent settlements. The FTC enforces the HBNR when a security breach concerns individually identifiable health information not protected by HIPAA. Employee Benefits Security Administration enforcement of fiduciary obligations related to cybersecurity is possible, as cybersecurity questions commonly factor into a DOL audit of ERISA plans.

Assess how federal policy encouraging health data interchange (aka interoperability) may affect data privacy and security priorities of group health plans. A refreshed HealthData.gov initiated by the Living HHS Open Data Plan "aims to demystify and encourage the US healthcare system to leverage high-quality data to create innovative ecosystems that benefit patients" (see press release). At the same time, CMS announced a new partnership with health and information technology companies to share patient data more freely, as early as the first quarter of 2026, and HHS's IT arm issued a final rule easing Medicare electronic prescribing, prior authorization and real-time prescription benefit checks. Assess how these efforts may impact data privacy and security for group health plans and member PHI. Watch for interoperability improvements necessary to provide advance explanation of benefits (EOBs) to plan enrollees. (See *Group health plan transparency* section.)

- **Watch for new tech tools for disease management and increased use of AI in the delivery of healthcare.** Independently evaluate the data privacy and security of personalized digital health tools expected to be listed in an app library at Medicare.gov before incorporating them into group health plans or wellness programs.
- **Consult with group health plan service providers about planned participation in the new CMS Aligned Networks.** Providers, payers and others can voluntarily agree to adhere to the CMS Interoperability Framework to support a standardized system to share information electronically. For those group health plan service providers that join the Aligned Network, assess for continued vigilance with respect to compliance with HIPAA privacy and security requirements.
- **Become familiar with updated tech requirements in the HTI-4 final rule on health data, technology and interoperability.** A fact sheet and press release outline major updates in the rule, including: (1) national standards for e-prescriptions so that data flows seamlessly from a provider through the pharmacy networks and to payers; (2) a requirement to include electronic prior authorization in the e-prescription module, which was optional before; (3) real-time prescription benefit checks; and (4) streamlined prior authorizations for tests, procedures and medications. When HTI-4's requirements are fully implemented and operational (before 2028), providers should have better tools for checking drug coverage and completing prior authorization without the need for phone calls or faxes. For example, if a medication requires prior approval, the authorization request will be triggered automatically as part of the prescribing process. In addition, providers and patients should have cost and coverage details before the prescription is sent to the pharmacy. While the rule applies only to Medicare, providers and patients may expect the same from commercial health plans. Ask plan service providers, particularly PBMs and TPAs, whether they are working to implement the HTI-4 rule for their employer-sponsored health plans (and continuing to assess cybersecurity risks).

Review HIPAA privacy policies and procedures for any revisions needed following the vacatur of the 2024 HIPAA privacy rule. In light of this change, plan sponsors, with the advice of their legal counsel, should consider:

- **Whether to remove heightened privacy protections that are no longer required by HIPAA**
  - Some plan sponsors may want to unwind changes made to comply with the reproductive healthcare privacy rule, and others may want to work with legal counsel to determine what changes to keep, if any.
- **How to handle future requests for PHI related to certain sensitive healthcare, including reproductive and gender-affirming healthcare**
  - Certain covered entities have been under pressure to disclose PHI related to medical care that is being scrutinized at the federal level and in some states (see for example, subpoenas from the Department of Justice). Remember that HIPAA permits but does not require disclosure of PHI in response to a judicial or administrative proceeding (including a subpoena), and note that these disclosure demands have been met with judicial skepticism. Lastly, although patients and plan beneficiaries cannot bring an action against a covered entity for a HIPAA violation, damages may be available under state law (for example, actions under negligence or tort law if the individual suffers harm from the disclosure).
- **Whether to provide additional training for staff related to PHI requests**
- **How the plan will handle an employee or business associate who fails to comply with the HIPAA privacy rule or the plan's HIPAA policies**
  - HIPAA's privacy rule requires covered entities to impose sanctions against employees who fail to comply with the rule or the plan's privacy policies. At the same time, the current administration is offering protection from HIPAA sanctions for whistleblowers (and the HIPAA-covered entity for which they work) voluntarily disclosing PHI related to gender-affirming healthcare. This is in direct conflict with state laws prohibiting such disclosure (at least 22 states and the District of Columbia have shield laws protecting reproductive and gender-affirming healthcare).
- **Determine whether HIPAA materials need to be revised.** Depending on decisions made about maintaining heightened privacy protections for certain PHI, plan sponsors may need to revise the HIPAA policies and procedures manual and training materials — possibly retraining relevant workforce members — as well as the operational workflow used to respond to requests for PHI. Confirm chosen procedures are adopted and implemented by business associates and memorialized in business associate agreements.
- **Be prepared to update and distribute the revised HIPAA privacy notice.** Portions of the 2024 HIPAA privacy rule requiring amendments to the privacy notice related to substance use disorder records were not vacated, and the changes are required before February 16, 2026. Note that HHS has not explicitly committed to providing a new model notice incorporating the required changes. Confirm with group health plan service providers that an updated notice will be available or work with counsel do draft one.

Watch for new federal legislation and additional guidance. Federal legislators continue to show concern for health data privacy, considering whether legislation is necessary to modernize HIPAA, safeguard health data not covered by HIPAA and preempt the patchwork of state data protection laws. HIPAA and the HBNR only preempt state law to the extent that

complying with both the federal and state laws would be impossible. State laws can require more protection for sensitive information and apply in addition to the federal laws. Stakeholders emphasize hacking incidents involving third-party service and software providers, international cyber threats and the need for cybersecurity training resources for the healthcare industry workforce.

Related resources

Section 5

Artificial intelligence (AI) in benefits

Action

Become familiar with — if not already — the use of AI in healthcare and employee benefits. Monitor the federal policy shift regarding the use of AI in healthcare and employment. Consider implications for design and administration of employee benefits, including group health plans and the effects on plan participants and beneficiaries. Consider setting guardrails encouraging the responsible use of AI internally and by employee benefit plan vendors, given the risks and opportunities of this fast-evolving technology. Remember that ERISA plan fiduciaries must act prudently in selecting and monitoring service providers, including with respect to their use of AI. Watch for federal legislation, state regulation and litigation to unfold, and apply any new requirements or best practices to plans.

Specific steps

Become familiar with — if not already — the use of AI in healthcare and benefits. AI is technology that allows machines to perform tasks that historically have required human intelligence, such as making decisions, recognizing speech and learning from experience. AI systems use algorithms — sets of rules or instructions — to analyze data and make predictions or decisions based on that data. Traditional AI is structured, rule-based, constrained and supervised. Generative AI, on the other hand, uses large data sets (e.g., large language models or LLMs) to create new content similar in style or content to the original materials. AI has the potential to have a huge impact on health and benefits, and group health plan service providers are already using AI in different contexts.

Be aware of the federal policy shift regarding the use of AI in healthcare. Consider implications for design and administration of employee benefits, including group health plans and the effect on plan participants and beneficiaries.

- Under President Biden, federal regulators were directed to develop strategic plans for the responsible use of AI. At that time, focus was on the safe, secure and trustworthy development and use of AI in federal agencies (see for example, guidance from EEOC, HHS, CMS and DOL) and Congress (see also House and Senate reports). Healthcare providers and payers pledged these same priorities with respect to the development and use of AI. In the final weeks of President Biden's administration, OCR reminded healthcare providers and payers of their obligation to identify and mitigate discrimination, particularly when AI is used in patient care decision support tools.
- President Trump signaled a significant shift away from these priorities on his first day in office this term (see Executive Order No. 14148 rescinding Biden's AI Executive Order No. 14110). Just days later, the agencies were directed to develop an AI action plan in accordance with the new administration's policy focused on sustaining and enhancing

"American's global AI dominance in order to promote human flourishing, economic competitiveness and national security." The resulting AI action plan focuses on deregulation (federal and state), infrastructure and international diplomacy. Shortly after the action plan was published, an EO was issued directing the agencies (and vendors) to ensure LLMs and other AI models are not influenced be diversity, equity and inclusion "ideologies." Two other EOs issued the same day focus on exporting "American AI" and accelerating federal approval of data center infrastructure necessary for AI development and use.

- Employers and plan sponsors may want to consider the implications of this shift in federal policy on the design and administration of employee benefits, including group health plans and the effect on plan participants and beneficiaries. The current administration's actions could be an indication of longer-term market and regulatory trends in AI. Keep in mind state regulations, federal nondiscrimination laws and continuing litigation risks associated with the use of AI that does not conform to plan documents (see discussion below).

ERISA plan fiduciaries should monitor internal and service providers' use of AI. Include AI models (e.g., development, inputs/outputs, use and outcomes) when reviewing service providers and plan management. Review AI tools through the lens of the fiduciary duties of prudence, loyalty and diversification. Engage experts as necessary. Gauge plan participant experience with AI and make adjustments accordingly. (See *ERISA fiduciary issues* section.)

- Work with counsel on request for proposals (RFPs) and service provider contract terms specifically related to the use of AI. Confirm AI (and algorithms) will not be the final adjudicator for claim denials. Request third-party audits of AI use in plan management. Alternatively, request certification for AI Management Systems from International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) or adoption of the NIST AI risk management framework. Determine if vendor has an AI governance committee, and if so, request to review the charter and/or AI protocols. If applicable, assess compatibility of vendor's AI use committee charter with plan sponsor's AI use committee charter. Consider performance guarantees and indemnification provisions for AI-related failures.
- Work with counsel to develop RFPs and contract terms governing the use of the plan's data to train or develop the vendor's AI tools. (See *Group health plan transparency* section.)
- Educate fiduciary committee on AI and the risks/benefits of use in plan administration.

Ask carriers and all third-party service providers about their use of AI for plan design, administration and decision-making purposes. Find out if, and to what extent, TPAs and carriers are using algorithms and/or AI to adjudicate claims, including pre-authorization and medical necessity determinations. According to a May 2025 NAIC survey report, 84% of health insurers use AI and machine learning in some capacity. Inquire as to vendors' adoption of NAIC's recommendations regarding the use of AI in product development and claims management (even if not required). Inquire if vendor AI use policies differ for self-funded plans.

- Where applicable, determine what controls are in place to ensure compliance with existing state law. A growing number of states have passed laws governing the use of AI by carriers, especially with respect to adverse benefit determinations (see, for example, California SB 1120, Illinois HB 2472 and Texas SB 815).

Inquire within the plan sponsor's organization about the use of AI for plan administrative functions. For example, determine if AI is used for advanced analytics, communications, personalized health and wellness, benefit navigation or customer service. Consider how AI can be used to improve plan participant experiences (for example, through the use of chatbots for basic plan coverage inquiries). Create an inventory of the plan's use of AI.

- Watch for state AI regulation impacting employment practices and consider application to the design and administration of health and welfare benefit plans. For example, automated decision-making technology (ADMT) and the need to protect citizens from unintended consequences was the focus of multiple state legislatures in 2025. Colorado's AI Act proved to be the model for bills introduced in Georgia, Illinois, Iowa, Maryland and other states. The law in Colorado (SB 24-205), effective in 2026, focuses on consumer protections, particularly with respect to "algorithmic discrimination" in "consequential decisions" — meaning decisions effecting the provision or denial of, or cost or terms of, employment, healthcare and insurance (among other things). The law also requires identification of the use of AI as a "substantial factor" in such decisions, imposes a duty of care, and affirms Colorado citizens' right to an explanation of AI's role in decision making.

Understand and apply current legal and compliance requirements to any AI used under a group health plan. Consider requiring group health plan service provider agreements to disclose how AI is used and tested (or include in RFPs). Consider covering AI-related failures in performance guarantees and indemnification provisions. Review plan documents and processes to determine what updates need to be made to reflect the use of AI. Be mindful of litigations challenging the use of AI or algorithms in claims administration. Examples of requirements to review for any AI used under the plan include:

- **Health Insurance Portability and Accountability Act (HIPAA)**. Review and update HIPAA privacy and security training, policies and procedures, as well as business associate agreements. Identify any new business associates. Understand whether and how AI tools are using PHI (for example, for training the AI) and review for HIPAA compliance. Ensure any plan data used for AI training is de-identified.
- **Mental health parity.** Identify algorithms that may create a nonquantitative treatment limitation (NQTL), examine for compliance and include in the comparative analysis. For example, a potential class action in California alleged that the use of an algorithm to process mental health and substance use disorder (MH/SUD) claims violated the Mental Health Parity and Addiction Equity Act and constituted a breach of fiduciary duty. The carrier used an algorithm only for MH/SUD claims to assess progress and refer cases for peer review, which the plaintiffs argued was not in accordance with the plan terms and was more restrictive than the process used for medical/surgical claims.
- **ERISA claims and appeals procedures**. Ensure proper timelines and processes are met. Review claims and appeals decided through AI for fraud, waste, abuse and discrimination. Confirm use of AI is in alignment with plan terms. Even where claim

denials are reviewed and ultimately decided by a clinician, be mindful of the use of algorithms. Consult with counsel on how to mitigate litigation risk. For example, in a recent case the algorithm allegedly allowed the claim administrator's clinicians to automatically deny payments in large batches, evading the physician review process required by state law (and in violation of ERISA's fiduciary duties), and in other cases algorithms were allegedly used to override doctors' recommendations and deny post-acute care.

- **ACA Section 1557 nondiscrimination**. The 2024 final rule issued under the Biden administration includes a ban on discriminatory patient care decision support tools, including those using AI or clinical algorithms. Specifically, the 2024 rule requires that covered entities make reasonable efforts to identify and mitigate discrimination caused by the use of patient care decision support tools. Although portions of the 2024 rule related to gender identity and sex discrimination have been enjoined by courts, provisions of the rule prohibiting the discriminatory use of AI remain in effect. (See *Other ongoing ACA concerns* section.)

  — Identify tools supporting clinical decision-making and review for input variables or factors that measure race, color, national origin, sex, age or disability and assess efforts to mitigate the risk of discrimination from using such tools.

  Example: An algorithm used to target high-risk individuals for additional resources considers costs as a proxy for need. The algorithm may have a racial bias in predicting who needs extra care, since patients of a particular race with the same level of need have lower healthcare costs for various reasons, such as lack of access to care or distrust of the healthcare system. The algorithm falsely concludes that those patients are healthier than equally sick patients who do access care.

Watch for federal legislation, state regulation and litigation to unfold. Consult with legal counsel and apply any new requirements or best practices to employment policies and benefit plans. As federal regulators in the Trump administration work on deregulation, states will likely continue to make laws and develop regulations imposing guardrails on the use of AI in employment, benefits and healthcare. An early version of the One Big Beautiful Bill Act (HR 1) included a ten-year moratorium on state and local AI regulation, but the Senate voted to strike the moratorium from the bill that became law. Monitor cases that continue to challenge the use of AI in health plan administration.

Related resources

Section 6

Health savings account (HSA), health reimbursement arrangement (HRA) and health and dependent care flexible spending arrangements (FSAs) developments

Action

Consider adopting provisions to reinstate and/or permanently allow HSA-qualifying high-deductible health plans (HDHPs) to cover telehealth and other remote care services on a pre- or no-deductible basis. Study whether to add HSA-compatible direct primary care service arrangements (DPCSAs) into a benefit design strategy and monitor IRS guidance for clarification on various unresolved issues related to DPCSAs. Update HSA-qualifying HDHPs, HSAs, excepted-benefit HRAs (EBHRAs) and health FSAs for 2026 indexed dollar limits. Identify pre- or no-deductible health benefits, programs or point solutions that could jeopardize an individual's eligibility to make or receive HSA contributions and confirm strategy. Review IRS guidance that expands the list of preventive care benefits that HSA-qualifying HDHPs may cover on a pre- or no-deductible basis. Evaluate whether to offer fertility benefits through an HRA — either an integrated HRA or an EBHRA (limited to $2,200 for 2026). Determine whether to raise the annual income exclusion for dependent care assistance programs (DCAPs), such as dependent care FSAs (DCFSAs), and monitor impact on nondiscrimination testing. Monitor legislation that would provide safeguards for pre-deductible coverage for chronic disease treatments under HSA-qualifying HDHPs. Follow pending proposed IRS regulations on individual-coverage HRAs (ICHRAs) that could influence benefit strategy and compliance efforts. Review future IRS guidance on the definition of a tax dependent for any impact on account-based health plans.

Specific steps

Consider adopting provisions to reinstate (retroactively to Jan. 1, 2025) and/or permanently allow HSA-qualifying HDHPs to cover telehealth and other remote care services on a pre- or no-deductible basis.

- Permanent relief added under the One Big Beautiful Bill Act (OBBBA, Pub. L No. 119-21, section 71306) allows HSA-qualifying HDHPs to cover telehealth and other remote care services on a pre-deductible or no-deductible basis. Additionally, HSA-eligible individuals may receive such coverage from standalone vendors outside the HDHP without affecting

their eligibility to make or receive HSA contributions. This relief, initially established by the 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act for plan years through Dec. 31, 2021, was renewed in the 2022 Consolidated Appropriations Act (CAA) for April 1 through Dec. 31, 2022, and extended by the 2023 CAA for plan years starting after Dec. 31, 2022, and before Jan. 1, 2025. Although it expired on Jan. 1, 2025, OBBBA retroactively reinstated and made this relief permanent as of that date. Without this provision, HDHP/HSA participants would have been responsible for paying the fair-market value of any pre-deductible telehealth and remote care services not classified as HSA-compatible preventive care. Review plan communications and design related to telehealth coverage to determine if any updates are needed or desired.

- It is anticipated that regulators will clarify outstanding issues including (but not limited to): (i) a definition of the term "other remote care services" and (ii) the scope of ancillary telehealth services that may be covered on a pre- or-no-deductible basis (e.g., post-visit lab testing or prescription drugs prescribed by telehealth provider).

Study whether to add HSA-compatible DPCSAs into a benefit design strategy; monitor IRS guidance for clarification on various unresolved issues related to DPCSAs.

- Effective in 2026, OBBBA (section 71308) provides that enrollment in a DPCSA will not affect an individual's eligibility to make or receive HSA contributions. Furthermore, HSA funds may be used to pay for certain DPCSA fees.
  - A DPCSA is defined as an arrangement that (i) provides medical care consisting solely of "primary care services" delivered by "primary care practitioners," (ii) compensates providers solely with a fixed periodic fee and (iii) limits aggregate fixed fees to $150 per month for an individual or $300 per month if covering two or more individuals, with these amounts indexed annually for inflation.
    - "Primary care services" exclude (i) procedures requiring general anesthesia, (ii) prescription drugs other than vaccines and (iii) laboratory services not typically administered in an ambulatory primary care setting.
    - "Primary care practitioners" is defined by reference to Social Security Act Section 1833(x)(2)(A)(i), which defines that term to mean an individual who is a: (i) physician who has a primary specialty designation of family medicine, internal medicine, geriatric medicine or pediatric medicine or a (ii) nurse practitioner, clinical nurse specialist or physician assistant.
- Outstanding issues requiring clarification include:
  - Whether an HSA-compatible DPCSA can be offered through an employer's on-site clinic
  - Whether DPCSA fees must be paid monthly or if alternative fixed billing periods (e.g., quarterly, annually) are allowed
  - Further details regarding the definition of "primary care services"

Update HSA, HDHP and EBHRA limits for 2026 amounts announced in Rev. Proc. 2025-19 and health FSA limits for 2026 announced in Rev. Proc. 2025-32.

- **HSA annual contribution limits.** The 2026 contribution limits will increase to $4,400 (self-only) and $8,750 (family) — up from $4,300 and $8,550 in 2025. The annual catch-up contribution for individuals ages 55 and older remains $1,000 (not indexed).
- **HDHP in-network out-of-pocket maximums (OOPMs).** The 2026 OOPM will increase to $8,500 (self-only) and $17,000 (family) — up from $8,300 and $16,600 in 2025. HDHPs may set lower — but not higher — caps on in-network OOP expenses. The Affordable Care Act's (ACA's) higher OOPMs ($10,600 for self-only and $21,200 for family coverage in 2026) for nongrandfathered group health plans apply only when an HDHP must embed an ACA individual in-network OOP limit into family HDHP coverage.
- **HDHP minimum annual deductible.** The 2026 minimum deductibles will increase to $1,700 (self-only) and $3,400 (family) — up from $1,650 and $3,300 in 2025.
- **EBHRA annual maximum contribution.** The 2026 maximum annual employer contribution to an EBHRA will increase to $2,200, up from $2,150 in 2025.
- **Health FSA annual salary-reduction contribution limit.** The 2026 salary reduction contribution limit to increase to $3,400, up from $3,300 in 2025.
- **Health FSA carryover limit.** For health FSA plan years starting in 2025, the maximum carryover to the 2026 plan year is $660 (20% of the 2025 salary-reduction contribution limit of $3,300). For health FSA plan years starting in 2026, the maximum carryover to the 2027 plan year is $680 (20% of the 2026 salary-reduction contribution limit of $3,400).

Identify pre- or no-deductible health benefits, programs or point solutions that could jeopardize an individual's eligibility to make or receive HSA contributions and confirm strategy.

- Look broadly at various benefits the employer may provide, including on-site medical clinics, wellness programs, expert medical-opinion services or executive supplemental health benefits. Employers could also offer international and travel health plans and coupons for prescription drugs or manufacturer cost-sharing assistance, in addition to specialized care or disease-management programs. Examples of such programs include diabetes control, genetic tests, sleep apnea treatment, maternity support, fertility and infertility services and behavioral health support.
  - Long-standing IRS guidance (Notice 2024-50, Q/A-10; Notice 2008-59, Q/A-10) permits HSA-qualifying HDHPs to cover pre- or no-deductible preventive care and health benefits that do "not provide significant benefits in the nature of medical care or treatment," such as certain on-site clinics, disease-management programs, wellness programs or employee assistance programs (EAPs).
- IRS Notice 2023-37 makes clear that items and services recommended with an "A" or a "B" rating by the United States Preventive Services Task Force (USPSTF) on or after March 23, 2010, are treated as preventive care for HSA/HDHP purposes, regardless of whether these items must be covered free of cost sharing under the ACA's preventive services mandate.

Review IRS Notice 2024-75 that expands the list of preventive care benefits that HSA-qualifying HDHPs may — but don't have to — cover on a pre- or no-deductible basis; consider whether to make any corresponding plan changes.

- **Over-the-counter (OTC) oral contraceptives and emergency contraception.** Preventive care for HSA-qualifying HDHPs includes OTC oral contraceptive benefits for covered individuals potentially capable of becoming pregnant. These contraceptives include but are not limited to OTC birth control pills (Opill) and emergency contraception (levonorgestrel), regardless of whether purchased with a prescription.
  - The 2020 CARES Act permits — but does not require — HRAs and health FSAs to reimburse the costs for OTC drugs purchased without a prescription. HSAs likewise may reimburse the costs of OTC drugs purchased without a prescription, such as Opill, on a tax-free basis.
- **Male condoms.** Preventive care for HSA-qualifying HDHPs includes all benefits for male condoms purchased with or without a prescription and regardless of the gender of the HDHP-covered individual who purchases them. Notice 2024-71 separately provides a safe harbor to treat amounts paid for male condoms as an Internal Revenue Code (IRC) Section 213(d) medical expense. This notice, as well as the expansion of the Health Resources and Services Administration (HRSA) women's preventive services guidelines to encompass male condoms, supersedes the guidance on male condoms in Notice 2018-12.
- **Breast cancer screening.** Preventive care for HSA-qualifying HDHPs includes not just mammograms (like ACA-mandated preventive services) but also breast cancer screening using magnetic resonance imaging, ultrasounds and similar screening services. This updates and clarifies the HDHP preventive care safe harbor in Notice 2004-23.
- **Continuous glucose monitors (CGM).** Preventive care for HSA-qualifying HDHPs includes all benefits for CGMs that measure glucose levels using a similar detection method or mechanism to other glucometers (i.e., by piercing the skin). If a CGM has additional medical or nonmedical functions, they would need to qualify as preventive care (with the exception of minor functions, such as clock and date functions) for an HDHP to cover the CGM on a pre- or no-deductible basis. A CGM that both monitors and provides insulin may be treated as preventive care because it is a device for delivering insulin. Smartwatches or smart rings that do not pierce the skin and are intended to measure or estimate blood glucose values are not preventive care for this purpose.
- **Insulin.** Preventive care for HSA-qualifying HDHPs includes benefits for "selected insulin products," whether prescribed to treat an individual diagnosed with diabetes or to prevent the exacerbation of diabetes or the development of a secondary condition. Selected insulin products mean any dosage form (such as vial, pump or inhaler dosage forms) of any different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting and premixed) of insulin.

Evaluate whether to offer fertility benefits through an HRA. Many employers and other plan sponsors already offer fertility benefits through an integrated HRA, and new guidance confirms that an EBHRA (limited to $2,200 for 2026) may reimburse an employee's out-of-pocket costs with respect to fertility benefits. Recent guidance confirms the ability of EBHRAs to reimburse fertility benefits, however, there may be

advantages to offering such benefits through an integrated HRA instead. Most notably, the EBHRA has an annual dollar limit for employer contributions, while the integrated HRA does not. Additionally, employees in an integrated HRA must participate in a traditional group health plan, while participants in an EBHRA must be offered, but do not need to be enrolled in, other traditional group health plan coverage that typically covers additional qualified medical expenses like clinical or laboratory expenses or even prenatal care and labor/delivery. Following is a brief comparison:

- **Integrated HRA with a group health plan providing ACA-defined minimum value (MV).** A plan sponsor pairing an integrated HRA with a group health plan providing MV (as defined in IRC Section 36B(c)(2)(C)(ii)) must satisfy these requirements:
  - Offer a group health plan to HRA-eligible employees that provides MV.
  - Make the HRA available only to employees who are actually enrolled in a group health plan that provides MV (either the employer's group health plan or another group health plan, such as the spouse's plan).
  - Limit reimbursements to IRC Section 213(d) medical expenses; however, reimbursement for individual health insurance coverage is not allowed unless that insurance is for excepted benefits (like dental or vision). Certain fertility expenses may not be qualified medical expenses.
  - Give employees at least an annual opportunity to permanently opt out of and waive future reimbursements from the HRA.
  - At termination of employment, give former employees an opportunity to permanently opt out of and waive future reimbursements from the HRA if their balance is not automatically forfeited (plan sponsor discretion).
  - If the HRA is *integrated with an group health plan that does **not** provide MV* then reimbursements under the HRA are limited to one or more of the following: copays, coinsurance, deductibles and premiums under the non-HRA group health plan, as well as IRC Section 213(d) medical expenses that do not constitute essential health benefits.
- **EBHRA.** A plan sponsor offering an EBHRA (limited to $2,200 for 2026, indexed) must satisfy the following requirements:
  - Offer a traditional group health plan that is not limited to excepted benefits to EBHRA-eligible employees; however, enrollment in that traditional group health plan is not required.
  - Make the HRA available on the same terms and conditions to all similarly situated employees, regardless of health factors (e.g., infertility).
  - Amounts available to the participant in any other HRA offered by the plan sponsor must be aggregated with the EBHRA in determining whether the annual dollar limit for employer contributions ($2,200 for 2026) is met. Carryover amounts, if allowed by the plan sponsor, are disregarded in determining the annual benefit limit. Additionally, HRAs that reimburse only expenses for excepted benefits (like dental or vision) aren't aggregated.

  - Reimbursements are limited to IRC Section 213(d) medical expenses such as copays, coinsurance, deductible or expenses not covered by a traditional group health plan. Certain fertility expenses may not be qualified medical expenses.
  - Reimbursements can't be made for premiums for individual or group health plan coverage (other than COBRA or other continuation coverage or excepted benefits) or Medicare.

Determine whether to raise the annual income exclusion for DCAPs, such as DCFSAs; monitor impact on nondiscrimination testing.

- **Increased dependent care assistance programs (DCAPs) annual income exclusion.** Starting in 2026, OBBBA (section 70404) permanently increases the annual income exclusion for DCAPs under IRC Section 129, which covers employee pretax contributions to DCFSAs and employer-subsidized childcare expenses, including onsite daycare centers. The exclusion amount rises from $5,000 to $7,500, and from $2,500 to $3,750 for married individuals filing separately. These limits are not indexed for inflation.
- **Enhanced child and dependent care tax credit.** Beginning in 2026, OBBBA (section 70405) permanently expands the dependent care tax credit (non-refundable) under IRC Section 21, enhancing its benefits for eligible taxpayers. The maximum applicable percentage of dependent care expenses increases from 35% to 50%. The credit gradually phases down from 50% for individuals with an Adjusted Gross Income (AGI) over $15,000 to 35% for those with AGI between $43,001 and $75,000. It then further phases down from 35% to 20% for individuals with AGI above $75,000 ($150,000 for joint filers), leveling off at 20% for those with AGI exceeding $103,000 ($206,000 for joint filers). The maximum eligible dependent care expenses remain unchanged at $3,000 for one qualifying individual and $6,000 for two or more qualifying individuals.
- **Impact on DCFSA nondiscrimination testing.** For employers that have historically had difficulty passing the 55% average benefits nondiscrimination test for DCFSAs, increasing the contribution limit could make compliance more challenging, as higher contributions are typically made by highly compensated employees (HCEs). This test requires that the average benefits provided to non-HCEs be at least 55% of the average benefits provided to HCEs — generally defined for 2026 testing as employees earning over $160,000 in 2025 — across all DCAPs offered by the employer. If the test is not satisfied, all benefits paid to or received by HCEs become taxable. Furthermore, the enhanced dependent care tax credit (as described above) may encourage more non-HCEs to claim the credit instead of participating in the employer's DCFSA, which could further complicate efforts to meet the 55% average benefits test.

Monitor legislation that would provide safeguards for pre-deductible coverage for chronic disease treatments under HSA-qualifying HDHPs.

- House-passed legislation (HR 919) would statutorily enshrine the current flexibility that HSA-qualifying HDHPs have under IRS guidance (Notice 2019-45) to cover chronic disease treatments before employees meet their deductibles. Currently, these plans can cover 14 critical chronic care services pre-deductible, such as beta-blockers for heart failure, blood pressure monitors for hypertension, glucometers for diabetes and inhalers for asthma. The bill also permits updates to the preventive care list over time to maintain access to new and evolving treatments.

Monitor pending proposed IRS regulations on ICHRAs that could influence benefit strategy and compliance efforts. Review future IRS guidance on the definition of a tax dependent for any impact on account-based health plans.

- **ICHRAs.** IRS anticipates finalizing by May 2026 regulations detailing how ICHRAs interact with ACA's employer shared-responsibility (ESR) requirements and the nondiscrimination rules for self-funded group plans under IRC Section 105(h). For now, employers may rely on the 2019 proposed regulations. Employers offering or considering ICHRAs should monitor whether IRS issues new final rules on how an employer offering ICHRAs can avoid ESR assessments. (See *Other ongoing ACA concerns* section.)
- **Tax dependents.** IRS anticipates finalizing by May 2026 IRS rules (proposed in 2017) clarifying the definition of tax dependent under IRC Section 152. Review these rules once issued for any impact on HRA, HSA or health FSA reimbursements.

Related resources

Section 7

ACA preventive services

Action

Update a nongrandfathered group health plan's preventive services covered without cost sharing for the latest Affordable Care Act (ACA) guidance and any new or revised recommendations from the US Preventive Services Task Force (USPSTF), the Health Resources & Services Administration (HRSA) and the Advisory Committee on Immunization Practices (ACIP). Review guidance addressing coverage of pre-exposure prophylaxis (PrEP) HIV medications and confirm that your third-party administrator (TPA) and/or pharmacy benefits managers (PBMs) have updated their claims processing systems to comply. Monitor ongoing litigation and administrative/regulatory actions that might modify or rescind some of the ACA-mandated preventive services and consider whether the group health plan might continue no-cost coverage of particular preventive services if current recommendations change. Update official plan documents, summary plan descriptions (SPDs), summaries of benefits and coverage (SBCs) and other materials as needed.

Specific steps

Update a nongrandfathered group health plan's preventive services covered without cost sharing for the latest ACA guidance and any new or revised recommendations from USPSTF, HRSA and ACIP.

- Coverage generally must conform for plan years that begin on or after the one-year anniversary of the date when the preventive care recommendation or guideline was issued or updated. However, nongrandfathered group health plans must "immediately" cover any newly approved or authorized COVID-19 vaccine and associated administrative costs.
- USPSTF recommendations or guidelines are considered issued on the last day of the month in which they are released or published. The issuance date of an ACIP recommendation or guideline is considered to occur when adopted by the director of the Centers for Disease Control and Prevention (CDC). A HRSA recommendation or guideline is deemed issued once accepted by the HRSA administrator or, if applicable, adopted by the secretary of the Department of Health and Human Services (HHS).
  - If an "A" or "B" USPSTF recommendation is downgraded to a "C," or if an ACIP recommendation is rescinded, coverage without cost sharing of the service must continue through the end of the plan year.
  - Plans may immediately eliminate no cost-sharing coverage of a particular preventive service during the plan year if (i) an "A" or "B" recommendation is downgraded to a "D," or (ii) the item/service is subject to a safety recall or poses a significant safety concern, as determined by a federal agency with regulatory authority.

Add or update no-cost in-network coverage of preventive services with a USPSTF A or B recommendation issued in 2024 and effective Jan. 1, 2026, for calendar-year plans, and for updated HRSA women's preventive services guidelines. For noncalendar-year plans, the USPSTF recommendation effective dates could be the plan year beginning in 2025 or 2026, depending on when the plan year starts relative to the date USPSTF issued the recommendation. The HRSA's updated guidelines are effective for plan years beginning in 2026.

- **Biennial breast cancer screening for women ages 40–74.** Screen for breast cancer (mammography) biennially for women ages 40–74. This recommendation updates the January 2016 USPSTF recommendation that required coverage of biennial screening mammography for women ages 50–74. The 2016 recommendation individualized the decision to undergo screening for women ages 40–49 to consider factors like individual risk and personal preferences and values. Current evidence remains insufficient to assess the balance of benefits and harms of screening mammography in women ages 75 or older. While USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of supplemental screening for breast cancer using breast ultrasonography or magnetic resonance imaging (MRI), these other types of breast cancer screening are included in the updated HRSA's women's preventive services guidelines as described below. (USPSTF, issued April 2024.)
  - *HRSA's women's preventive services guidelines* continue to recommend "women at average risk of breast cancer initiate mammography screening no earlier than age 40 years and no later than age 50 years" and then "at least biennially and as frequently as annually." Additionally, the HRSA updated guidelines specify that if women require additional imaging — such as MRI, ultrasound or mammography — to complete the screening process or to follow up on findings from the initial screening mammogram, these services, along with any necessary pathology evaluations, are recommended to complete the screening for malignancies. Additionally, the HRSA updated guidelines recommend patient navigation services for breast and cervical cancer screening and follow-ups to increase utilization of screening rates. Patient navigation services involve individualized person-to-person (e.g., in-person, virtual, hybrid models) contact with the patient. Services include person-centered assessment and planning, healthcare access and health system navigation, referrals to appropriate support services (e.g., language translation, transportation and social services) and patient education. As a result, the additional imaging screenings, pathology evaluations and patient navigation services must be covered without any cost sharing for plan years beginning in 2026.
  - On a related note, regulators clarified that Women's Health and Cancer Rights Act (WHCRA) coverage protections for mastectomy-related breast reconstructive surgery includes coverage for chest wall reconstruction with aesthetic flat closure, if elected by the patient in consultation with the attending physician. Under WHCRA, plans and issuers may impose cost sharing for these benefits only if those cost-sharing requirements are deemed appropriate and are consistent with cost sharing established for other benefits under the plan.
- **Fall-prevention intervention for community-dwelling adults ages 65 or older.** Offer exercise interventions to prevent falls in community-dwelling adults ages 65 or older at increased risk for falls. This recommendation replaces but remains generally consistent with one from 2018, except that the current recommendation does not address the use of

vitamin D to prevent falls (this evidence will be reviewed in a separate USPSTF recommendation currently in progress). (USPSTF, issued June 2024.)

- **Behavioral interventions for children and adolescents ages 6 or older with a high body mass index (BMI).** Provide comprehensive, intensive behavioral interventions for children and adolescents ages 6 or older with a high body mass index (BMI) (≥95th percentile for age and sex). This recommendation updates one from 2017 on obesity screening for children and adolescents ages 6 or older. The current recommendation does not include use of pharmacotherapy (i.e., phentermine/topiramate, semaglutide and liraglutide) due to inadequate evidence of the benefits. (USPSTF, issued June 2024.)
- **Intimate partner and domestic violence screening and counseling.** Screen adolescent and adult women for intimate partner and domestic violence, at least annually, and, when needed, provide or refer to intervention services. Intimate partner and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect and the threat of violence, abuse or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies and appropriate supportive services. In the current recommendation, HRSA updates its terminology from 'interpersonal' to 'intimate partner.' Aside from this change, the recommendation remains generally consistent with the previous one. (HRSA, issued Dec. 2024.)

Prepare to add or update no-cost in-network coverage of preventive services with a USPSTF A or B recommendation issued in 2025 and effective Jan. 1, 2027, for calendar-year plans. For noncalendar-year plans, the effective date could be the plan year beginning in 2026 or 2027, depending on when the plan year starts relative to the date USPSTF issues the recommendation.

- **Osteoporosis screening for women ages 65 years and older and postmenopausal women ages 40–64 years who are at increased risk for an osteoporotic fracture.** Screen for osteoporosis to prevent osteoporotic fractures in women ages 65 and older and postmenopausal women ages 40–64 years who are at increased risk for an osteoporotic fracture as estimated by clinical risk assessment. This recommendation updates one from 2018. In 2018, the USPSTF recommended screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures, as determined by a formal clinical risk assessment tool. In the current recommendation, USPSTF recommends that screenings can include DXA BMD, with or without fracture risk assessment, in addition to bone measurement testing. Aside from this change, the recommendation remains generally consistent with one from 2018. Current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men. (USPSTF, issued Jan. 2025.)
- **Breastfeeding primary-care counseling interventions for pregnant and postpartum women.** Provide interventions or referrals during pregnancy and after birth to support breastfeeding. This recommendation updates but remains consistent with one from 2016. (USPSTF, issued April 2025.)
- **Syphilis infection screening for pregnant women.** Screen for syphilis infection during pregnancy; if someone is not screened early in pregnancy, screen at the first available opportunity. This recommendation reaffirms one from 2018. (USPSTF, issued May 2025.)

- **Intimate partner violence (IPV) screening for women of reproductive age, including those who are pregnant and postpartum.** Screen for IPV in women of reproductive age, including those who are pregnant and postpartum. Provide or refer women who screen positive for evidence-based interventions that include multiple components and ongoing support to ongoing support services. Current evidence remains insufficient to assess the balance of benefits and harms of screening for caregiver abuse and neglect in older or vulnerable adults. This recommendation updates but is consistent with one from 2018. (USPSTF, issued June 2025.)
- **Any additional preventive services recommended during 2025.** If additional preventive service recommendations come out in November or December 2025, ensure noncalendar-year plans comply by the applicable 2026 or 2027 effective date and calendar-year plans comply by Jan. 1, 2027.

Check ACIP's list of vaccines and the updated CDC immunization schedules to determine whether the plan must add or amend the types of vaccines that must be covered without cost sharing.

- **COVID-19 vaccine for all individuals ages 6 months and older**. Provide the COVID-19 vaccine, using shared clinical decision-making, for the recommended population. Under the previous ACIP recommendation, the vaccine was "routine" for most children ages 6 months–17 years and adults ages 18 and older, including pregnant women.
  - *Overall vaccine uptake may be reduced.* Shared clinical decision-making means that the decision to vaccinate is individualized and may be based on a provider's recommendation. A provider is anyone who provides or administers vaccines (primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses and pharmacists). The change from routine vaccine to shared clinical decision-making may increase the number of associated provider visits (and thus plan costs) for those getting the vaccine, and in turn, may increase employee absenteeism and lead to fewer people getting the vaccine.
  - *Access to COVID vaccines may be more difficult than before.* Ease of access at pharmacies depends in part on where one lives, as not all states allow pharmacists to administer shots that aren't routine without a prescription. For example, in some states the pharmacist may require a prescription to administer the shot to a child and confirmation of an underlying condition for adults, while a prescription may be required in other states for anyone seeking the shot.
  - *Claim administration for COVID shots may be more challenging.* If plan members seek advice from providers about the shot, these encounters must be covered without cost sharing. Consultation with carriers, TPAs and PBMs is recommended to understand the claims administration process and medical coding requirements to ensure these claims are properly adjudicated as preventive. Importantly, a group health plan can't deny a COVID vaccine claim simply because there isn't a prescription or an accompanying provider encounter claim.
- **Measles, mumps, rubella and varicella (chickenpox)**. Vaccination against measles, mumps, rubella (MMR) and varicella (V) is typically administered to children in 2 doses: the first between ages 12–15 months and the second between ages 4–6 years. Updated recommendation is to provide separate MMR and V vaccines for the first dose in children

ages 12–47 months; MMRV is still an option for the second dose. Under the previous recommendation, the recommendation was for separate MMR and V vaccines for the first dose in children ages 12–47 months, but combined MMRV could have been used if preferred by parents or caregivers.

Review guidance addressing coverage of pre-exposure prophylaxis (PrEP) HIV medications and confirm that your TPA and/or PBM have updated their claims processing systems to comply.

- Triagency guidance reiterates the requirement for nongrandfathered group health plan to cover three formulations of PrEP HIV medication — *Truvada* (daily pill), *Descovy* (daily pill) and *Apretude* (every-other-month injectable) — plus related baseline and monitoring services without cost sharing. There is also a generic version of Truvada available.
  - Plans can cover a generic without cost sharing and subject the brand version to cost sharing only if cost sharing is waived when the generic is inappropriate for an individual. But medical management techniques can't favor one formulation over another, and are only permitted if frequency, method, treatment or setting is unspecified in the USPSTF recommendation.
- Absent further guidance, or another update to the most recent USPSTF recommendation on PrEP, group health plans are not required to cover *Yeztugo*, a recently FDA-approved twice-a-year injectable, without cost sharing.

Monitor ongoing litigation and administrative/regulatory actions that might modify or rescind some of the ACA-mandated preventive services and consider whether the group health plan might continue no-cost coverage of particular preventive services.

- ***Kennedy v. Braidwood Management Inc.*** As background, in June 2025, the US Supreme Court ruled that the USPSTF was properly appointed under the US Constitution by the HHS Secretary and has authority to make preventive service recommendations. The *Braidwood* case also confirmed the HHS Secretary's authority to remove current USPSTF members and appoint new ones. As a result, nongrandfathered group health plans must continue to cover all USPSTF-recommended A and B items and services, as well as ACA-mandated ACIP recommendations and HRSA women's preventive services without cost sharing. The case is still pending, however, as a challenge to the authority of ACIP and HRSA preventive service recommendations is still under review by the lower courts. The outcome of this case and the resulting group health plan implications are uncertain. In the interim, the ACIP and HRSA coverage requirements remain in effect.
  - The district court had ruled that mandatory cost-free coverage of ACIP- and HRSA-recommended preventive services recommendations (which include women's contraception) is constitutional as the HHS secretary has the authority to ratify those recommendations. Nevertheless, the appeals court sent this issue back to the district court for further consideration to determine whether the HHS secretary has, in fact, ratified those recommendations. The district court also ruled that mandatory coverage of PrEP HIV medications without cost sharing cannot be enforced on some plaintiffs if this requirement violates their Religious Freedom Restoration Act (RFRA) rights. These issues were not addressed by the US Supreme Court.
  - States could — and some already do — require fully insured plans to cover the same or a similar set of preventive services without cost sharing.

- The HHS Secretary has replaced members of ACIP, and more changes are possible.

Update official plan documents, SPDs, SBCs and other materials as needed.

Related resources

Section 8

Other ongoing ACA concerns

Action

Review planned 2026 benefits against employer shared-responsibility (ESR) standards, including minimum essential coverage (MEC) for Affordable Care Act (ACA) full-time employees and the affordability and minimum value of health coverage. Ensure the adequacy of ESR and MEC recordkeeping and reporting, and consider revisions to take advantage of reporting relief legislation. Review plan design for compliance with ACA benefit mandates and market reforms. Consider whether to modify or implement benefits or update communications based on recent developments related to noncoordinated excepted benefits. Continue to monitor the impact of ACA Section 1557's prohibition on discrimination on the basis of race, color, national origin, sex, age or disability. Continue to calculate and pay the Patient-Centered Outcomes Research Institute (PCORI) fee for self-funded group health plans, including certain health reimbursement arrangements and retiree-only plans. Prepare for continued medical loss ratio (MLR) rebates if sponsoring a fully insured group health plan. Continue to provide summaries of benefit coverage (SBCs) and ACA claims and appeals notices in a culturally and linguistically appropriate manner, consistent with updated guidance. Monitor legislation and regulations expected to reduce ACA marketplace and Medicaid enrollment, and consider potential impact on employer-sponsored group health plans.

Specific steps

Review planned 2026 benefits against ESR standards, including MEC for ACA full-time employees and the affordability and minimum value of health coverage.

- **Affordability.** Evaluate required employee contributions for the lowest-cost, self-only option against the 2026 affordability percentage and the employer affordability safe harbors. For 2026, the ESR-required contribution percentage will increase significantly to 9.96%, up from 9.02% in 2025.
  - *2026 calendar-year plans.* The maximum monthly 2026 employee contribution for the lowest-cost, self-only option for employers using the federal poverty line (FPL) affordability safe harbor will increase to $129.90 (up from $113.20 in 2025), calculated as (9.96% x $15,650 FPL for 2025) ÷ 12, rounded to the nearest penny. Note that the FPL affordability safe harbor contribution limits are greater for employees who work in Alaska ($162.27, calculated as (9.96% x $19,550 FPL for 2025) ÷ 12), and Hawaii ($149.32, calculated as (9.96% x $17,990 FPL for 2025) ÷ 12).
  - *Noncalendar-year plans beginning in 2026.* Noncalendar-year plans may use the FPL in effect within six months before the first day of the plan year. If the 2026 FPL is issued in January, noncalendar-year plans starting in February to July 2026 may use either the 2025 FPL of $15,650 for mainland US — resulting in an FPL affordability safe harbor of $129.90 per month — or the 2026 FPL. (If the 2026 FPL is issued in

February, noncalendar-year plans starting in March to August 2026 would have that same choice.) These noncalendar-year plans would likely benefit from waiting to use the 2026 FPL since it will almost certainly exceed the 2025 FPL and yield a higher FPL safe harbor contribution limit, calculated as (9.96% x 2026 FPL) ÷ 12. However, depending on when the 2026 plan year starts and the 2026 FPL is issued, waiting for the 2026 FPL may not be possible. Note: Noncalendar-year plans beginning in 2025 using the mainland US FPL continue to use $117.64, calculated as (9.02% x $15,650 FPL in 2025) ÷ 12, as the FPL safe harbor amount until their new 2026 noncalendar-year plan starts.

- **Minimum value.** Evaluate whether the plan satisfies the ACA's minimum-value standards. To meet minimum value, a plan's share of the total costs for covered benefits must equal — on an actuarial basis — at least 60% of the cost for a typical self-funded group health plan. A plan also fails to satisfy the minimum-value standards if it doesn't provide substantial coverage of inpatient hospital services and physician services, despite otherwise satisfying the minimum-value 60% test.
  - Employers offering plans that do *not* meet minimum-value standards (such as plans that cover only preventive services or other "skinny" benefits that do not pass the minimum-value 60% test) should periodically review whether such coverage serves strategic goals and review all plan communications with counsel to ensure that employees and their dependents understand the coverage (and its limits). Biden administration regulators expressed concern that employees might mistake such plans, especially when combined with a fixed-indemnity program, for comprehensive medical coverage. They intended to address this issue in future rulemaking as current rules do not prohibit this type of combined offering.
- **Assessments.** IRS guidance sets the 2026 ESR assessments as follows:
  - $3,340 (up from $2,900 in 2025) per ACA full-time employee for employers that do not offer MEC to at least 95% of ACA full-time employees (and their dependents), if at least one of those employees receives federally subsidized coverage through the ACA marketplace
  - $5,010 (up from $4,350 in 2025) per ACA full-time employee receiving federally subsidized coverage through the ACA marketplace because the employee wasn't among the 95% of ACA full-time employees who were offered employer MEC or who received an offer of employer MEC that was unaffordable or less than minimum value

Ensure the adequacy of ESR and MEC recordkeeping and reporting, and consider revisions to take advantage of reporting relief legislation. The Paperwork Burden Reduction Act (H.R. 3797) and the Employer Reporting Improvement Act (H.R. 3801), both enacted on Dec. 23, 2024, reduce employers' reporting obligations starting with the 2024 reports.

- **Prepare to furnish individual statements on health coverage and/or offers of coverage to ACA full-time employees (Forms 1095-B and 1095-C).**
  - *Final IRS regulations permanently allow a 30-day automatic extension of the Jan. 31 deadline to March 2 (March 1 in leap years) for furnishing ACA individual statements.* This means that reporting for 2025 will be due March 2, 2026. IRS will not grant additional extensions.

- *The Paperwork Burden Reduction Act permits employers to furnish Forms 1095-B and C to **all** employees and covered individuals by posting specific information on the employer's website.* (This alternative manner of furnishing statements was previously available only for nonemployees and employees not considered full-time under the ACA.) The Paperwork Burden Reduction Act and relevant IRS guidance specify that employers must post a clear, conspicuous and accessible notice on the employer's website stating that any individual may receive a copy of a form (paper, or electronic if consent is provided) upon request.
    - The notice must contain an email and postal address for requests, and a telephone number for questions.
    - The notice must be written in plain, nontechnical terms, and must be in sufficiently large font (including visual clues or graphics) to flag that the information relates to individual health coverage tax statements.
        - An example of a clear, conspicuous and accessible notice: A statement on the main webpage (or a secondary webpage linked to the words "Tax Information" on the main webpage) in capital letters that says, "IMPORTANT HEALTH COVERAGE INFORMATION," and provides guidance on how an individual may request a copy of their Form 1095-B or C.
    - The website notice must be retained until Oct. 15 of the year after the calendar year to which the statement relates.
    - Employers must respond to requests for forms by the later of Jan. 31 of the year following the calendar year of the applicable report, or 30 days after the date of the request.
- *Employers may, if they wish, continue to furnish the forms directly to individuals by previously available methods — by mail, in-person delivery or electronically with the individual's consent.* The Employer Reporting Improvement Act codifies and eases current MEC and ESR electronic delivery rules by specifying that an individual has consented to electronic delivery by affirmatively consenting at any prior time, and such consent lasts until it is revoked in writing.

- **Prepare to file Forms 1094-B or C with the IRS.** IRS regulations (as corrected) require electronic filing (due by March 31, 2026, for the 2025 year) for any entity filing 10 or more information returns with the IRS. This threshold is determined by aggregating Forms 1094, 1095 and W-2, among others.
- **Ensure that reporting is complete and accurate.** Transitional relief for certain good-faith filings ended after 2020. However, for reporting and information returns that must be filed or furnished after Jan. 1, 2024, IRS regulations establish a safe harbor for de minimis errors in dollar amounts (generally less than $100), subject to specific requirements.
- **Review process to collect Taxpayer Identification Numbers (TINs) of covered individuals.** The Employer Reporting Improvement Act allows reporting entities to substitute any covered individual's date of birth for their TIN for purposes of reporting MEC (i.e., Forms 1095-B and Part III of Form 1095-C) if the reporting entity is unable to collect the individual's TIN. Guidance confirming that the Employer Reporting

Improvement Act replaces the existing rule, which generally requires three attempts to solicit the TIN, would be helpful.

- **Check for reporting errors that can result in inaccurate ESR assessments.** The Treasury Inspector General for Tax Administration (TIGTA) found that employer reporting errors cause most adjustments to proposed ESR assessments. Some employers have made the same reporting error multiple years in a row. The most common mistake leading to a revised assessment has involved reporting on Form 1094-C that the employer did not offer MEC to at least 95% of ACA full-time employees (and their dependents) when the employer actually did satisfy that threshold.
- **Address any Form 1094-C or 1095-C reporting deficiencies identified in an initial IRS Letter 226-J, and correct prior-year reports as necessary.**
  - The Employer Reporting Improvement Act gives applicable large employers at least 90 days (instead of the 30 days previously available) to respond to proposed ESR assessments (via Letter 226-J) after Dec. 31, 2024, for alleged ESR violations.
  - Litigation could result in changes to the Letter 226-J process. The IRS uses Letter 226-J to inform employers that they may be liable for an ESR assessment. In particular, the letter is used to satisfy the ACA Section 1411 certification requirement (42 USC § 18081). A district court rejected the IRS Letter 226-J process in *Faulk Company, Inc. v. HHS*, No. 4:24-cv-00609 (N.D. Tex. April 10, 2025), and it is not yet clear whether the Trump administration will pursue its appeal to the Fifth Circuit.
- **Review recordkeeping practices with counsel.** The Employer Reporting Improvement Act establishes a six-year statute of limitations on ESR assessments. (Previously, the IRS had concluded that no statute of limitations applies to ESR assessments.)
- **Determine whether any additional information is required to fulfill state reporting obligations.** Check for guidance from jurisdictions (California, New Jersey, Rhode Island and Washington, DC) that have their own individual mandates and disclosure/reporting requirements and that allow employers and plan sponsors to use Form 1095 (and Form 1094) on whether the Paperwork Burden Reduction Act reporting relief is applicable for state and local purposes. (See *State-mandated paid leave and other state law trends* section.)
- **Continue to collect information for 2026 reports due in 2027.** Confirm the appropriate measurement method — lookback or monthly — is used to identify ACA full-time employees.

Review plan design for compliance with ACA benefit mandates and market reforms. Group health benefits should continue to comply with ACA benefit mandates and market reforms, such as the ban on lifetime and annual dollar limits for essential health benefits (EHBs), required first-dollar coverage of specified preventive services (see *ACA preventive services* section), patient protections for emergency services and annual in-network out-of-pocket maximums (OOPMs) for EHBs. The Centers for Medicare and Medicaid Services (CMS) updated the 2026 OOPM to $10,600 for self-only and $21,200 for other than self-only

coverage in 2026, superseding an earlier announcement that 2026 OOPMs would be $10,150 for self-only and $20,300 for other coverages.

- **EHBs.** While self-funded and large insured group health plans are not required to cover EHBs, covered EHBs can't have lifetime or annual dollar limits, and cost-sharing for any covered EHBs must count towards the in-network OOPM. Self-funded and large insured group health plans select a state benchmark plan for purposes of identifying which covered items or services are —or are not — EHBs. Sponsors of self-funded and large insured group health plans that apply dollar limits to non-EHBs, or don't count non-EHB expenditures toward the ACA in-network OOPM, should monitor changes to their state benchmark plans, including federal guidance that would change what is (or is not) an EHB.

  - *Gender-affirming care.* A CMS *2025 Marketplace integrity final rule* (CMS marketplace integrity rule) prohibits insurers from classifying certain gender-affirming care as an EHB starting with the 2026 plan year, even if such coverage is mandated by a state for its insured plans. The rule applies to "specified sex-trait modification procedures," defined as pharmaceutical or surgical interventions to align an individual's physical appearance or body with an asserted identity different from their sex. Twenty states have challenged this provision in federal court.

  - *Dental services.* CMS is permitting states to update their benchmark plans to include routine nonpediatric dental services, effective for the 2027 plan year.

  - *Prescription drugs.* The Trump administration has not announced whether it will issue guidance requiring self-funded and large insured group health plans to treat *all* covered prescription drugs as EHBs, as the Biden administration intended to do. Such a rule would ban certain industry programs — "copay maximizers" — that rely on reclassifying specified high-cost covered drugs as non-EHBs so plans can exclude participant cost sharing from accumulating toward the ACA OOPM and impose annual/lifetime dollar limits on high-cost non-EHB drugs. (A 2024 rule from CMS requires that nongrandfathered individual and small group market plans treat all covered drugs beyond a state benchmark plan as EHBs and accumulate participant cost sharing for all covered drugs to the ACA OOPM.) Nor does guidance appear imminent that would address whether drug manufacturer financial assistance (e.g., coupons) is ACA "cost sharing," since the Trump administration marked this for long-term action. The Biden administration intended to address this issue through rulemaking — as promised in a court filing after a court vacated a rule finalized during President Trump's first term in office. Such guidance could impact the viability of "copay accumulator programs," which allow plans to not apply drug manufacturer assistance toward the ACA OOPM. (See *Prescription drugs* section.)

- **Grandfathered plans.** Grandfathered plans do not have to meet a number of ACA benefit mandates and market reforms (such as the annual in-network OOPM and the required first-dollar coverage of preventive services). Employers that want to continue sponsoring grandfathered plans should ensure compliance with the requirements for preserving grandfathered status. Agency FAQs confirm that reversing benefit enhancements related to COVID-19 testing, diagnosis and treatment or expanded telehealth and other remote care services after the COVID-19 emergencies ended does not jeopardize a plan's grandfathered status. Plans that continued such enhancements beyond the emergency periods should also be able to reverse course without losing

grandfathered status — as long as the reversal doesn't affect the benefits and cost sharing in place in 2010.

Consider whether to modify or implement benefits or update communications based on recent developments related to noncoordinated excepted benefits. Group health plans qualifying as excepted benefits are exempt from many federal requirements, including certain ERISA and ACA benefit mandates and insurance market reforms such as the prohibition on annual or lifetime dollar limits on EHBs and coverage of ACA-mandated preventive services without cost-sharing. One category of excepted benefits—noncoordinated benefits—includes specified disease or illness (such as a cancer-only policies) or group hospital or other fixed-indemnity insurance if it satisfies each of the following conditions:

- The benefits are provided under a separate policy, certificate or contract of insurance (i.e., the benefits cannot be self-funded)
- The provision of benefits isn't coordinated with exclusions in other group health plan benefits provided by the same employer
- The program pays benefits with respect to an event regardless of whether other group health plan coverage provided by the same employer pays for benefits with respect to the same event
- The insurance pays a fixed dollar amount per day (or other period) of hospitalization or illness, regardless of the amount of expenses incurred *(Note: This applies only to group hospital or other fixed-indemnity insurance; specified disease or illness insurance is not required to pay a fixed dollar amount on a periodic basis.)*

- **Consider whether to offer fertility benefits as a noncoordinated excepted benefit.** In response to an executive order (EO) seeking policy recommendations to reduce costs for *in vitro* fertilization treatment, the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) issued ACA implementation FAQs part 72 to clarify the existing categories of excepted benefits that employers can use to offer fertility benefits as a standalone benefit. Specifically, an employer may offer fertility benefits through a specified disease or illness policy or fixed-indemnity insurance if it satisfies the requirements listed above. The FAQs also clarify that self-funded fertility benefits cannot qualify as noncoordinated excepted benefits under current regulations. Additionally, the FAQs state that coverage under specified disease or illness insurance does not jeopardize an otherwise health savings account (HSA)-eligible individual's ability to make or receive HSA contributions. It is important to note employers may continue to offer fertility benefits coverage as part of their comprehensive group health plan (whether self-funded or fully insured), either as a covered benefit or through an integrated health reimbursement arrangement, without satisfying the excepted benefit rules.
- **Other categories of excepted benefits to cover fertility benefits.** FAQs part 72 also identify other excepted benefit categories employers could use to offer fertility benefits.
  - *Employee assistance programs (EAP)*. Employers may cover coaching and navigator services to help individuals understand fertility options as part of an excepted benefit EAP, provided that the EAP satisfies other applicable standards to maintain excepted benefit status (i.e., not coordinating with benefits under another group health plan, not charging employees premiums or contributions, and not imposing cost sharing). An

EAP offering fertility benefits that are "significant benefits in the nature of medical care" would not qualify as an excepted benefit (for this purpose, the amount, scope and duration of covered services are taken into account).

- *Excepted-benefit health reimbursement arrangement (EBHRA).* An employer may also sponsor an EBHRA to reimburse an employee's out-of-pocket fertility expenses, provided that the EBHRA satisfies other applicable standards to maintain excepted benefit status. Of note, the amounts newly available for each plan year under an EBHRA are capped ($2,200 for plan years beginning in 2026, adjusted annually for inflation). (See *Health savings account (HSA), health reimbursement arrangement (HRA) and health and dependent care flexible spending arrangement (FSA) developments* section).
- *Possible additional guidance.* The Departments intend to propose excepted benefits rules that would create new "other, similar limited benefits" allowing fertility benefits to be offered on a standalone self-funded basis and are considering whether to modify the existing excepted benefit standards for supplemental health insurance coverage.

- **Consider removing consumer notice from enrollment materials for group hospital or other fixed-indemnity excepted benefit programs.** A 2024 final rule required the consumer notice on any marketing, application, enrollment and reenrollment materials for plan years beginning on or after Jan. 1, 2025, as a condition of maintaining excepted-benefit status. A federal district court vacated this requirement in *Manhattan Life Ins. v. HHS* (E.D. Tex. Dec. 4, 2024) and the court dismissed the case after the Trump administration chose not to pursue an appeal. A plan sponsor that wants to keep the notice in any of its enrollment materials should consult with counsel about whether carrier approval is required. Plan sponsors should continue to ensure group hospital or other fixed-indemnity insurance satisfies all remaining conditions for excepted benefit status, and ensure all communications adequately inform participants about the limits of fixed-indemnity coverage and could not be construed as misleading (see Minimum value discussion above).

Continue to monitor the impact of ACA Section 1557's prohibition on discrimination on the basis of race, color, national origin, sex, age or disability.

- **The 2024 final rule.** Except for portions of the rule related to gender identity and sexual orientation, the 2024 final rule interpreting ACA Section 1557 remains in effect.
  - *Not directly applicable to most employer-sponsored group health plans.* The 2024 final rule applies to any "health program or activity" if any part of it receives direct or indirect federal financial assistance from HHS.
    - Most employer-sponsored plans will not be directly subject to Section 1557 because they do not receive federal financial assistance from HHS. However, employer group waiver plans (EGWPs) and plans receiving the Part D retiree drug subsidy are directly impacted by the rule.
    - Under the 2024 final rule, Section 1557 doesn't apply directly to any employer or group health plan sponsor with regard to its employment practices, including providing employee health benefits.

- Most employer-sponsored plans will be indirectly subject to Section 1557. Most health insurers receive federal financial assistance in some form (such as for Medicare Advantage plans, Medicare Part D plans or qualified health plans offered through the ACA marketplace). The 2024 final rule applies Section 1557 to all operations of covered health insurers (i.e., any health insurer that receives federal financial assistance from HHS) — including when administering their fully insured commercial plans or acting as a third-party administrator (TPA) for self-funded employer plans.
- Excepted benefits — such as limited-scope dental and vision plans or Medicare supplemental insurance (Medigap), insured or administered by a covered health insurer/TPA — will also be subject to Section 1557 as part of that insurer's/TPA's operations under the 2024 final rule. As a result, some excepted benefit plans may require modification (for example, eliminating rating based on age).

— *Provisions related to gender identity have been invalidated by court order.* The 2024 rule interprets discrimination on the basis of sex to include gender identity and bans certain discriminatory coverage exclusions or limits related to gender transition or other gender-affirming care. In *State of Tennessee v. Kennedy*, No. 1:24-cv-00161 (S.D. Miss., Oct. 22, 2025), the court invalidated provisions in the 2024 rule nationwide to the extent that they expand the definition of sex discrimination to include gender identity discrimination. Federal district courts in Florida and Texas have temporarily stayed the rule's gender identity provisions — the Texas court's decision, which applies nationwide, also enjoins a provision related to discrimination based on sexual orientation.

— *Other provisions of the 2024 final rule remain in effect.* Other key changes from the prior version of the Section 1557 rule remain in effect including:

- The 2024 final rule bans benefit designs that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.
- The 2024 final rule clarifies that Section 1557 applies to telehealth.
- Additional administrative requirements include:
  - A covered entity must designate a Section 1557 coordinator and provide a notice of nondiscrimination to enrollees.
  - Covered entities must provide a notice of the availability of language services and auxiliary aids and services and adopt written policies and procedures (and train relevant employees on those policies and procedures). However, HHS has removed the web resource providing samples in multiple languages.
- A ban on discriminatory patient-care decision support tools requires covered entities to look for such tools and mitigate risks. Patient-care decision support tools include a range of automated and nonautomated tools; the 2024 final rule gives examples like a Crisis Standards of Care flowchart, algorithms used to assess a patient's risk of severe cardiac event and a medical-necessity review tool that denies enrollees' medical claims for rehabilitative care. (See *Artificial intelligence (AI) in benefits* section.)

  - *Conflict with Trump administration's priorities.* Several provisions of the 2024 final rule conflict with recent presidential EOs that would designate English as the official language of the US, remove barriers to artificial intelligence innovation and end certain medical care for transgender individuals under age 19. The 2024 rule remains in effect, but entities subject to ACA Section 1557 may wish to discuss the impact of the EOs with counsel.
  - *Churches and employers with religious objections.* Churches and employers with religious objections to covering same-sex spouses or transgender services should consult with counsel. The 2024 final rule permits recipients of HHS financial assistance to rely on the protections in religious freedom and conscience laws. They may — but are not required to — seek assurance of these protections from HHS's Office of Civil Rights. The final rule describes the process for obtaining such an assurance, including the right to administrative appeal of any adverse determination. At least one federal court has ruled that HHS cannot enforce Section 1557 or the 2024 final rule in a manner that requires plaintiffs (a group of religious employers) to cover "gender-transition procedures," as that would violate an individual's rights under the Religious Freedom Restoration Act.

- **Other guidance related to gender identity and sexual orientation rescinded.** HHS rescinded 2021 guidance interpreting Section 1557 to apply to discrimination based on sexual orientation and gender identity and withdrew a 2022 guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy."
- **Entities subject to ACA Section 1557 should assess the litigation risk of plan limits or exclusions with counsel.** Plaintiffs have challenged a variety of plan provisions under Section 1557, including exclusions of GLP-1 exclusions for obesity, hearing aids, gender-affirming care and plan provisions requiring a specified amount of unprotected heterosexual sex or artificial insemination before accessing plan fertility benefits.

Continue to calculate and pay the PCORI fee for self-funded group health plans, including certain health reimbursement arrangements and retiree-only plans.

- **The PCORI fee remains in place for plan years ending before Oct. 1, 2029 (i.e., through the 2028 calendar plan year).** The fee funds research on the clinical effectiveness of various medical treatments and care options. Carriers are responsible for paying the fee for insured plans.
  - The fee due July 31, 2026, for noncalendar-year or short calendar-year plans ending in 2025 before Oct. 1 is $3.47 (up from $3.22 for the prior year) multiplied by the average number of lives covered under the plan.
  - The adjusted applicable fee per covered life due July 31, 2026, for 2025 calendar-year plans and noncalendar-year plans ending in 2025 on or after Oct. 1 will be announced in the late fall/early winter.

Prepare for continued MLR rebates if sponsoring a fully insured group health plan. ACA requires these rebates if an insurer fails to spend a minimum percentage of premiums on healthcare claims and quality improvements.

- **Review plan documents for language addressing the handling of rebates and follow those provisions accordingly.** If plan documents are silent, consider an

amendment to address rebates, refunds, plan distributions and other details. When the plan document is silent, the employer must determine how much of the rebate is a plan asset that must be used to benefit participants.

  - Nonfederal government employers and church plans should consult CMS rules on the management of MLR rebates.
  - Once informed about a carrier's intent to issue a rebate, communicate with plan participants on how the rebate will be handled.

Continue to provide SBC and ACA claims and appeals notices in a culturally and linguistically appropriate manner, consistent with updated guidance effective beginning with the 2025 plan year. Monitor whether the Trump administration rescinds or revises current guidance to align with President Trump's EO designating English as the United States' official language.

- Nongrandfathered group health plans must provide the following claims and appeals support in a culturally and linguistically appropriate manner:
  - Oral language services in any applicable non-English language (such as a telephone assistance hotline) to answer questions and help with filing claims and appeals (including external review)
  - Notices, on request, in any applicable non-English language
  - A statement in any applicable non-English language indicating how to access language services (referred to as "taglines") in the English language version of all notices
- All group health plans, regardless of grandfathered status, must provide an SBC and uniform glossary in a culturally and linguistically appropriate manner, including a tagline in any applicable non-English language.
- For ACA claims and appeals notices and SBCs, an applicable non-English language means that 10% or more of the US county population to which a notice is sent is literate only in the same non-English language. As explained in ACA and 2021 CAA implementation FAQs part 63, DOL has posted a list of counties with language(s) that meet the 10% threshold, plus sample taglines in each relevant language.

Monitor legislation and regulations expected to reduce ACA marketplace and Medicaid enrollment, and consider the potential impact on employer-sponsored group health plans.

- **ACA marketplace**. The non-partisan Congressional Budget Office (CBO) estimates that an additional 2.9 million individuals would have health insurance in 2026 (and 5.5 million in 2027) if the expanded/enhanced ACA subsidies are permanently extended and select provisions in the CMS marketplace integrity rule and the One Big Beautiful Bill Act (OBBBA) (Pub. L. No. 119-21) modifying the ACA marketplace are repealed or nullified.
  - *Expanded/enhanced ACA subsidies set to expire*. Expanded/enhanced subsidies to purchase ACA marketplace coverage put in place during the coronavirus pandemic and most recently extended by the Inflation Reduction Act (Pub. L. No. 117-169), are set to expire at the end of 2025. According to health policy research group Kaiser

Family Foundation, of the approximately 24 million Americans that obtained ACA marketplace coverage in 2025, about 92 percent — more than 22 million people — are receiving expanded/enhanced subsidies. Absent Congressional action, premiums for ACA marketplace coverage will increase, particularly for those eligible for expanded subsidies (individuals earning more than 400% of the FPL) and/or enhanced subsidies (fully covering the cost of ACA marketplace coverage for individuals earning up to 150% of the FPL).

- *ACA marketplace modifications in OBBBA and the CMS marketplace integrity rule.* The CMS marketplace integrity rule includes many modifications to ACA marketplace coverage (some of which were codified by OBBBA), including tightening the standards to enroll and receive subsidies for such coverage by shortening the open enrollment period, eliminating auto-reenrollment for certain individuals receiving subsidies, requiring additional income verification, ending the monthly special enrollment periods for low-income individuals and eliminating subsidies based on immigration status. Many provisions of the CMS marketplace integrity rule that were scheduled to take effect on Aug. 25, 2025, have been temporarily paused by a federal court while legal challenges to the rule proceed. (See *City of Columbus v. Kennedy*, 1:25-CV-02114 (D. Md. Jul. 1, 2025) and *California v. Kennedy*, CV-25-12019 (D. Mass. July 1, 2025)).

- **Medicaid.** The ACA permits states to expand Medicaid coverage to individuals with incomes up to 138% of the FPL, with the federal government paying 90% of the expansion costs. The OBBBA makes significant changes to Medicaid, including — beginning in 2027 — requiring that individuals in the Medicaid expansion group verify work or other community engagement as a condition of enrollment. The CBO estimates that this and other OBBBA changes to Medicaid will increase the number of uninsured individuals by 7.8 million relative to baseline projections by 2034.

- **Potential impact on employer-sponsored group health plans.** If Congress allows the expanded/enhanced ACA subsidies to expire or substantially pares them back for 2026:

  - Employer-sponsored health coverage may become more affordable and valuable as compared to the ACA marketplace coverage in the eyes of current and potential employees and, as a result, could become a more powerful tool to attract and retain employees.

  - Some employers might see increased enrollment in their health plan. For example, the Urban Institute projects an additional 3.2 million individuals would enroll in employer-sponsored health plans if the expanded/enhanced ACA marketplace subsidies are allowed to expire.

  - Hospitals and other healthcare providers stand to lose considerable revenue as a result of these and other changes. They may respond by raising the prices charged to employer-sponsored group health plans (i.e., cost shifting) and/or consolidating with other providers — which can also increase costs for employer-sponsored group health plans. Decreasing revenue, combined with an increase in uncompensated care, could reduce the availability of providers to treat employees and their families, particularly in rural areas.

  - ACA marketplace premiums are predicted to rise for a variety of reasons, including healthier individuals exiting the ACA marketplace without the expanded/enhanced ACA subsidies. The CBO estimates that premiums for ACA marketplace benchmark plans will be 7.6 percent lower, on average, each year from 2026-2034, relative to baseline projections, if the ACA marketplace subsidies are permanently extended. Employers contemplating offering individual-coverage health reimbursement arrangements (ICHRAs) will need to monitor premium increases in the individual market.

- **Watch for mitigating legislation or agency activity.**
  - Bipartisan legislation has been introduced that would extend the expanded/enhanced ACA subsidies for one year.
  - In anticipation of premium increases in the individual market for 2026, CMS announced expanded access to catastrophic coverage for individuals who are ineligible for ACA subsidies. Catastrophic plans cover EHBs and have lower premiums than other available coverage on the individual market — but, other than ACA-mandated preventive services (which are covered without cost sharing) and three primary care visits, enrollees must satisfy a deductible set at the ACA OOPM ($10,600 for self-only and $21,200 for other than self-only coverage in 2026) before the catastrophic plan pays any benefits. Section 1302(e) of the ACA, 42 USC 18022(e), limits enrollment to those under 30 or experiencing a hardship. Under the new guidance, individuals who are either determined or expect to be ineligible for ACA subsidies based on their projected household income may qualify for a hardship exemption.

Related resources

Section 9
Mental health parity

Action

Continue to comply with the Mental Health Parity and Addiction Equity Act (MHPAEA) by ensuring that no financial or treatment limits on mental health/substance use disorder (MH/SUD) benefits apply only to MH/SUD benefits, or are more restrictive than those applied to medical/surgical (M/S) benefits. Maintain a written analysis of all nonquantitative treatment limits (NQTLs) that is ready to disclose upon request to federal regulators, states or plan enrollees. Watch for developments related to the Trump administration's nonenforcement of new requirements in the 2024 final rule. Require that vendors provide adequate assistance with MHPAEA compliance. Consider parity requirements when improving a plan's M/S benefits. Monitor parity and behavioral health coverage litigation. Watch for changes to MHPAEA enforcement, as well as additional guidance or legislation.

Specific steps

Identify plans subject to MHPAEA.

- MHPAEA applies to grandfathered and nongrandfathered insured and self-funded group health plans that offer MH/SUD benefits, including self-funded state or local government plans after the sunset of any once available opt out.
- MHPAEA does not apply to retiree-only plans, excepted-benefit arrangements or self-funded plans sponsored by small employers (generally 50 or fewer employees, although a few states have expanded the definition to include employers with 100 or fewer employees).

Continue to comply with MHPAEA by ensuring that no financial requirements or treatment limits apply only to MH/SUD benefits, or are more restrictive than those applied to M/S benefits.

- Financial limits (such as deductibles) and other quantitative limits (such as visit limits) on MH/SUD benefits limits are subject to mathematical testing using plan-level data within each of six classifications (in- and out-of-network inpatient and outpatient treatment, emergency services and prescription drugs). These limits can't be more restrictive, as written or in operation, than the predominant ones for substantially all M/S benefits in the same classification.
- No NQTL (such as prior authorization, fail first protocols, etc.) may be imposed on MH/SUD benefits in a classification unless the processes, strategies, evidentiary standards or other factors used in applying the NQTL under the plan's written terms and in actual operation are comparable to and applied no more stringently than those used for M/S benefits in the same classification.

Confirm that the plan has completed a written NQTL comparative analysis reflecting current plan coverage and terms. MHPAEA was amended by the Consolidated

Appropriations Act, 2021 (Pub. L. No. 116-260) (2021 CAA) to require health plans to complete and document a comparative analysis of the plan's NQTLs.

- Make sure that the comparative analysis includes the nine data elements required for each NQTL, as outlined in FAQ 2 of the MH/SUD parity implementation and 2021 CAA FAQs Part 45.
  - Identifying all NQTLs in a group health plan may require assistance from legal counsel or other experts since regulators have not provided an exhaustive list of NQTLs.
  - Review common comparative analysis failures and NQTLs that have been the focus of prior agency enforcement — while recognizing that the Trump administration may approach MHPAEA enforcement differently going forward (as discussed below).
    - During the Biden administration, regulators focused on NQTLs related to network composition including participation standards for providers (e.g., credentials, reimbursement rates) and network assessment standards (e.g., provider-to-member ratios, time and distance standards and maximum wait times). A group health plan may wish to document any efforts to improve the behavioral health network to assist with any future audit.
    - Plan exclusions identified as potentially impermissible include those for residential treatment, partial hospitalization, speech therapy, autism spectrum disorder (ASD) treatment based on age, applied behavioral analysis therapy for ASD, medication for opioid use disorder and nutritional counseling for eating disorders.
- Update the comparative analysis as necessary to reflect the plan's *current* terms and coverage. While the rules do not specify how often a comparative analysis must be updated, the comparative analysis should be reviewed to see if revisions are required whenever the plan's terms or coverage change. An outdated comparative analysis due to the passage of time, a change in plan structure or for any other reason is insufficient.
- Be ready to produce a comparative analysis on request from a federal or state agency. Agency guidance requires that ERISA-covered plans provide the comparative analysis to participants and beneficiaries on request and that nongrandfathered group health plans must also make the comparative analysis available on request in connection with an appeal of an adverse benefit determination.

Watch for developments related to the Trump administration's nonenforcement of the 2024 final rule. On May 15, 2025, the departments of Labor, Health and Human Services and Treasury (the departments) announced that they will not enforce new requirements in the Biden administration's 2024 MHPAEA final rule. Compliance with MHPAEA — and the 2021 CAA that requires health plans to complete and document an NQTL comparative analysis — continues to be required during the nonenforcement period.

- The nonenforcement policy will continue until 18 months after a final decision in the lawsuit filed by the ERISA Industry Committee challenging provisions of the 2024 final rule. The lawsuit is currently on hold while the departments consider whether to rescind or modify the 2024 final rule through notice and comment rulemaking.

- The nonenforcement policy applies only to *new* requirements in the 2024 final rule as compared with the 2013 final rule. Some of the 2024 rule's most challenging requirements were not in the 2013 final rule and thus are presumably subject to the nonenforcement policy, including:
  - *Fiduciary certification*. ERISA-covered group health plans were required to include, as part of their written comparative analysis, certification by at least one named fiduciary to the prudent process of selecting and monitoring the service provider(s) preparing the written comparative analysis.
  - *Meaningful benefits standard***.** A plan offering benefits for an MH/SUD condition in any classification was required to provide meaningful benefits for that MH/SUD condition in every classification for which M/S benefits are provided, including, in some instances, a "core treatment" for the MH/SUD condition.
  - *Material differences in access standard***.** Plans were required to collect relevant data to assess each NQTL's impact on outcomes related to MH/SUD benefit access and include an outcomes data evaluation in the comparative analysis.

  Defined key terms (such as MH/SUD benefits) and the ban on factors and evidentiary standards that disfavor access to MH/SUD benefits are also new in the 2024 rule. Note that the 2024 rule is wide-ranging and the departments did not specifically identify which requirements it considers "new," so plan sponsors may need to consult with counsel if unsure whether a particular requirement is subject to the departments' nonenforcement policy.
- Plans and insurers should continue to refer to the 2013 final rule, FAQs Part 45 and other subregulatory guidance issued under MHPAEA for compliance requirements during the nonenforcement period. States — which generally have primary enforcement authority over health insurers and insured plans — are encouraged to adopt a similar nonenforcement approach. It's unclear whether states will adopt the federal agencies' nonenforcement policy. At least one state (Colorado) recently amended its regulations to mirror certain provisions of the 2024 final rule.

Require the plan's vendors to provide adequate assistance with MHPAEA compliance. Make sure vendor contracts include an agreement to comply with MHPAEA, including disclosure requests from federal or state regulators or plan participants, and specify the required level of support to produce a written comparative analysis.

- Confirm the extent to which the plan sponsor may rely on its service providers for the NQTL comparative analysis.
  - Employers sponsoring fully insured plans should confirm with their insurer that they can rely on the insurer's comparative analysis, since insurers are directly subject to MHPAEA.
  - Employers sponsoring self-funded plans should confirm the assistance available from their third-party administrator (TPA), since MHPAEA does not directly regulate TPAs or other benefit administrators.
  - Plans with multiple vendors (for example, plans that offer a point solution or carve out certain benefits to an administrator other than the TPA) may need to engage other

third parties (e.g., legal counsel, clinical experts, actuaries and data analysts) to identify all NQTLs and demonstrate they are applied comparably to M/S and MH/SUD benefits.

- Consider negotiating performance guarantees related to MHPAEA compliance, such as a guarantee to respond in a timely manner to disclosure requests or a guarantee to conduct periodic self-audits for MHPAEA compliance.
- Require vendors to inform plan sponsors of any agency MHPAEA investigation, even one that might occur in the vendor's fully insured business.
- Require vendors to inform employers if a federal or state authority finds a parity violation.

Consider MHPAEA when expanding M/S benefits. Ensure that improving a plan's M/S benefits doesn't inadvertently result in MHPAEA noncompliance.

- Consider how reducing financial or other quantitative limits on M/S benefits might affect MHPAEA testing for MH/SUD financial or quantitative limits.
- Consider how removing NQTLs on M/S benefits could affect the parity analysis for MH/SUD NQTLs. For example, a three-visit limit on nutritional counseling — with an exception for diabetes treatment but no exception for MH/SUDs (such as eating disorders) — would fail to comply with MHPAEA.

Monitor ongoing and emerging litigation against employer-sponsored health plans and TPAs concerning parity and behavioral health coverage. Court challenges often involve coverage denials for residential treatment, wilderness therapy, ASD treatments or nutritional counseling. Complaints typically include breach of fiduciary duty allegations, as well as failure to administer the plan according to its terms.

- Class actions contesting the clinical guidelines used to decide behavioral health claims continue, even after a 2023 appellate decision (*Wit v. United Behavioral Health (UBH))* rejected such claims to the extent that they require plans to cover all care consistent with generally accepted standards. For example, Anthem recently settled a class action lawsuit challenging its behavioral health guidelines (*Collins. v. Anthem Inc*. (E.D.N.Y. No 2:20-cv-01969)). Two federal district courts have allowed class actions challenging UBH's behavioral health guidelines to proceed: *Jones v. United Behavioral Health* (N.D. Cal. April 14, 2025) denied UBH's motion to dismiss a proposed class action challenging post-*Wit* guidelines, while *Beach v. United Behavioral Health* (N.D. Cal. May 5, 2025) certified a class of residential treatment claimants.

Watch for changes to MHPAEA enforcement. The departments are undertaking a "broader reexamination" of their MHPAEA enforcement, which may include updates to subregulatory guidance, including FAQs Part 45.

- The Department of Labor's Office of Inspector General issued a February 2025 audit report on MHPAEA enforcement from 2018 to 2024 with recommendations — including that MHPAEA violations be referred to the Department of Treasury to seek excise taxes — but it's unclear if the report will influence the Trump administration's reexamination of MHPAEA enforcement.

- Legislation introduced this year related to MHPAEA enforcement that would add civil monetary penalties against plan sponsors or service providers or that would require annual reports to Congress providing reasons for investigations exceeding 36 months are unlikely to gain traction in 2026.

Watch for additional compliance guidance and parity legislation. In the 2024 report to Congress released at the end of the Biden administration, the departments stated that they intend to update the MHPAEA self-compliance tool and provide a sample comparative analysis. It is unclear whether the Trump administration will make this a priority. Legislation introduced this year would require behavioral health parity in disability benefit plans.

Related resources

Section 10

State-mandated paid leave and other state law trends

Action

Look for bills affecting paid leave, pharmacy benefit managers (PBMs), fully insured plan coverage mandates and telehealth access as 46 states (except Montana, Nevada, North Dakota and Texas) convene their regular sessions in 2026. Do not overlook ongoing regulatory activity, particularly in the three states where paid family and medical leave (PFML) programs will be in full effect in 2026: Delaware, Maine and Minnesota. Examine how state PFML, paid sick and safe leave (PSSL) and other paid and unpaid leave mandates fit with existing employer programs, and assemble the puzzle pieces into a rational leave mosaic. Keep an eye out for renewed debate on a federal PFML program, given heightened interest and several pending bills. Review changes to the § 45S employer tax credit for PFML benefits as a result of the One Big Beautiful Bill Act (OBBBA). Monitor telehealth developments, particularly related to behavioral health. Discuss with insurers how new state coverage mandates affect fully insured plans and consider whether to mirror those mandates for self-funded coverage. Be aware of access issues related to abortion and gender-affirming care. Continue health-coverage reporting where required. Maintain compliance with state laws related to group health plan assessments (and related reporting). Pay attention to PBM developments and ERISA preemption issues in the courts and state legislatures.

Specific steps

Examine how state PFML, PSSL and other paid and unpaid leave mandates fit with existing employer programs, and assemble the puzzle pieces into a rational leave mosaic. While state leave laws have common elements, each law has variations. Delaware's PFML law is a prime example, given its minimum-hours eligibility standard and uncommon waiver program for part-time and seasonal employees. A third-party administrator's assistance may be valuable for multistate employers beyond any cost savings connected with offering the benefit through a private, equivalent plan.

- **Reassess your overall paid leave strategy.** Create or revise a long-term PFML and accrued paid leave strategy, with the aim of multistate parity where achievable. Dissimilarities routinely show up in these areas: contribution rates, benefit levels, duration, permitted uses, eligibility and paid time-off (PTO) accruals. Pay attention to how a new law defines covered family members, usually broader than the federal Family and Medical Leave Act (FMLA), to include domestic partners, designated persons and extended family. This assessment is worthwhile even if an employer is not subject to a state mandate (because of workforce size), in light of recruiting, retention and employee care considerations.
- **Follow agency guidance from states launching PFML programs.** Four states are currently in the implementation stage: Delaware, Maine, Maryland and Minnesota. In

some cases, comprehensive regulations, guidance and model notices have already been issued. In others, these items are forthcoming. Delaware and Maine started contributions this year. Minnesota contributions and benefits will start on Jan. 1, 2026. Benefits will start in Delaware on Jan. 1, 2026, and in Maine on May 1, 2026. In Maryland, contributions will start on Jan. 1, 2027, and benefits will start no later than Jan. 3, 2028. Private, equivalent plans typically have earlier deadlines. Consider joining state email distribution lists for timely updates.

- **Check your compliance with federal taxation of state-mandated PFML contributions and benefits.** In January, IRS issued Rev. Ruling 2025-4, which provides a framework for assessing the taxability of contributions and benefits under state PFML programs. The guidance does not apply to private, equivalent plans. While there is enforcement relief for the 2025 tax year, preparing for compliance in 2026 will likely require system updates. Review of tax guidance from each applicable state is warranted.
- **Determine how PFML changes in states with existing programs affect compliance.** A PFML law is not set in stone. States frequently amend major portions of the law well after its go-live date. For example, at least eight states enacted substantive PFML changes in 2025.
- **Double-check PFML program contribution rates.** Most states adjust contribution rates each year, based on utilization. Modify systems, payroll deductions and employee communications before the start of 2026.
- **Track states considering new PFML mandates.** Every year, a handful of states consider PFML legislation. In 2024 and 2025, Virginia's PFML bill made it to the governor's desk, only to be vetoed each time. Due to term limits, Virginia will have a new governor next year so the third time may be the charm. Put these states on your 2026 PFML radar: Hawaii, Illinois, Michigan and New Mexico. Other states may become worthy of attention.
- **Do not ignore states contemplating voluntary paid family leave (PFL) insurance.** While no new states adopted voluntary PFL insurance in 2025, it is a possible first step toward a comprehensive PFML mandate. Laws in eight states allow PFL insurance as a separate policy or a rider to an existing disability or life insurance plan. Laws in two other states (New Hampshire and Vermont) allow employers to opt-in to the program for state governmental employees. To date, these programs have not gained meaningful traction, but times may change, especially in light of changes to the § 45S employer tax credit discussed below.
- **Stay current on state and local accrued paid leave and supplemental pay mandates.** Keep a close watch on state legislation and local ordinances that initiate or modify PSSL and PTO-related requirements, particularly in states where PSSL legislation has previously stalled (or in the case of Missouri, has been repealed). Several states in the Midwest may take up the PSSL mantle in 2026, perhaps by voter referendum as we saw in three states in 2024.
- **Keep tabs on other leave laws.** States continue to consider expanding unpaid, job-protected leave for a variety of reasons, including bereavement and organ donation.

Keep an eye out for renewed debate on a federal PFML program. In early 2024, the House Bipartisan Paid Family Leave Working Group issued a PFML policy framework. That framework found its way into three House bills introduced this year:

- The Interstate Paid Leave Action Network (I-PLAN) Act (HR 3090) would facilitate coordination and harmonization of state PFML programs and provide a grant program to incentivize states to adopt provisions that mirror the I-PLAN.
- The More Paid Leave for More Americans Act (HR 3089) would simply provide the grants for I-PLAN-conforming states. Both bills have bipartisan sponsorship, but to date remain in committee.
- An alternative approach — sponsored solely by more than 190 Democrats — is the FAMILY Act (HR 5390), which would create a PFML office within the Social Security Administration to administer a nationwide program with an exception for "legacy state" programs.

Expect Congress to continue the PFML discussions and make incremental progress in 2026.

Review changes to the § 45S employer tax credit for PFML benefits as a result of OBBBA. In addition to removing the credit expiration date, the law removes policy requirements that previously put the credit out of reach for many employers. Beginning in 2026, even employers in states with mandatory PFML programs can take advantage of a general business tax credit ranging from 12.5% to 25% of wages paid to qualifying employees for up to 12 weeks of leave with an employer-provided PFML benefit meeting certain requirements.

Monitor telehealth developments, particularly related to behavioral health.

- **Consider how to enhance telehealth access.** This applies particularly to behavioral health services, which increasingly are accessed via telehealth. More than 80% of the states (plus Washington, DC) are members of the Psychology Interjurisdictional Compact (PSYPACT), which enables cross-state use of behavior health services. Montana became the latest state to join PSYPACT in 2025. Massachusetts and New York may follow suit in 2026.
- **Monitor telehealth reimbursement parity mandates for fully insured plans.** Most states require fully insured plans to reimburse telehealth providers at the same rate as in-person providers. The trend may continue.
- **Keep an eye out for state simplification of preliminary requirements for use of telehealth services.** In the early days of telehealth, several states conditioned telehealth use on a prior in-person office visit. More states are either removing or simplifying this requirement (like New Hampshire in 2025).

Discuss with insurers how new state coverage mandates affect fully insured plans and consider whether to mirror those mandates for self-funded coverage.

- **Watch for additional coverage mandates for fully insured plans.** Each year, state legislators enact new insurance laws requiring coverage for specific services. Recent trends have included ground-ambulance balance billing limitations, prior authorization reform, expansive fertility coverage and specified abortion, weight-loss or gender-affirming care services.

- **Keep in mind that some state insurance laws apply on an extraterritorial basis to fully insured plans issued in another state.** Be cognizant of the state where your fully insured plan was issued, and review with your insurer how other states' insurance laws may apply to participants who reside in those states.

Be aware of access issues related to abortion and gender-affirming care. In the June *US v. Skrmetti* decision, the US Supreme Court upheld a Tennessee law banning gender-affirming care for minors, and, as a result, similar bans in about half the states remain in place. To the extent plan members reside in these states or one of the dozen or so states with abortion bans, they will need to travel to another state to access services covered by a plan. Some employers may want to review and perhaps modify their healthcare travel policies.

Continue health-coverage reporting where required. California, Massachusetts, New Jersey, Rhode Island and Washington, DC, require reporting, while Vermont simply requires employees to maintain copies of IRS Form 1095-B or 1095-C. State reporting deadlines mostly mirror the Affordable Care Act (ACA) deadlines. Submission of Form 1095-C usually satisfies the state reporting obligation. Double-check any reporting changes, particularly whether compliance with the revised ACA electronic disclosure rules — under the Paperwork Burden Reduction Act and IRS Notice 2025-15 — will satisfy state requirements. Massachusetts has two requirements: the Health Insurance Responsibility Disclosure (due Dec. 15) and Form MA 1099-HC (due Jan. 31).

Maintain compliance with state laws related to group health plan assessments (and related reporting). Satisfy the requirements for group health plan assessments in New York (Health Care Reform Act covered-lives assessment (CLA)), Washington (Partnership Access Lines CLA) and San Francisco (Health Care Security Ordinance Annual Reporting Form and for the Health Care Accountability Ordinance (applicable to city and county contractors)).

Pay attention to PBM developments and ERISA preemption issues in the courts and state legislatures. ERISA preemption continues to be a hot topic related to state PBM laws extending to self-funded plans. (See *Prescription drugs* section.)

Related resources

Appendix A
Related resources

1. Prescription drugs (Rx)

Non-Mercer resources

- Medicare drug price negotiation program final guidance for initial price applicability year 2028 and manufacturer effectuation of the maximum fair price in 2026, 2027 and 2028 (CMS, Sept. 30, 2025)
- Fact Sheet: President Donald J. Trump ensures American pharmaceutical supply chain resilience by filling the strategic active pharmaceutical ingredients reserve (White House, Aug. 13, 2025)
- Fact Sheet: Medicare Part D negotiated prices (CMS, May 12, 2025)
- Fact Sheet: Actions to put American patients first by lowering drug prices and stopping foreign free-riding on American pharmaceutical innovation (White House, May 12, 2025)
- Fact Sheet: Actions to lower Rx prices (White House, April 15, 2025)
- Specialty Generic Drugs: A growing profit center for vertically integrated pharmacy benefit managers (FTC, Jan. 14, 2025)
- Prescription drug data collection (RxDC) website (CMS, regularly updated)
- RxDC reporting instructions (CMS, Jan. 15, 2025)
- RxDC file templates (CMS, Jan. 16, 2025)
- RxDC FAQs (CMS, Feb. 22, 2023)
- ACA implementation FAQ Part 66 (April 4, 2024)
- Sec. 11001 of Pub. L. No. 117-69, Inflation Reduction Act (Congress, Aug. 16, 2022)
- Field Assistance Bulletin 2021-03 (DOL, Dec. 30, 2021)
- 26 CFR 54.9825-4T, Reporting requirements related to prescription drug and healthcare spending
- Section 202 of Pub. L. No. 116-260, the No Surprises Act (NSA), 2021 Consolidated Appropriations Act (CAA) (Congress, Dec. 27, 2020)
- Section 204 of Pub. L. No. 116-260, the NSA, 2021 CAA (Congress, Dec. 27, 2020)
- *Pharmaceutical Care Management Association v. Mulready*, No. 22-6074 (10th Cir. Aug. 15, 2023) (cert. denied)

Mercer Law & Policy resources

- Roundup of selected state health developments, third-quarter 2025 (Oct. 21, 2025)
- What employers need to know about federal vaccine policy changes (Oct. 2, 2025)
- Some states look to strengthen PBM standards (Sept. 25, 2025)
- Roundup of selected state health developments, second-quarter 2025 (Aug. 5, 2025)
- Governors play ace cards in recent legislative showdowns (July 30, 2025)
- Plan coverage of GLP-1s for weight loss: Compliance considerations (July 24, 2025)
- ERISA preemption debate heats up in 2025 (July 1, 2025)
- Healthcare transparency: Nice in theory; practical data usage lags (June 18, 2025)
- Will most-favored nation pricing lower prescription drug costs? (May 15, 2025)
- Roundup of selected state health developments, first-quarter 2025 (April 21, 2025)
- President Trump's executive orders and their impact on employer health programs (Jan. 29, 2025)

Other Mercer resources

- Top five developments in GLP-1s and weight-loss drugs (Oct. 23, 2025)
- Tariffs, TrumpRx and the shift to DTC prescription drug sales (Oct. 16, 2025)
- GLP-1 considerations for 2026: Your questions answered! (July 24, 2025)
- As benefit costs surge, employers face tough decisions for 2026 (July 17, 2025)
- Supreme Court action: Good news for employer Rx benefits (July 10, 2025)
- Preventive vaccines and workforce health (June 18, 2025)
- Employers are evaluating alternatives to traditional PBM contracts (June 12, 2025)
- Employers and legislators aren't perfectly aligned on PBM reform (May 15, 2025)
- The impact of tariffs on healthcare costs (April 10, 2025)
- Measles outbreaks: A reason to revisit vaccination policies (March 20, 2025)
- Rx transparency: Cracking the code (Jan. 30, 2025)
- MercerRx
- MercerWell

2. ERISA fiduciary issues

Non-Mercer resources

- 29 USC § 1104, Fiduciary duties (US Code)
- Executive Order No. 14273, Lowering drug prices by once again putting America first (April 15, 2025)
- Multiple employer welfare arrangements under the Employee Retirement Income Security Act (ERISA): A guide to federal and state regulation (EBSA, Aug. 22, 2024)
- Understanding your fiduciary responsibilities under a group health plan (EBSA, Aug. 22, 2024)
- Press release, DOL reaches settlement with New York insurer, third-party health plan administrator to end 'cross-plan offsetting' practice (DOL, Oct. 5, 2023)
- Press release, US Department of Labor sues Wisconsin-based third-party claims administrator for denying medical claims for thousands of participants (DOL, Aug. 4, 2023)
- Reporting and disclosure guide for employee benefit plans (EBSA, December 2022)
- *Lockheed Corp. v. Spink*, 517 U.S. 882 (1996)
- Technical Release No. 1992-01, DOL enforcement policy for welfare plans with participant contributions (May 28, 1992)

Mercer Law & Policy resources

- Updated regulatory agendas have few new retirement items (Oct. 10, 2025)
- What plan sponsors should know about DOL's final fiduciary rule (June 20, 2024)
- ERISA plan sponsors are responding to heightened fiduciary risk (Nov. 22, 2023)

Other Mercer resources

- Navigating fiduciary risk in health and welfare benefits (Mercer webinar replay series, Oct. and Nov. 2024)

3. Group health plan transparency

Non-Mercer resources

- Hospital price transparency (CMS)
- Technical implementation guide for the triagency price transparency rule (GitHub, updated daily)
- Proposed rule, Medicare and Medicaid Programs: Hospital outpatient prospective payment and ambulatory surgical center payment systems; quality reporting programs;

overall hospital quality star ratings; and hospital price transparency (Federal Register, July 17, 2025)

- CMS proposes bold reforms to modernize hospital payments, strengthen transparency and put patients back in control (CMS, July 15, 2025)
- 2021 CAA implementation FAQs part 70 (DOL, IRS and HHS, May 22, 2025)
- Updated hospital transparency guidance implementing executive order 14221 (CMS, May 22, 2025)
- Hospital price transparency FAQs (CMS, May 8, 2025)
- Executive order 14273, Lowering drug prices by once again putting Americans first (Federal Register, April 15, 2025)
- Executive order 14221, Making America health again by empowering patients with clear, accurate, and actionable healthcare pricing information (Federal Register, Feb. 28, 2025)
- 2021 CAA implementation FAQs Part 69 (DOL, IRS and HHS, Jan. 14, 2025)
- Healthcare transparency: CMS needs more information on hospital pricing data completeness and accuracy (US GAO, Oct. 2, 2024)
- Gag-clause prohibition compliance attestation (CMS, Sept. 19, 2024)
- CMS technical clarification Q&As (CMS, Sept. 10, 2024)
- Steps for making public hospital standard charges in a machine-readable format (CMS, March 15, 2024)
- ACA implementation FAQs part 65 (DOL, IRS and HHS, Feb. 2, 2024)
- ACA implementation FAQs part 61 (DOL, IRS and HHS, Sept. 27, 2023)
- CY 2024 hospital outpatient prospective payment system (OPPS) policy changes: hospital price transparency proposals (CMS-1786-P) (CMS, July 13, 2023)
- Press release, CMS proposes policies to expand behavioral health access and further efforts to increase hospital price transparency (CMS, July 13, 2023)
- ACA and 2021 CAA implementation FAQs part 60 (DOL, IRS and HHS, July 7, 2023)
- Press release, Hospital price transparency enforcement updates (CMS, April 26, 2023)
- ACA and 2021 CAA implementation FAQs part 57 (DOL, IRS and HHS, Feb. 23, 2023)
- Request for information, Advanced explanation of benefits and good-faith estimate for covered individuals (Federal Register, Sept. 16, 2022)
- ACA and 2021 CAA implementation FAQs part 55 (DOL, IRS and HHS, Aug. 19, 2022)
- ACA implementation FAQs part 53 (DOL, IRS and HHS, April 19, 2022)
- Field Assistance Bulletin 2021-03 (DOL, Dec. 30, 2021)

- Final rule, Updated hospital transparency requirements (Federal Register, Nov. 16, 2021)
- Proposed rule, Requirements related to air ambulance, broker and consultant disclosures, and provider enforcement (Federal Register, Sept. 16, 2021)
- ACA and 2021 CAA implementation FAQs part 49 (DOL, HHS and Treasury, Aug. 20, 2021)
- Pub. L. No. 116-260, the 2021 CAA (Congress, Dec. 27, 2020)
- Final rule, Transparency in coverage (Federal Register, Nov. 12, 2020)
- Final rule, Transparency requirements for hospitals (Federal Register, Nov. 27, 2019)

Mercer Law & Policy resources

- Healthcare transparency: Nice in theory; practical data usage lags (June 18, 2025)
- Plans and issuers will need to submit "gag clause" attestations by Dec. 31, 2023 (March 8, 2023)
- CMS issues late, breaking guidance on posting machine-readable files (June 22, 2022)
- Health plans face new liabilities for inaccurate provider directories (Jan. 4, 2022)
- Healthcare cost transparency rules and MLR changes finalized (Dec. 2, 2020)
- Mercer comments on proposed transparency in coverage rules (Jan. 31, 2020)
- House passes package of PBM, price transparency, billing reforms (Dec. 14, 2023)

Other Mercer resources

- What happened to all that medical price data? (June 22, 2023)

4. Data privacy and security

Non-Mercer resources

- Cybersecurity & Infrastructure Security Agency (CISA)
- Privacy, security and HIPAA (HealthIT.gov)
- Security rule guidance material (HHS)
- Press release, Americans to gain new access to real-time prescription drug price information (HHS, Sept. 2, 2025)
- Final rule, Health Data, Technology and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (CMS, Aug. 4, 2025)
- Press release, White House, tech leaders commit to create patient-centric healthcare ecosystem (HHS, July 30, 2025)

- Proposed rule, HIPAA security rule to strengthen the cybersecurity of electronic protected health information (HHS, Jan. 6, 2025)
- Fact sheet, HIPAA security rule notice of proposed rulemaking to strengthen cybersecurity for electronic protected health information (HHS, Dec. 27, 2024)
- Compliance assistance release no. 2024-01 (DOL, Sept. 6, 2024)
- Collecting, using or sharing consumer health information? Look to HIPAA, the FTC Act and the health breach notification rule (FTC, August 2024)
- Complying with FTC's health breach notification rule (FTC, July 29, 2024)
- Mobile health app interactive tool (FTC, Office of the National Coordinator for Health Information Technology (ONC), OCR and FDA, July 29, 2024)
- Use of online tracking technologies by HIPAA covered entities and business associates (OCR, June 26, 2024)
- Final rule, Health breach notification rule (FTC, May 30, 2024)
- Final rule, HIPAA privacy rule to support reproductive healthcare privacy (HHS, April 26, 2024)
- Cybersecurity resources for HIPAA-regulated entities (NIST, March 18, 2024)
- Implementing the HIPAA security rule: A cybersecurity resources guide (NIST, Feb. 27, 2024)
- HIPAA privacy and security rules (45 CFR Part 164)

Mercer Law & Policy resources

- DOL cyber guidance applies to ERISA health and welfare plans (Oct. 21, 2024)
- New HIPAA privacy protections for reproductive healthcare (July 30, 2024)
- Make cybersecurity part of your 2024 New Year's resolutions (Jan. 4, 2024)

Other Mercer resources

- HIPAA reproductive healthcare privacy rule vacated (Sept. 17, 2025)
- It's time to craft a robust cyber strategy specific to your business (Sept. 24, 2024)
- Modernize HR data strategy to address cybersecurity risks (May 2, 2024)

5. Artificial intelligence (AI) in benefits

Non-Mercer resources

- Executive Order 14319: Preventing woke AI in the federal government (July 23, 2025)
- Winning the race: America's AI action plan (White House, July 10, 2025)

- Executive Order 14179: Removing barriers to American leadership in artificial intelligence (Federal Register, Jan. 23, 2025)
- Executive Order 14148: Initial rescissions of harmful executive orders and actions (Federal Register, Jan. 28, 2025)
- Ensuring nondiscrimination through use of artificial intelligence and other emerging technologies (OCR, Jan. 10, 2025)
- A roadmap for artificial intelligence policy in the US Senate (Bipartisan Senate AI Working Group, May 15, 2024)
- Final rule, Nondiscrimination in health programs and activities (ACA Section 1557) (Federal Register, May 6, 2024)
- Joint statement on enforcement of civil rights, fair competition, consumer protection and equal opportunity laws in automated systems (Bureau of Consumer Financial Protection, Department of Housing and Urban Development, DOL, Education Department, EEOC, Federal Trade Commission, HHS, Homeland Security Department and Justice Department, April 4, 2024)
- Health data, technology and interoperability (HTI-1) final rule (Federal Register, Jan. 9, 2024)
- Delivering on the promise of AI to improve health outcomes (White House, Dec. 14, 2023)
- Executive Order 14110: Safe, secure and trustworthy development and use of artificial intelligence (Fed. Reg. Nov. 1, 2023)

Mercer Law & Policy resources

- Roundup: Global employer resources on artificial intelligence (regularly updated)
- 'Usual suspects' expected in 2025 state benefits legislation (Jan. 29, 2025)
- Health plan administrators should consider AI guardrails (Jan. 22, 2025)
- California-Illinois legislative sessions may forecast 2025 activity (Nov. 13, 2024)
- States start to take action on AI and insurance (July 25, 2024)

Other Mercer resources

- An employer guide to AI and health insurance (Aug. 7, 2025)
- The move to modernize prior authorization: What employers should know (Aug. 6, 2025)
- Embracing innovation in health programs to combat risk (March 27, 2025)
- I, pharmacist? AI and robot-powered prescriptions (Jan. 22, 2025)
- My therapist is a chatbot: Using AI in mental health (Jan. 22, 2025)
- The transformative role of AI in health and benefits (Jan. 22, 2025)

- The transformative impact of generative AI on HR shared services (2024)

6. Health savings account (HSA), health reimbursement arrangement (HRA) and health and dependent care flexible spending arrangement (FSAs) developments

Non-Mercer resources

- Publication 15-B, *Employer's tax guide to fringe benefits* (IRS, annually updated)
- Publication 502, *Medical and dental expenses* (IRS, annually updated)
- Publication 969, *HSAs and other tax-favored health plans* (IRS, annually updated)
- Rev. Proc. 2025-32, Tax inflation adjustments for tax year 2026 (Oct. 8, 2025)
- Agency rule list for spring 2025: Treasury Department (Office of Information and Regulatory Affairs, Sept. 4, 2025)
- Pub. L. No. 119-21, One Big Beautiful Bill Act (Congress, July 4, 2025)
- Rev. Proc. 2025-19, 2026 inflation-adjusted HSA, HDHP and excepted-benefit HRA amounts (IRS, May 1, 2025)
- Health savings accounts (Congressional Research Service, Feb. 11, 2025)
- Notice 2024-75, Preventive care for purposes of qualifying as a HDHP under Section 223 (IRS, Oct. 17, 2024)
- Notice 2024-71, Expenses treated as amounts paid for medical care (IRS, Oct. 17, 2024)
- Notice 2023-37, Expenses related to COVID-19 and preventive care for purposes of HDHPs (IRS, June 23, 2023)
- Pub. L. No. 117-328, Consolidated Appropriations Act, 2023 (Congress, Dec. 29, 2022)
- Pub. L. No. 117-103, Consolidated Appropriations Act, 2022 (Congress, March 15, 2022)
- Health reimbursement arrangements (HRAs): Overview and related history (Congressional Research Service, March 7, 2022)
- A comparison of tax-advantaged accounts for healthcare expenses (Congressional Research Service, May 3, 2021)
- Pub. L. No. 116-136, Coronavirus Aid, Relief and Economic Security (CARES) Act (Congress, March 27, 2020)
- Proposed rule, Application of the ESR provisions and certain nondiscrimination rules to HRAs and other account-based group health plans integrated with individual health insurance coverage or Medicare (Federal Register, Sept. 30, 2019)
- Proposed rule, Definition of dependent under the Working Families Tax Relief Act of 2004 (Federal Register, Jan. 19, 2017)

- Notice 2008-59, Health saving accounts Q&A guidance (June 25, 2008)
- Notice 2004-50, Health saving accounts Q&A guidance (Aug. 9, 2004)
- Notice 2004-23, Safe harbor for preventive care benefits allowed to be provided by an HDHP without satisfying the minimum deductible under Section 223(c)(2) of the Internal Revenue Code

Mercer Law & Policy resources

- Quick benefit facts and COLA resources for benefit plans (annually updated)
- Wondering if ICHRAs have a role in your program? What you need to know (Sept. 18, 2025)
- 2026 health FSA, other health and fringe benefit limits now set (Oct. 10, 2025)
- Big Beautiful Bill permanently enhances dependent care benefits (July 23, 2025)
- One Big Beautiful Bill includes employer-friendly provisions (July 8, 2025)
- 2026 HSA, HDHP and excepted-benefit HRA figures set (May 1, 2025; updated June 27, 2025)
- Employers support HSA changes to make them more flexible (April 3, 2025)
- Two-year renewal of pre-deductible HDHP telehealth coverage now law (Jan. 11, 2023)
- HSAs: Saving for, and during, an emergency (May 14, 2020)
- CARES Act boosts telehealth, makes other health, paid leave changes (March 27, 2020)
- To treat or to prevent? That is (still) the HSA question (Jan. 7, 2020)
- IRS outlines how individual-coverage HRAs can meet ACA employer mandate (Oct. 29, 2019)
- Final rules ease restrictions on health reimbursement arrangements (June 14, 2019)
- HSA vs. 401(k): Help your employees win the battle for account funding (Jan. 31, 2019)
- How to maximize HDHPs and HSAs to save costs, promote health and retain talent (March 17, 2022)

Other Mercer resources

- Eight ways to make HSAs work better for more of your people (May 1, 2025)
- Direct primary care gains ground as employer strategy (July 9, 2020)

7. ACA preventive services

Non-Mercer resources

- Preventive health services (Healthcare.gov)

- A and B recommendations (USPSTF)
- ACIP recommendations (CDC)
- Immunization schedules (CDC)
- Women's preventive services guidelines (HRSA)
- Recommendations for preventive pediatric healthcare (HRSA)
- § 2590.715-2713 Coverage of preventive health services (Code of Federal Regulations)
- Tracking state actions on vaccine policy and access (Kaiser Family Foundation, Sept. 24, 2025)
- *Kennedy v. Braidwood Mgmt. Inc.*, 145 S. Ct. 2427 (June 27, 2025)
- ACA preventive services coverage requirement (Congressional Research Service, May 23, 2025)
- ACIP shared clinical decision-making recommendations (CDC, Jan. 7, 2025)
- ACA and WHCRA implementation FAQs part 68 (DOL, HHS and Treasury, Oct. 21, 2024)
- *Braidwood Mgmt. Inc. v. Becerra*, 104 F. 4th 930 (5th Cir. June 21, 2024)
- Preventive services access on the docket in *Braidwood v. Becerra* (Congressional Research Service, Sept. 12, 2023)
- ACA and CARES Act implementation FAQs part 59 (DOL, HHS and Treasury, April 13, 2023)
- Final judgment in *Braidwood Mgmt. Inc. v. Becerra*, 666 F. Supp. 3d 613 (March 30, 2023)
- Second memorandum opinion and order on remedies in *Braidwood Mgmt. Inc. v. Becerra*, No. 4:20-cv-00283 (N.D. TX, March 30, 2023)
- Memorandum opinion and order in *Braidwood Mgmt. Inc. v. Becerra*, 627 F. Supp. 3d 624 (Sept. 7, 2022)
- ACA, HIPAA and CARES Act implementation FAQs part 50 (DOL, HHS and Treasury, Oct. 4, 2021)
- Pub. L. No. 116-136, Coronavirus Aid, Relief and Economic Security (CARES) Act (Congress, March 27, 2020)
- Notice 2019-45, Additional preventive care benefits permitted to be provided by a high-deductible health plan under § 223 (IRS, July 17, 2019)

Mercer Law & Policy resource

- New PrEP option and employer coverage considerations (Oct. 16, 2025)
- What employers need to know about federal vaccine policy changes (Oct. 2, 2025)

- Employers to continue covering preventive care after SCOTUS decision (June 27, 2025)
- ACA preventive services mandate gets its day at the Supreme Court (April 17, 2025)
- ACA preventive services coverage and litigation continue, for now (June 27, 2024)
- Texas judge pares back ACA preventive services coverage requirement (March 31, 2023)
- IRS expands pre-deductible preventive care for HSA-qualifying health plans (July 23, 2019)

Other Mercer resources

- Employers: Don't stay in the dark about HIV prevention (June 18, 2025)
- CMS clarifies the preventive services requirements for PrEP (Feb. 5, 2025)

8. Other ongoing ACA concerns

Non-Mercer resources

- 26 CFR § 301.6724-1(e), Regulation on reasonable cause (Code of Federal Regulations (CFR))
- 29 CFR § 2590.732(c)(3)(vi), Regulation on excepted benefit employee assistance programs (CFR)
- 29 CFR § 2590.732(c)(3)(viii), Regulation on excepted benefit heath reimbursement arrangements (CFR)
- 29 CFR § 2590.732(c)(4), Regulation on excepted benefits that are noncoordinated (CFR)
- 45 CFR § 155.310(i), Regulation on certifying employer has employees receiving subsidized public exchange coverage (CFR)
- Information on EHB benchmark plans (CMS)
- Medical loss ratio (CMS)
- Employer shared-responsibility provisions (IRS)
- Information reporting by applicable large employers (IRS)
- Information reporting by providers of minimum essential coverage (IRS)
- PCORI fee (IRS)
- Understanding your Letter 226-J (IRS)
- Order and memorandum opinion, State of Tennessee v. Kennedy, No. 1:24-cv-00161 (S.D. Miss., Oct. 22, 2025)
- ACA implementation FAQs part 72 (DOL, Treasury and HHS, Oct. 16, 2025)

- Changes in healthcare spending and uncompensated care under enhanced tax credit expiration for marketplace coverage (Urban Institute, Sept. 25, 2025)
- Memorandum, Information regarding *City of Columbus v. Kennedy,* No. 25-cv-2114 (D. Md.) (CMS, Sept. 23, 2025)
- Letter, Estimated effects of enacting selected health coverage policies on the federal budget and on the number of people with health insurance (Congressional Budget Office, Sept. 18, 2025)
- H.R. 5145, Bipartisan Premium Tax Credit Extension Act (introduced in the House of Representatives, Sept. 4, 2025)
- Press Release, HHS expands access to affordable health insurance (CMS, Sept. 4, 2025)
- Guidance, Hardship exemptions for individuals ineligible for advance payment of the premium tax credit or cost-sharing reductions due to income, and streamlining exemption pathways to coverage (CMS, Sept. 4, 2025)
- CAA, 2021 and ACA FAQs part 71 (July 30, 2025)
- Rev. Proc. 2025-26 (IRS, July 22, 2025)
- Rev. Proc. 2025-25 (IRS, July 17, 2025)
- Pub. L. No. 119-21, the One Big Beautiful Bill Act (Congress, July 4, 2025)
- Final rule, CMS marketplace integrity and affordability (Federal Register, June 25, 2025)
- Letter, Information concerning Medicaid-related provisions of Title IV of H.R. 1 (Congressional Budget Office, June 24, 2025)
- Notice of appeal, *Faulk Company, Inc. v. HHS,* No. 4:24-cv-00609 (N.D. Tex., June 20, 2025)
- Dismissal of appeal (5th Cir. June 10, 2025), granting the unopposed motion to dismiss the appeal of *Manhattan Life Ins. v. HHS* (E.D. Tex., Dec. 4, 2024)
- Order, *Catholic Benefits Association v. Kennedy* (E.D.N.D., June 5, 2025)
- Notification of HHS documents identified for rescission (Federal Register, May 14, 2025)
- Opinion and order, *Faulk Company, Inc. v. HHS,* No. 4:24-cv-00609 (N.D. Tex., April 10, 2025)
- Executive order, Designating English as the official language of the United States (White House, March 1, 2025)
- Notice 2025-15, Guidance related to health coverage reporting required by Sections 6055 and 6056 (IRS, Feb. 21, 2025)
- Letter, Rescission of HHS notice and guidance on gender affirming care, civil rights and patient privacy (HHS, Feb. 20, 2025)

- Executive order, Expanding access to in vitro fertilization (White House, Feb. 18, 2025)
- Executive order, Protecting children from chemical and surgical mutilation (White House, Jan. 28, 2025)
- Executive order, Removing barriers to American leadership in artificial intelligence (Jan. 23, 2025)
- HHS poverty guidelines for 2025 (Federal Register, Jan. 17, 2025)
- Final rule, Federal civil penalties Inflation Adjustment Act annual adjustments for 2025 (Federal Register, Jan. 10, 2025)
- Pub. L. No. 118-167, Paperwork Burden Reduction Act (Congress, Dec. 23, 2024)
- Pub. L. No. 118-168, Employer Reporting Improvement Act (Congress, Dec. 23, 2024)
- *Manhattan Life Ins. v. HHS,* No. 6:24-cv-00178 (E.D. Tex., Dec. 4, 2024)
- Notice 2024-83, Insured and self-insured health plans adjusted applicable dollar amount for fee imposed by Sections 4375 and 4376 (IRS, Dec. 2, 2024)
- Letter, Premium adjustment percentage, maximum limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage for the 2026 benefit year (CMS, Oct. 8, 2024)
- *State of Texas v. Becerra*, No. 6:24-cv-211 (E.D. Tex., Aug. 30, 2024)
- *State of Tennessee v. Becerra*, No. 1:24-cv-00161 (S.D. Miss., July 3, 2024)
- *Florida v. HHS*, No. 8:24-cv-1080 (M.D. Fla., July 3, 2024)
- Final rule, Nondiscrimination in health programs and activities (ACA Section 1557) (Federal Register, May 6, 2024)
- Final rule, HHS notice of benefit and payment parameters for 2025 (Federal Register, April 15, 2024)
- Final rule, Short-term, limited-duration insurance and independent, noncoordinated excepted benefits coverage (Federal Register, April 3, 2024)
- ACA implementation FAQs part 66 (DOL, Treasury and HHS, April 2, 2024)
- Final rule, *De minimis* error safe harbor exceptions to penalties for failure to file correct information returns or furnish correct payee statements (Federal Register, Dec. 19, 2023)
- 2023 Culturally and linguistically appropriate services county data (DOL, Treasury and HHS, Nov. 28, 2023)
- ACA and 2021 CAA implementation FAQs part 63 (DOL, Treasury and HHS, Nov. 28, 2023)
- Motion to clarify scope of court's order, *HIV and Hepatitis Policy Institute v. HHS*, No. 1:22-cv-2604 (D.D.C., Nov. 27, 2023)

- Final rule, Electronic-filing requirements for specified returns and other documents (Federal Register, Feb. 23, 2023)
- Final rule, Information reporting of health insurance coverage and other issues under Sections 5000A, 6055 and 6056 (Federal Register, Dec. 15, 2022)
- Pub. L. No. 117-169, Inflation Reduction Act (Congress, Aug. 16, 2022)
- Final rule, Grandfathered group health plans and grandfathered group health insurance coverage (Federal Register, Dec. 15, 2020)
- FFCRA and CARES Act implementation FAQs part 43 (DOL, HHS and Treasury, June 23, 2020)
- Final rule, HHS Notice of benefit and payment parameters for 2021 (Federal Register, May 14, 2020)
- Memorandum 20200801F, Statute of limitations for IRC § 4980H (IRS, Dec. 26, 2019)

Mercer Law & Policy resources

- Quick benefit facts and COLA resources for benefit plans (annually updated)
- Wondering if ICHRAs have a role in your program? What you need to know (Sept. 18, 2025)
- 2026 affordability percentage for employer health coverage increases (July 22, 2025)
- President Trump's executive orders and their impact on employer health programs (Jan. 29, 2025)
- 2025 federal poverty levels can impact ESR affordability (Jan. 21, 2025)
- DOL sets 2025 penalties for health and welfare benefit plan violations (Jan. 10, 2025)
- Congress eases ACA employer reporting, looks for year-end healthcare deal (Dec. 12, 2024)
- Some states require group health plan sponsor reporting (Dec. 2, 2024)
- Group fixed-indemnity plans pose legal, tax issues (Aug. 27, 2024)
- HHS adjusts 2024 HIPAA, certain ACA and MSP monetary penalties (Aug. 21, 2024)
- Drug copay accumulator programs: A many-sided argument (Oct. 26, 2023)
- Agencies propose overhaul of fixed-indemnity plan rules (July 18, 2023)
- Final regulations extend ACA individual statement due dates (Dec. 20, 2022)
- Employers face ongoing liability for ACA play-or-pay assessments (March 2, 2020)
- IRS outlines how individual-coverage HRAs can meet ACA employer mandate (Oct. 29, 2019)
- Final rules ease restrictions on health reimbursement arrangements (June 14, 2019)

Other Mercer resources

- What might US healthcare look like after One Big Beautiful Bill Act? (July 17, 2025)

9. Mental health parity

Non-Mercer resources

- 29 CFR § 2590.712, Parity in mental health and substance use disorder benefits (eCFR.gov)
- Mental health parity and substance use disorder resources (DOL)
- Mental Health Parity and Addiction Equity Act (CMS)
- Statement regarding enforcement of the final rule on requirements related to the Mental Health Parity and Addiction Act (DOL, HHS and Treasury, May 15, 2025)
- Report to EBSA on mental health parity (DOL Office of Inspector General, Feb. 19, 2025)
- Complaint, *ERISA Industry Committee v. HHS*, No. 25-cv-136 (D.D.C. Jan. 17, 2025)
- 2024 MHPAEA Report to Congress (DOL, HHS and Treasury, Jan. 17, 2025)
- FY 2023 MHPAEA enforcement fact sheet (DOL, Jan. 17, 2025)
- Final rule, Requirements related to the Mental Health Parity and Addiction Equity Act (Federal Register, Sept. 23, 2024)
- FY2022 MHPAEA enforcement fact sheet (DOL, July 2023)
- 2023 MHPAEA report to Congress (DOL, HHS and Treasury, July 24, 2023)
- Appendix: MHPAEA guidance compendium (DOL, July 21, 2023)
- MH/SUD parity implementation and 2021 CAA FAQs part 45 (DOL, HHS and IRS, April 2, 2021)
- Pub. L. No. 116-260, the 2021 CAA (Congress, Dec. 27, 2020)
- Final rule, Final rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Federal Register, Nov. 13, 2013)

Mercer Law & Policy resources

- PSYPACT gets an A (for access, among other things) (May 29, 2025)
- Administration won't enforce 2024 mental health parity rule (May 15, 2025)
- Mental health parity report released, lawsuit filed (Feb. 5, 2025)
- Alert: Sweeping mental health parity rules add new requirements (Sept. 13, 2024)
- MHPAEA opt-out ends for nonfederal government plans (June 29, 2023)
- Mental health parity compliance gets a boost in 2021 spending act (April 13, 2021)

- Mental health parity FAQs address nonquantitative limits, disclosures (Dec. 17, 2019)

Other Mercer resources

- Has virtual been a gamechanger for behavioral health? (Sept. 11, 2025)
- As benefit costs surge, employers face tough decisions for 2026 (July 17, 2025)
- Mental health challenges remain omnipresent (Oct. 10, 2024)
- Help for opioid addiction: Some progress, much more to do (May 30, 2024)
- The most common employee disability is invisible (May 23, 2024)
- Offering benefits that matter (April 11, 2024)

10. State-mandated paid leave and other state law trends

Non-Mercer resources

- Psychology Interjurisdictional Compact (PSYPACT)
- One Big Beautiful Bill Act, § 70304 (Pub. L. No. 119-21)
- 26 USC § 45S, Employer credit for PFML
- Paperwork Burden Reduction Act, § 2 (Pub. L. No. 118-167)
- IRS Notice 2025-15, Guidance related to health coverage reporting required by §§ 6055 & 6056
- IRS Rev. Ruling 2025-4, Federal income and employment tax treatment of state PFML contributions and benefits

Mercer Law & Policy resources

- Roundup of selected state health developments, third-quarter 2025 (Oct. 21, 2025)
- Some states look to strengthen PBM standards (Sept. 25, 2025)
- Paid family and medical leave — snapshots across the US (slide deck) (Sept. 23, 2025)
- State paid family and medical leave contributions and benefits (Sept. 23, 2025)
- Maryland delays paid family and medical leave again (Sept. 2, 2025)
- Roundup of selected state health developments, second-quarter 2025 (Aug. 5, 2025)
- Governors play ace cards in recent legislative showdowns (July 30, 2025)
- Roundup: State accrued paid leave mandates (July 23, 2025)
- ERISA preemption debate heats up in 2025 (July 1, 2025)
- SCOTUS on gender-affirming care for minors: Employer takeaways (June 23, 2025)

- PSYPACT gets an A (for access, among other things) (May 29, 2025)
- IRS clarifies taxation of state and DC PFML contributions, benefits (April 29, 2025)
- Independent contractors “got a brand new (benefits) bag” (April 24, 2025)
- Roundup of selected state health developments, first-quarter 2025 (April 21, 2025)
- Massachusetts sets 2026 individual-mandate coverage dollar limits (March 13, 2025)
- Minnesota earned sick and safe time (slide deck) (Feb. 21, 2025)
- Roundup of selected state health developments, fourth-quarter 2024 (Feb. 20, 2025)
- Some states require group health plan sponsor reporting (Dec. 2, 2024)
- California-Illinois legislative sessions may forecast 2025 activity (Nov. 14, 2024)
- Small state, BIG impact: Delaware PFML offers challenges for employers (Oct. 28, 2024)

Other Mercer resources

- Life, absence and disability benefits
- MercerRx

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