Mercer

Law & Policy Group | GRIST

Top 10 health and leave benefit compliance and policy issues in 2025

By Mercer's Rich Glass, Cheryl Hughes, Geoff Manville, Katharine Marshall, Dorian Z. Smith and Jennifer Wiseman

Oct. 30, 2024; revised Nov. 19, 2024

This revised document reflects the results of the 2024 presidential and congressional elections, with the Introduction and Congressional Outlook sections updated accordingly. All other sections are current as of Oct. 30, 2024.

A business of Marsh McLennan

Contents

Introduction: Health and leave benefit compliance issues for 2025

Republican control of the White House and Congress next year will put many 2025 employer-sponsored health plan compliance issues in flux and generate extensive federal and state regulatory activity, legislation, and litigation. This GRIST summarizes potential year-end 2024 and expected 2025 compliance and policy developments affecting health and leave benefits and suggests action steps for employers. Topics covered include the following:

- **Congressional outlook.** Congress this year could pass bipartisan legislation aimed at lowering healthcare costs that requires employers to comply — if not immediately — by sometime in 2025. Legislators also may give paid family and medical leave (PFML) serious consideration next year.
- **Regulatory outlook.** Issues in the spotlight include sweeping new mental health parity rules that take effect starting in 2025, ongoing compliance with numerous group health plan transparency requirements, and efforts to rein in healthcare and prescription drug costs.
- **Outlook for 2025 election-related policy changes.** Republican control of the White House and Congress will set a new direction for healthcare and leave policies. While President-elect Trump has not laid out a detailed health policy agenda, ongoing bipartisan efforts in Congress aimed at lowering costs will continue.
- **Litigation outlook.** Active litigation continues on several key health policy issues, including surprise billing, preventive services required under the Affordable Care Act (ACA), ERISA fiduciary issues for health plan sponsors, abortion-related services, and ERISA preemption of state benefit laws, especially those affecting prescription drug benefits and pharmacy benefit manager (PBM) practices.
- **State outlook.** Employers must contend with the growing patchwork of state rules, particularly ones targeting prescription drug pricing and paid family and/or sick leave.
- **Top 10 2025 health and leave benefit planning.** This list highlights 10 top compliance-related priorities for planning 2025 health, leave and fringe benefits and recommends general actions for each item.

Congressional outlook

Despite a narrowly divided Congress and a politically charged election year, numerous bipartisan healthcare proposals have a chance of making their way into a possible year-end healthcare package. Whether any of these proposals might get enacted and pose 2025

compliance issues probably will not become clear until late in 2024. Legislation that does pass Congress this year would probably delay many effective dates until 2026 or later, though some provisions could apply in 2025. Legislation that does not pass Congress in 2024 will need to be reintroduced in 2025 or later.

2024 year-end congressional outlook

Many bipartisan bills have advanced in Congress, including House-passed legislation that would reform PBM business practices; increase health plan, provider and hospital transparency; foster greater competition among providers and hospitals, including site-neutral payment reforms in Medicare; extend pandemic-related telehealth flexibilities; lower prescription drug prices; and ease employers' ACA reporting duties, among other things.

Plan sponsor groups and other stakeholders are urging lawmakers to add these proposals to possible lame-duck healthcare legislation that could get tacked onto a must-do government funding bill or other measure. Republicans' election sweep could, however, result in a limited lame-duck agenda that punts many issues to next year when they will have more negotiating leverage.

Legislation may extend pandemic-related relief that allows high-deductible health plans (HDHPs) paired with health savings accounts (HSAs) to cover telehealth and other remote care services on a pre- or no-deductible basis. The current relief expires Dec. 31, 2024, for calendar-year plans and during 2025 for noncalendar-year plans.

Other provisions in a year-end healthcare package would likely defer many effective dates to 2026 or later, though some requirements could hit next year. Bipartisan healthcare legislation that does not cross the finish line in 2024 will need to be reintroduced in 2025.

PBM reforms

Congress has shown bipartisan support for reforming how PBMs do business, and numerous proposals are in play for potential year-end action. Any final legislation will likely draw from the Lower Costs, More Transparency Act (HR 5378), which the House overwhelmingly approved in December 2023. The bill would mandate that plan sponsors receive extensive semiannual PBM reports with detailed information on rebates, drug spending, total out-of-pocket spending and formulary placement rationale, among other things. Another provision would require PBMs and third-party administrators (TPAs) to disclose extensive information about their direct and indirect compensation to plan fiduciaries. Similar legislation is pending in the Senate.

Additional PBM reforms 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 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.

Increased transparency and provider competition

The Lower Costs, More Transparency Act would implement more price and operational transparency in the healthcare industry. Provisions would codify and strengthen current price transparency rules for health plans and hospitals. Besides enhancing existing transparency-in-coverage (TiC) rules, the measure would require new price transparency for services like diagnostic lab tests, imaging and ambulatory surgical centers owned by hospitals.

The bill also advances "site-neutral" Medicare payment policies, which plan sponsor groups hope lawmakers will extend to the commercial market. The legislation includes proposals to require that Medicare and Medicare beneficiaries pay the same rates for certain physician-administered drugs in off-campus hospital outpatient departments and physician offices. In addition, each off-campus hospital outpatient department would have to include a unique provider identifier on payment claims to help Medicare determine whether charges are appropriate.

Another provision in the bill would strengthen one provision of the No Surprises Act (NSA) in the 2021 Consolidated Appropriations Act (CAA) (Pub. L. No. 116-260). In particular, the bill would amend the NSA's 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 House and Senate bills seek to expand transparency and encourage more provider competition by barring anticompetitive contract provisions that prevent plans from directing employees to higher-value, lower-cost providers. Other proposals would ban hospital facility fees for telehealth and certain other services.

Many PBM and site-neutral Medicare and Medicaid reforms are projected to raise substantial revenue and could prove attractive to lawmakers looking for ways to pay for other priorities in a final healthcare package.

Extension of telehealth flexibilities

Bipartisan House and Senate bills would make permanent the pandemic-related relief that allows HSA-qualifying HDHPs to cover telehealth and other remote care services on a pre- or no-deductible basis. Lawmakers have shown broad support for extending the relief. Nonetheless, some Democrats have concerns that the policy might discriminate against communities facing obstacles to telehealth, such as a lack of broadband, and that HSAs favor more affluent individuals. Any extension Congress might grant at the end of 2024 is likely to be temporary, possibly for only one year. Without an extension, the relief will expire on Dec. 31, 2024, for calendar-year plans and during 2025 for noncalendar-year plans.

Congress is not expected to take up separate telehealth legislation to extend the now-expired relief that treated stand-alone telehealth benefits and other remote care services for certain employees like an excepted benefit, exempt from many ERISA and ACA group health plan mandates.

Eased employer ACA reporting duties

Bipartisan House-passed bills that could make their way into year-end legislation would streamline reporting requirements under the ACA's employer shared-responsibility (ESR) provisions:

- The Paperwork Burden Reduction Act (HB 3797) would codify and expand existing IRS rules that excuse an employer from having to mail paper copies of Forms 1095-B and 1095-C to all employees if its website contains a "clear and conspicuous notice" that employees may receive paper copies on request.
- The Employer Reporting Improvement Act (HR 3801) would allow substituting any covered individual's birthdate for that person's taxpayer identification number (TIN) if the reporting entity has been unable to collect the TIN. Another provision would give employers more time — 90 days instead of the current 30 days — to respond to proposed IRS assessments (via Letter 226-J) for alleged ESR violations. The bill would also set a six-year statute of limitations for ESR assessments. IRS's current position is that no statute of limitations applies to ESR assessments.

Regulatory outlook

Extensive regulatory activity continues as the Biden administration works to complete as much of its policy agenda as possible before President-elect Trump takes office on Jan. 20, 2025. Besides recently finalizing mental health parity regulations, the administration is considering proposed and/or final rules increasing transparency (e.g., addressing air ambulance reporting, agent/broker disclosures, provider enforcement and advanced explanations of benefits (EOBs)). Other regulatory developments could address the permissible use of voluntary employees' beneficiary association assets for welfare benefits, along with moral and religious exemptions to certain ACA preventive services.

On the drug front, regulators intend to issue rules addressing the extent to which drug manufacturers' financial assistance programs (e.g., coupons) must count toward (or can be excluded from) a health plan's deductible and out-of-pocket maximum. The regulators also intend to issue rules on whether all prescription drugs covered by large insured and self-funded group health plans are ACA essential health benefits (EHBs) and thus subject to EHB requirements, including in-network OOPMs and restrictions on annual and lifetime dollar limits.

In response to the Supreme Court's *Dobbs* decision (142 S. Ct. 2228 (2022)), regulators have asked for comments on a possible requirement that nongrandfathered group health plans cover certain over-the-counter (OTC) preventive items and services, including contraceptives and male condoms, without cost sharing or a prescription. In response, the regulators issued a proposed rule that would adopt that change for OTC contraceptives and would expand preventive services coverage in other ways.

But any proposed rules not made final when the Trump administration takes over on January 20 will be subject to an expected regulatory freeze while the administration assesses which rules it wants to stop or revise. Even rules finalized by then, however, could be overturned and rewritten by the Trump administration under the more lengthy notice-and-comment rulemaking process.

Outlook for 2025 election-related policy changes

Healthcare was not a central campaign issue, and neither presidential candidate offered detailed health policy proposals. However, healthcare affordability bears watching in 2025 since President-elect Trump highlighted the topic in his platform.

Trump priorities

Trump's website states that he will "increase fairness through price transparency, and further reduce the cost of prescription drugs and health insurance premiums." These themes likely align him with bipartisan legislation on PBM reforms, price transparency and site neutrality.

Although Trump apparently has not ruled out the possibility of another ACA repeal-and-replace effort, congressional Republicans are not likely to go along. Nonetheless, his first term suggests that he would do little to promote ACA coverage, and he supports allowing the expanded and enhanced ACA public exchange subsidies to expire. The incoming Trump administration could also reprise his first-term implementation of non-ACA coverage options for individuals and employers, such as short-term, limited-duration insurance and association health plans — reforms since rolled back by the Biden administration.

The first Trump administration also focused on drug costs and price transparency. Trump signed several executive orders aimed at lowering prescription drug costs, including one on healthcare price and quality transparency that resulted in new price transparency rules for hospitals and insurers.

Trump's drug pricing plans for a second term, however, are not clear. He has not stated a position on the Inflation Reduction Act's drug price negotiation program in Medicare enacted by Democrats, though some conservative think tanks hope a potential Republican-led Congress will repeal the law and its drug price controls.

Congress will debate tax policy in 2025, and Republicans plan to pursue much of their agenda (including extending virtually all the 2017 tax cuts set to expire at the end of 2025) through a budget "reconciliation" process that allows legislation to pass the Senate by a simple majority instead of the usual 60-vote threshold. That legislation could include a proposal from conservative House GOP members (with input from several think tanks) to limit the current uncapped employee tax exclusion and/or employer tax deduction for employer-provided healthcare coverage. Trump has not weighed in on whether he would support capping the tax exclusion or deduction for employer-sponsored coverage.

Even with full control of government, however, Republicans may find it difficult to fulfill some aspects of their legislative agenda. Their majorities in both chambers are narrow, providing little room for defections. As a result, the Trump administration will likely lean heavily on its executive and regulatory authority to implement its health policy priorities, although a recent US Supreme Court decision could make it easier for successful legal challenges to how that authority is exercised. (See the Litigation outlook section below.)

Employers planning for 2025 and beyond will need to keep a close eye on potential health and tax policy changes under the Trump administration and Republican-controlled Congress.

Litigation outlook

Federal regulations facing litigation may now become subject to review under the US Supreme Court's *Loper Bright* decision (144 S. Ct. 2244 (2024)), which overturned a 40-year-old principle of administrative law known as the *Chevron* deference doctrine. That doctrine required courts to defer to administrative agencies' reasonable interpretation of a federal law that is silent or ambiguous on a point. Now, federal courts must exercise independent judgment when determining the best interpretation of a statute and cannot

simply defer to agency interpretations, however reasonable. This will probably increase courts' scrutiny of federal regulations subject to legal challenges.

Under a Trump administration, litigation challenging prior Democrat administration regulatory efforts to implement and expand healthcare reforms will likely increase. Ongoing legal challenges target the ACA's preventive services mandate and ban on discrimination in health programs and activities (Section 1557). Other cases involve the surprise billing regulations implementing the 2021 CAA's provisions and the administration's position on access to abortion-related services and medications. Litigation over ERISA preemption of state PBM laws and regulations will have major implications for employers' pharmacy benefit programs.

There may also be a shift in whether and how vigorously the Department of Justice will challenge or defend federal regulations and state laws in court, such as a challenge to a Tennessee state law prohibiting gender-affirming care for minors (US v. Skrmetti), and on-going litigation regarding whether all group health plans and insurers would be allowed to exclude coverage of, or impose cost sharing on, many ACA-mandated preventive services, and allow employer plan sponsors with religious objections to exclude coverage of PrEP HIV medications (*Braidwood Mgmt. Inc. v. Becerra*). *Skrmetti* will be heard by the US Supreme Court in their 2024-2025 term. The Court has yet to decide whether it will hear *Braidwood*. Another case focuses on whether a former employee has the right to sue under the Americans with Disabilities Act for discrimination in post-employment benefits (*Stanley v. Sanford*).

State outlook

At the state level, employers can expect states to seek expansion of paid leave laws, prescription drug pricing reforms, access to telehealth services and health insurance coverage mandates.

Top 10 2025 health and leave benefit planning

The following list highlights 10 top compliance-related priorities for planning 2025 health, leave and fringe benefits and recommends general actions for each item. The links below take readers to more detailed information. The appendix provides resources related to each compliance topic.

1. **Prescription drugs (Rx).** The state and federal focus on PBMs will continue next year, given that lawmakers view PBM restrictions and prohibitions as the primary solution for controlling Rx costs. These actions will challenge plan sponsors. Monitor activities by the Federal Trade Commission (FTC), which will continue its investigation of the PBM industry — following up on a July interim report — and the agency's lawsuit against the three major PBMs over allegedly anticompetitive insulin practices. Keep an eye out for industry trends, particularly with glucagonlike peptide 1 (GLP-1) agonists to treat obesity and other conditions. Monitor Medicare Rx price negotiations between the Centers for Medicare & Medicaid Services (CMS) and drug manufacturers under the Inflation Reduction Act of 2022 (Pub. L. No. 117-169) and any indirect impact on group health plan costs. Look for triagency guidance on whether a group health plan must count third-party financial assistance toward a plan's deductible and out-of-pocket maximum. Continue to meet the deadline for submitting prescription drug data collection (RxDC) reports to CMS. Look for a follow-up CMS report using RxDC data. Stay abreast of developments related to drug importation now that the Food & Drug Administration (FDA) has given preliminary authorization to Florida's plans to import drugs from Canada.

2. **ERISA fiduciary issues.** To mitigate heightened ERISA fiduciary risks, reassess with legal counsel relevant fiduciary roles, responsibilities, delegations, processes and insurance coverage. Monitor litigation against group health plans and their service providers. Recent cases have involved pharmaceutical rebates, prescription drug prices, service provider fees (including "shared savings"), cross plan-offsetting, automated claims administration and plan failures to obtain data from service providers. Keep track of recent DOL enforcement priorities, which may affect fiduciary duties. Timely comply with ERISA's reporting and disclosure requirements, including long-standing duties like filing Form 5500 and newer transparency obligations, such as gag clause attestations and RxDC submissions. Prudently select and regularly monitor service providers' qualifications, cybersecurity measures, quality of services, and compensation, including broker and consultant compensation disclosures. Ensure service providers mitigate cybersecurity risks, don't have contractual gag clauses and make plan data available on request when required. As part of vendor monitoring, review any mistakes or participant complaints. Consider how increased plan costs affect participants, and analyze those costs (when possible) using transparency data. Review all other applicable fiduciary matters (e.g., ERISA plan asset and bonding issues) for compliance. Update plan documents and communications as needed.

3. **Mental health parity.** Confirm all plans subject to the Mental Health Parity and Addiction Equity Act (MHPAEA) are in compliance with the requirements, including the 2024 final rule. Use the final rule's definitions to identify mental health and substance use disorder (MH/SUD) benefits entitled to MHPAEA protections. Ensure that no limits — financial, quantitative or nonquantitative — apply solely to MH/SUD benefits in a benefit classification. Confirm that no limit on MH/SUD benefits is more restrictive than the predominant limit on substantially all medical/surgical benefits in a classification. Revise the written comparative analysis of nonquantitative treatment limitations to incorporate the 2024 final rule's new content required for the 2025 plan year, including a fiduciary certification for ERISA plans. Be prepared to disclose the comparative analysis on request to federal regulators, states or plan enrollees. Evaluate whether the plan will need to cover additional MH/SUD benefits to satisfy the meaningful benefits standard in 2026. Consider parity requirements when improving a plan's medical or surgical benefits. Watch for new guidance, and monitor parity and behavioral health coverage litigation.

4. **Group health plan transparency.** Continue to offer the self-service cost-comparison tool (with data available for all items and services), as required by the final Transparency-in-Coverage (TiC) rule, and ensure data is accurate. Confirm that machine-readable files (MRFs) are updated monthly. Make sure those files have accurate and complete in-network provider rates and out-of-network allowed payments, including facility fees. Include additional data for alternative reimbursement arrangements when applicable. Prepare to post MRFs for prescription drugs, once regulators provide more information on prescription drug MRFs. Ensure timely 2025 submission of the required gag-clause attestations and prescription drug RxDC reports. Look for analyses of healthcare prices made public under the final transparency regulation for hospitals and by TPAs and insurers. Watch for new transparency legislation and guidance — especially on advanced EOBs — and continue good-faith efforts to comply in the interim. Work with vendors to ensure compliance, and update contracts as necessary — most plan sponsors don't have the required information for these disclosures. Consider requesting vendors provide reporting and performance guarantees related to transparency compliance.

5. **Data privacy and security.** Implement the heightened Health Insurance Portability and Accountability Act (HIPAA) privacy standards for reproductive healthcare. Assess how cybersecurity risks affect data security priorities for group health plans. Look for updated HIPAA guidance about online tracking technologies, and focus on how to address telehealth and digital solutions for behavioral health and other targeted health conditions. Evaluate vendors, new technologies, and apps to determine whether HIPAA or other data protection and privacy laws apply. Regularly review vendors' compliance with HIPAA and the DOL's cybersecurity measures for ERISA plans. Use compliance tools from regulators to identify and address security vulnerabilities, and monitor federal enforcement.

6. **Artificial intelligence in benefits.** Much about artificial intelligence (AI) is still unknown or unproven. Because AI presents risks and opportunities, consider setting guardrails encouraging the responsible use of AI. Plan fiduciaries must act prudently in selecting and monitoring service providers, including the use of AI. Also review any internal use of AI under the group health plan as part of plan management. In conducting this review, apply current legal and compliance requirements in novel ways. Watch for legislation, regulation, and litigation to unfold, and apply any new requirements to plans.

7. **Surprise billing.** Verify that emergency services are covered to the full extent required and plan administrators are properly administering emergency service claims. Confirm plan administrators are complying with cost-sharing and external review requirements for services protected under the NSA, part of the 2021 CAA. Make sure the plan is providing the required NSA notices online and in EOBs. Review the frequency and outcomes of independent dispute resolution (IDR) proceedings. Consider the appropriateness of additional vendor fees related to surprise-billing compliance and/or any shared-savings program charges. Monitor ongoing litigation and watch for new or revised regulations and other guidance.

8. **State-mandated paid leave and other state law trends.** States will likely focus on two issues in 2025: paid leave and PBM restrictions. Four states — Delaware, Maine, Maryland and Minnesota — will implement new PFML mandates that start in 2025 and 2026. As Congress considers a national PFML solution — with a state coordination and harmonization provision known as the Interstate Paid Leave Action Network (I-PLAN) — additional states may yet consider adding a PFML mandate or paid family leave insurance option. Paid sick and safe leave programs are on the November 2024 ballots in three states and on the agendas of several state legislatures in 2025. PBM limitations — particularly related to the use of affiliated pharmacies, mail-order programs and reimbursement practices — will top many state legislative agendas. ERISA preemption of state laws (particularly those regulating PBMs) remains a hot topic; a case seeking US Supreme Court review may provide clarity. Telehealth expansion — in the form of multistate compacts — is a trend that should continue next year.

9. **Preventive services.** Confirm nongrandfathered group health plans cover without cost sharing all in-network preventive services that ACA requires. Modify 2025 benefits for the latest ACA guidance and any new or updated preventive care recommendations. Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives approved by FDA, unless an exemption applies. Monitor a proposed ACA rule that would enhance coverage of prescribed and OTC contraceptives without cost sharing, clarify the exceptions process for all ACA-recommended preventive services, and require additional disclosures about contraceptive coverage. Keep an eye on a proposed preventive-services rule that would eliminate the moral exemption and amend the religious

exemption from mandated coverage of women's contraceptives. Review guidance addressing coverage pre-exposure prophylaxis (PrEP) and the use of industry-standard coding practices for recommended preventive services. Monitor ongoing litigation that would let all nongrandfathered group health plans and insurers exclude coverage of or impose cost sharing on many ACA-mandated preventive services, plus allow employer plan sponsors with religious objections to exclude coverage of PrEP HIV medications. Review IRS guidance expanding the preventive care benefits that HSAs-qualifying HDHPs may cover on a pre- or no-deductible basis; consider whether to make any corresponding plan changes. Review group health coverage of COVID-19 testing and vaccines, and determine whether to change coverage now that more than a year has elapsed since the public health emergency expired in May 2023. Update plan documents, summary plan descriptions (SPDs), summaries of benefits and coverage (SBCs), and other materials as needed.

10. **Other ongoing ACA concerns.** Confirm compliance with the ACA's group health plan benefit mandates and market reforms, and monitor litigation related to the scope of those mandates. Make sure hospital and other fixed-indemnity plans qualify as excepted from ACA group health plan mandates and certain other federal laws, and provide the newly required notice. Assess the impact of the 2024 final rule reinterpreting the ACA's Section 1557 nondiscrimination provision, and monitor litigation challenging this rule. Ensure that HIPAA special-enrollment practices are up to date, specifically for people losing individual short-term, limited-duration insurance or and Medicaid or Children's Health Insurance Program coverage. Make sure to provide the SBC as well as ACA claims and appeals notices in a culturally and linguistically appropriate manner, consistent with updated guidance effective for the 2025 plan year. Review 2025 group health plan coverage and eligibility terms in light of employer shared-responsibility (ESR) strategy, as well as ESR and minimum essential coverage (MEC) reporting duties. Continue to comply with other ongoing ACA obligations, such as maintaining accurate and timely ESR recordkeeping and reporting, monitoring changes to EHBs and state benchmark plans, paying the Patient-Centered Outcomes Research Institute fee for self-funded health plans, and properly handling medical loss ratio rebates.

Section 1

Prescription drugs (Rx)

Action

Expect continued attention on prescription drug issues at the state and federal levels; actions will likely impose restrictions and prohibitions on pharmacy benefit managers (PBMs) working on behalf of group health plans. Watch for state PBM laws that blur the distinction between fully insured and self-funded ERISA plans. Keep an eye on a 2023 pro-ERISA decision — *Pharmaceutical Care Management Association v. Mulready*, No. 22-6074 (10th Cir. Aug. 15, 2023); Supreme Court review requested. Keep tabs on PBM-related actions by the Federal Trade Commission (FTC) as it continues to investigate the industry's allegedly anticompetitive practices. Also monitor the FTC's case against several PBMs related to insulin prices. Developments related to glucagonlike peptide 1 (GLP-1) agonists (like Ozempic and Wegovy) warrant attention, given their relatively high price tags but growing popularity to treat obesity and other conditions. Other new or emerging drugs also merit a watchful eye. Look for joint guidance from the departments of Labor (DOL), Treasury, and Health and Human Services (HHS) on whether group health plans must count drug manufacturer assistance toward cost sharing and the impact on copay accumulator and maximizer programs. Prepare to submit the fourth prescription drug collection (RxDC) reports due June 1, 2025, and watch for regulations and updated instructions from the Centers for Medicare & Medicaid Services (CMS). CMS is overdue to report on already collected Rx data; the report may yield helpful insights to plan sponsors. Stay abreast of ongoing Medicare Rx price negotiations and their possible effect on employer-sponsored coverage. Evaluate Rx benefit coverage and costs, including the reasonableness of PBM compensation and the quality of PBM performance. Conduct this evaluation in light of heightened scrutiny of ERISA plan fiduciary requirements (see ERISA fiduciary issues for details). Now that the Food & Drug Administration (FDA) has given preliminary approval to Florida's drug importation program, monitor similar efforts by other states and Florida's progress; however, no immediate impact on employer-sponsored coverage is expected.

Specific steps

Consider the potential need for plan design changes due to any new federal PBM legislation enacted in late 2024 or 2025.

- **Monitor legislation during 2024 lame-duck session.** Of the numerous PBM bills introduced, only the Lower Costs, More Transparency Act (HB 5378) has received a floor vote, passing the House on Dec. 11, 2023, by a 320–71 margin. Proposals under consideration include increased transparency, a 100% rebate pass-through to the group health plan, a ban on spread pricing (i.e., setting PBM charges to a plan higher than what the PBM reimburses pharmacies) and a cap on out-of-pocket insulin costs for employer-sponsored plans. Some stakeholders are advocating for ERISA fiduciary status for PBMs. Provisions requiring greater transparency to the government, plans and participants appear to have the best chance of inclusion in a year-end bill. Otherwise, these proposals will need to be reintroduced in 2025. A recent Congressional Budget

Office (CBO) analysis reviewed seven cost-saving measures, including manufacturer inflation rebates, importation and increased transparency. Extending Medicare negotiation to the commercial market would be perceived to have a ~1% impact. At the top of the list is most-favored nation pricing (i.e., setting the maximum allowed prices based on prices outside the US). (See the *Congressional outlook* section for details.)

- **Address the implications of any enacted Rx legislation with PBMs, actuaries and other vendors.** Depending on plan year, required changes may have varying effective dates.

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

- **Track state bills limiting and/or prohibiting standard PBM activities.** Typical proposals would restrict common practices like spread pricing, incentivized network design, mail-order and specialty pharmacy steerage, fiduciary status, drug price delinking from fees, and other price-saving programs for fully insured and self-funded plans. PBM transparency and licensing are low-hanging fruit for states in the initial stages of reforms. In 2024, California, Idaho, Kentucky and Washington passed significant restrictions on PBM practices. Of the four states, only Washington clearly exempted self-funded ERISA plans. Plans may have to make design changes to comply in some cases.
- **Take heed of renewed state efforts to erode ERISA preemption.** Determine how new state PBM laws affect self-funded ERISA plans. In the 2023 *Mulready* decision, the 10th Circuit struck down key parts of an Oklahoma law on ERISA preemption grounds. However, the Supreme Court held in *Rutledge v. Pharmaceutical Care Management Association* (140 S. Ct. 812 (2020)) that state laws merely regulating costs avoid ERISA preemption. Self-funded plans should address any new law's impact with their PBMs and legal counsel.
- **Examine PBM contracts and processes.** Review PBMs' compliance with applicable state laws and regulations, especially new ones. Regular discussion with PBMs should include any program changes or terminations due to state laws and their impact on fees and plan costs. RxDC reporting may prompt sponsors to have more detailed discussions with PBMs about their compensation, both as a business and fiduciary issue.

Stay alert to ongoing FTC activities. In September, FTC filed an administrative complaint against major PBMs over insulin pricing and indicated that Rx manufacturers may be the agency's next target. The FTC interim staff report on PBMs and ongoing investigation into the industry are expected to result in enforcement through litigation. In response, Express Scripts has filed a lawsuit against FTC over the report, alleging violations of the US Constitution, the federal Administrative Procedure Act and Missouri's defamation law. The FTC's actions could have widespread repercussions on the industry beyond the large PBMs mentioned in the report.

- **Raise the issue with PBMs.** Confer with PBMs about how the FTC investigation and lawsuit may affect plan design and costs, including fees and clawbacks, patient steering, pharmacy reimbursements and specialty drug practices.
- **Monitor similar state activity.** Stay informed about any state investigations similar to the FTC inquiry.

Pay attention to developments related to GLP-1s and other obesity-related drugs. Earlier this year, the FDA approved the weight-loss drug Wegovy to treat serious cardiovascular events like heart attacks and strokes. Meanwhile, GLP-1s have shown growing popularity but also have a high rate of discontinuation, especially after one year. Group health plans are challenged to weigh the extent of GLP-1 coverage and the associated costs. State and federal legislators are aware of these issues and may enact coverage mandates in 2025. For example, a CBO analysis recently concluded that adding anti-obesity Rx to Medicare would cost about $35 billion through 2034, resulting in only a fraction of that amount in savings. CBO recognizes the uncertainties of these estimates, however, including potential savings from improved health as well as decreases in the cost of the drugs. Legal counsel review is recommended for any obesity-related plan design changes, since some courts have concluded that obesity is a protected disability.

Watch for further triagency guidance on drug manufacturers' financial assistance and plan cost sharing. 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 an issue for high-deductible health plans paired with health savings accounts (HSAs). A typical copay maximizer program likewise has a cost-saving goal but takes a different route by classifying some high-cost drugs as nonessential health benefits (non-EHBs) under the Affordable Care Act (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.

- **Stay abreast of HHS guidance on copay accumulators.** These programs currently remain permissible under federal law. In a now settled lawsuit (*HIV and Hepatitis Policy Inst. v. HHS*, No. 22-2604), HHS stated it would take a nonenforcement position on copay accumulators.
- **Keep an eye out for state laws banning copay accumulators.** About 20 states and Puerto Rico have enacted (and more states are likely to consider) legislation requiring fully insured plans to apply drug manufacturer assistance toward cost sharing. These insurance laws typically do not apply to self-funded ERISA plans.
- **Look for potential expansion of HHS policy on copay maximizers.** Under the EHB rules, insured individual and small-group plans will not be able to use copay maximizers starting in 2026. However, this prohibition does not apply to fully insured large-group plans or 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."

Review PBM and Rx consultant compensation in light of increased ERISA fiduciary scrutiny. Given the heightened fiduciary risk for group health plans, fiduciaries may want to evaluate PBM compensation carefully. ERISA fiduciaries must act in the best interests of the plan and its participants to monitor service providers and determine that they are paid 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 separately requires disclosure of direct and indirect compensation by service providers.

Modify RxDC processes as needed. The next RxDC reporting deadline under NSA Section 204 is June 1, 2025. As part of this process plan sponsors should renew efforts to gain access to their Rx data from PBMs if doing so makes sense.

- **Reconfirm which entities will submit data.** The Health Insurance Oversight System will continue to serve as the reporting mechanism. Make sure each reporting entity timely complies.
- **Stay on top of any updated instructions**, regulations or other guidance that may require changes.
- **Review insurer, third-party administrator (TPA), PBM and other vendor agreements.** Look for contractual provisions that address RxDC obligations. Plan sponsors may want to negotiate the right to obtain a copy of their plan's data submission.

Stay current on Medicare Rx price negotiations with manufacturers and the potential financial impact on employer-sponsored coverage.

- **Monitor CMS's Medicare Rx price negotiations.** The Inflation Reduction Act of 2022 (Pub. L. No. 117-169) gives CMS the authority to negotiate Medicare Part D drug prices, starting with 10 drugs in 2026 and more in future years. Other provisions apply to the standard Medicare Part D benefit, including a $35 monthly cap and a $2,000 annual OOPM on insulin cost sharing, effective in 2025. 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).
- **Follow any additional FDA developments related to Rx importation, as well as state legislation authorizing importation.** In January, Florida became the first state to receive FDA approval of a drug importation program. However, Canada, the source country, has communicated a reluctance to participate due to supply concerns.

Related resources

Section 2

ERISA fiduciary issues

Action

In light of elevated ERISA fiduciary risks, reassess with legal counsel relevant fiduciary roles, responsibilities, delegations and processes, including whether to establish a benefits committee. Monitor litigation against group health plans and their service providers. Recent cases have involved prescription drug prices, pharmaceutical rebates, service provider fees (including "shared savings"), cross plan-offsetting, automated claims administration and plan failures to obtain data from service providers. Track recent US Department of Labor (DOL) enforcement priorities, which may affect fiduciary duties. Prudently select and regularly monitor service providers' qualifications, cybersecurity, quality of services and compensation, including broker and consultant compensation disclosures. Ensure service providers mitigate cybersecurity risks, don't have contractual gag clauses and make plan data available on request when required. Consider how increased plan costs affect participants, and analyze plan costs (when possible) using the vast amount of newly available transparency data. Ensure claims and appeals processes are compliant, including the full and fair review of appeals. Address any mistakes or participant complaints as part of vendor monitoring. Timely comply with ERISA's reporting and disclosure requirements, including long-standing duties like filing Form 5500 and newer transparency obligations, such as gag clause attestations (see Group health plan transparency), RxDC submissions (see Prescription drugs (Rx), and the comparative analysis of mental health and substance use disorder benefits required by the Mental Health Parity and Addiction Equity Act (MHPAEA) (see Mental health parity). Review all other applicable fiduciary matters (e.g., ERISA plan asset and bonding issues) for compliance. Update plan documents and communications as needed. Ensure that fiduciary insurance coverage is appropriate.

Specific steps

Reassess with legal counsel relevant fiduciary roles, responsibilities, delegations and processes, including whether to establish a benefits committee. The high standards for ERISA fiduciaries require more careful decision-making and more disclosures to plan participants and beneficiaries than a typical business relationship involves. ERISA also expressly bars, with some exemptions, certain transactions between interested parties that create a heightened risk of conflicts of interest or self-dealing.

- **Pay particular attention to these core fiduciary duties:**
  - **Duty of loyalty.** Act primarily to benefit participants and beneficiaries.
  - **Exclusive benefit rule.** Act for the exclusive purpose of 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 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. A person can also be a ***functional fiduciary*** under ERISA to the extent that person exercises any discretionary authority or control over the employee benefit plan's management or administration.
  - A person acting solely on the plan sponsor's behalf in a "settlor capacity" (for example, adopting, modifying or terminating a plan) is not a fiduciary. The same person may sometimes act as a fiduciary but as a settlor at other times, and those actions (e.g., setting plan contributions or premiums) should be clearly delineated.
  - Employees engaging in ministerial activities for the plan aren't acting as fiduciaries.
  - Monitor litigation challenging the DOL's investment adviser rule, which is currently on hold. The rule — which expands the scope of fiduciary investment advice — applies to retirement plans, individual retirement arrangements and health savings accounts. While most health and welfare benefits are excluded, the 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).
- **Ensure any delegation of fiduciary responsibility is properly documented.** A named fiduciary may delegate fiduciary responsibility to another fiduciary or a third-party vendor. The plan document must include a procedure for delegation, which must be followed and documented. For example, a plan sponsor may delegate fiduciary responsibility for claims and appeals to its third-party administrator (TPA), if the TPA agrees to handle that responsibility. Some plans establish benefits committees to act as the plan fiduciary, but the delegation does ***not*** end the delegating fiduciary's responsibilities. The delegating fiduciary may still be liable as a co-fiduciary for a breach committed by the delegate.
- **Review all fiduciary processes, including recordkeeping.** All actions of plan fiduciaries should conform to plan documents and be properly recorded. Any delegation of authority also should be properly documented.
  - 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, agency investigations or inquiries (e.g. from the press) as quickly as possible.

Timely meet all ERISA reporting and disclosure requirements for group health plans. Reporting requirements include but are not limited to long-standing obligations like filing Form 5500, the gag clause attestation (see Group health plan transparency) and RxDC reports with the Centers for Medicare & Medicaid Services (see Prescription drugs).

- Prepare a response plan for addressing document requests. Some documents (like the summary plan description (SPD)) must be provided within legally required time lines, while other documents may be subject to a nondisclosure agreement. Confirm the written comparative analysis of nonquantitative treatment limits is included when responding to a general request for ERISA plan documents (see Mental health parity).
- Review DOL's Reporting and Disclosure Guide for Employee Benefit Plans.

When selecting service providers, consider qualifications, quality of services, reasonableness of compensation and cybersecurity standards (among other things). To ensure a meaningful comparison, provide 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 the provider's qualifications, its quality of services and the reasonableness of fees that will be paid from plan assets. Keep records of this process.

- DOL guidance provides additional best practices that fiduciaries should consider when selecting a service provider. Recommendations include:
  - Getting information from more than one provider
  - Comparing providers using the same information, such as services offered, experience, costs, etc.
  - Obtaining information about the provider itself, including its financial condition and its experience with group health plans of similar size and complexity
  - Evaluating information about the quality of the provider's services, including the identity, experience, and qualifications of professionals who will be handling the plan or providing medical services
  - Reviewing any recent litigation or enforcement action taken against the provider
  - Reviewing the provider's experience or performance record
  - Reviewing the scope, adequacy and quality of provider networks
  - Evaluating ease of access to medical providers and information about health their operations
  - Having procedures in place to timely consider and resolve patient questions and complaints
  - Having procedures for to preserve the confidentiality of patient records
  - Maintaining enrollee satisfaction statistics
  - Ensuring any required licenses, ratings or accreditations (for insurers, brokers, TPAs and healthcare service providers) are up to date.

Regularly conduct formal reviews to monitor service providers. Ensure that service providers are performing agreed-to services.

- DOL guidance identifies best fiduciary practices for monitoring service providers, including:
  - Review 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.
  - Ask about policies and practices (such as a TPA's claims-processing systems)
  - Read any reports the service provider provides
  - Ensure proper maintenance of plan records
  - Follow up on participant complaints
  - Modify or terminate service agreements as needed.
- Review DOL's Understanding Your Fiduciary Responsibilities Under a Group Health Plan for more information on fiduciary duties for monitoring service providers

Regularly review compensation arrangements and service agreements with brokers, consultants, and service providers. Work with legal counsel and other experts, as needed.

- Collect and review broker and consultant compensation disclosures.
- Working with counsel, review service provider agreements to:
  - Ensure the agreement does not have any no gag clauses and affirms that plan data will be made available on request, as permitted by the Health Insurance Portability and Accountability Act (HIPAA)
  - Confirm that service providers assist with meeting the new transparency (see Group health plan transparency) and parity (see Mental health parity) obligations.
  - Review indemnification provisions and liability limits.
  - Verify provisions allow for ongoing monitoring (e.g., audits or market checks) and contract termination if needed.
  - Review 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 SPD.
  - 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).
  - Review legal responsibilities assigned to service providers vs. the plan sponsor for compliance with ACA, ERISA, HIPAA, the Mental Health Parity and Addiction Equity Act (MHPAEA), and other laws.
- Regularly review cybersecurity measures. (See Data privacy.)
- 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.

Use transparency data to assess plan operations. Explore plan data, and evaluate companies or organizations that can summarize and validate the data. (See Group health plan transparency.)

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.

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 any new plan design changes related to prescription drugs or other benefits. Update as necessary for new legal requirements, such as reproductive healthcare protected health information, MHPAEA, and ACA Section 1557 nondiscrimination provisions, as well as any state laws that are not preempted by federal laws. Review terms against case-law developments.

Ensure 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 litigation related to group health plans and their service providers. Allegations in recent cases include breaches of fiduciary duty related to misallocated rebates, the price of drugs, service provider fees (including "shared savings"), cross plan-offsetting, and plan failures to obtain data from service providers. ERISA fiduciaries and plan sponsors generally should familiarize themselves with the cases below and the issues presented in each, and work with counsel to minimize their risk of similar litigations.

- Review plan documents for the allocation of prescription drug rebates. In *Knudsen v. MetLife Group*, No. 23-2420 (3rd Cir. Sept. 25, 2024), health plan beneficiaries alleged 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.

- Review management of prescription drug benefit. At least two cases filed this year allege health plan fiduciaries 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. Both cases are in the early stages of litigation (*Navarro v. Wells Fargo*, Docket No. 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 TPA services, including claims administration. A number of cases filed this year — *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) — allege wide-ranging TPA breaches of fiduciary duty related to:
  - Approval of allegedly 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 the providers receive
  - Cross-plan offsetting, allegedly benefiting TPA and its insured plans at the expense of self-funded plans
  - Comingling of the plan's funds with the funds of the TPA and other plans
- Demand disclosure about the use of AI or other automated processes in claims administration. Review the use of AI or other automated processes to administer claims (and potentially override physician recommendations) in violation of ERISA's full-and-fair-review requirement. (See Artificial intelligence in benefits.)
- 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. 21-CV-4796 (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. Sen. Amy Klobuchar (D-MN) requested the Justice Department and Federal Trade Commission (FTC) to investigate MultiPlan to see if it subverts competition or otherwise harms consumers.

Track recent DOL enforcement actions related to ERISA fiduciary requirements. ERISA fiduciaries and plan sponsors generally should familiarize themselves with the enforcement priorities below and the issues presented in each, and work with counsel to minimize the risk of facing similar enforcement actions.

- Review administration of emergency medical claims. DOL is in settlement talks with a TPA — the named fiduciary of a self-funded plan — that the agency accuses of not complying with the required "prudent layperson" standard when processing emergency medical claims. DOL alleged:
  - The TPA relied solely on diagnostic codes for emergency claims review and approval (or denial).
  - The TPA denied nearly all urinary drug-screening (UDS) claims without reviewing their medical necessity (as required by the plan document).
  - EOBs for denied emergency and UDS claims were deficient.
- Review full compensation — direct and indirect — that vendor partners receive for managing health plan. This appears to be a top priority for the DOL, particularly "hidden fees."
- Review the TPA's process for determining out-of-network provider reimbursement rates. DOL reportedly is requesting plan sponsors provide information related to shared savings and out-of-network provider reimbursement rates.
- DOL also continues to take enforcement action against self-funded multiple employer welfare arrangements (MEWAs) that fail to maintain adequate reserves, jeopardizing the plan's ability to pay claims. (This DOL guide provides guidance specific to MEWAs.)
- Review life insurance evidence of insurability (EOI) processes. Insurance carriers act as functional ERISA fiduciaries with the discretion to make eligibility and coverage determinations, according to recent settlements with DOL. Carriers were denying claims due to the lack of approved EOI after having accepted participants' life insurance premiums for months or years. Under the settlement's terms, carriers must make these determinations within 90 days of accepting coverage premiums to avoid a breach of fiduciary duty. Policyholders — typically employers — that collect employee premiums before confirming approval of the EOI risk liability to the beneficiary.

Related resources

Section 3

Mental health parity

Action

Confirm all plans subject to the Mental Health Parity and Addiction Equity Act (MHPAEA) are in compliance with requirements, including the 2024 final rule. Use the final rule's definitions to identify mental health and substance use disorder (MH/SUD) benefits entitled to MHPAEA protections. Ensure that no limits — financial, quantitative or nonquantitative — apply solely to MH/SUD benefits in a benefit classification. Confirm that no limit on MH/SUD benefits is more restrictive than the predominant limit on substantially all medical/surgical (M/S) benefits in a classification. Continue to apply mathematical testing to financial and quantitative treatment limits on MH/SUD benefits. Assess nonquantitative treatment limits (NQTLs) using the final rule's two-part framework — starting with the design and application requirements in 2025 and preparing to evaluate outcomes data in 2026. Revise the written comparative analysis of NQTLs to incorporate the 2024 final rule's new content required for the 2025 plan year, including a fiduciary certification for ERISA plans. Be prepared to disclose the comparative analysis on request to federal regulators, states or plan enrollees. Evaluate whether the plan will need to cover additional MH/SUD benefits to satisfy the meaningful benefits standard in 2026. Consider parity requirements when improving a plan's medical or surgical benefits. Watch for new guidance, and monitor parity and behavioral health coverage litigation.

Specific steps

Identify group health plans subject to MHPAEA. MHPAEA applies to grandfathered and nongrandfathered insured and self-funded group health plans that offer MH/SUD benefits.

- 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).
- Self-funded state or local government plans that could out of MHPAEA in the past are now subject to MHPAEA. The 2023 Consolidated Appropriations Act (CAA) (Pub. L. No. 117-328) eliminated opt-outs for self-funded state and local government employer plans after Dec. 29, 2022. In addition, any opt-out elections that expired on or after June 27, 2023, couldn't be renewed (with a longer transition for some collectively bargained plans).

Review the 2024 MHPAEA final rule, which is generally effective starting with the 2025 plan year (with a one-year delay for select provisions).

- The 2024 final rule aims to reduce barriers to MH/SUD services by focusing on benefit coverage and network adequacy.
- Most of the new requirements take effect for plan years starting on or after Jan. 1, 2025. However, select provisions — the outcomes data evaluation, the discriminatory factor prohibition, the meaningful benefits standard, and associated requirements in the written

comparative analysis — will take effect for plan years starting on or after Jan. 1, 2026. Regulators expect group health plans to use this one-year delay to prepare to come into compliance (for example, by updating systems and operations as necessary).

- Litigation challenging the 2024 final rule is expected.

Ensure that the plan is correctly identifying the MH/SUD benefits entitled to MHPAEA protections. For plan years starting on or after Jan. 1, 2025, the 2024 final rule amends existing definitions and requires plans to categorize benefits as M/S, MH, or SUD benefits consistent with generally recognized independent standards of current medical practice.

- Definitions must be consistent with the most current version of the World Health Organization's International Classification of Diseases (ICD) adopted by the US Department of Health and Human Services (HHS) or the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM).
- Eating disorders (e.g., anorexia nervosa, bulimia nervosa, or binge-eating disorders), autism spectrum disorders, and gender dysphoria are considered mental health conditions.

Confirm no financial requirements or treatment limits (quantitative or NQTLs) apply only to MH/SUD benefits and not to any M/S benefits in the same classification.

Continue to ensure that the plan does not apply any financial requirement or quantitative treatment limitation to MH/SUD benefits that is more restrictive than the predominant limit on substantially all M/S benefits in the same classification. The 2024 final rule does not change the standard for financial limits (such as deductibles) and other quantitative limits (such as visit limits) on MH/SUD benefits. These limits remain 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).

- Substantially all means the type of limit applies to at least two-thirds of the M/S benefits in the classification.
- Predominant means that level of the limit applies to more than half of the M/S benefits in the classification.

Ensure the plan does not impose any NQTL on MH/SUD benefits that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification. The 2024 final rule outlines a new two-part framework for satisfying this standard: (i) each NQTL must satisfy the design and application requirements, and (ii) outcomes data must be evaluated to assess each NQTL's impact on access to MH/SUD benefits.

- **Confirm comparable design and application requirements are met.** For plan years starting on or after Jan. 1, 2025, group health plans can't impose an NQTL on MH/SUD benefits unless the processes, strategies, evidentiary standards, or other factors used to design and apply the NQTL are comparable to and applied no more stringently than those for designing and applying the limit to M/S benefits in the same classification.
  - **Eliminate discriminatory standards or factors (required for plan years starting on or after Jan. 1, 2026).** Discriminatory standards or factors rely on information, evidence, sources or standards that are biased or not objective in a manner that

discriminates against MH/SUD benefits. Generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prove fraud and abuse while minimizing the negative impact on access to appropriate MH/SUD benefits are considered objective and unbiased information, evidence, sources, or standards.

- **Evaluate outcomes data (required for plan years starting on or after Jan. 1, 2026).** Collect and prepare to evaluate relevant data to assess each NQTL's impact on outcomes related to MH/SUD benefit access. If the outcomes data suggests that an NQTL contributes to material differences in access relative to M/S benefits in a classification, that is considered "a strong indicator" of a MHPAEA violation and the plan must take (and document) reasonable actions to address the differences. Whether a difference is material requires looking at the relevant facts and circumstances, including the NQTL terms, the data quality or limitations, the recurring (or nonrecurring) nature of the disparity, and the magnitude of the disparity, to determine whether the NQTL is likely to negatively impact access to MH/SUD benefits.
  - **Determine what data to collect.** The 2024 final rule gives plans some flexibility to determine what data to collect and provides examples (such as the number and percentage of claim denials) rather than a prescriptive list. However, a plan can't disregard data that it knows or should know suggest an NQTL is associated with material differences in access to MH/SUD benefits. For example, relevant data for NQTLs related to network composition could include data reflecting utilization rates (in and out of network), provider claim submissions, time and distance, providers accepting new patients, and provider reimbursement rates (benchmarked to a reference standard). Although the rule itself doesn't mention these items, the preamble to the rule identifies other potentially relevant data for NQTLs related to network composition, such as turnaround time for approval of provider applications and the number of providers per 1,000 participants. The departments also state that for NQTLs like prior authorization requirements, relevant data might include preservice approval and denial rates, denial rates of post-service claims, application of penalties for failing to obtain prior authorization, and turnaround times.
  - **Watch for additional guidance.** Future guidance may specify the type, form, and manner of collecting and evaluating required data. The departments intend to update the MHPAEA self-compliance tool to provide a framework and road map for plans to determine what data to collect and evaluate.
  - **Identify any material differences in access to MH/SUD benefits that are attributable to NQTLs based on medical or clinical standards or measures to prevent fraud and abuse.** If an NQTL is designed or applied based on generally recognized independent professional medical or clinical standards, the resulting differences in access to MH/SUD benefits may not be considered material. The same applies to NQTLs based on carefully circumscribed measures to prevent fraud and abuse, while minimizing the negative impact on access to MH/SUD benefits.
  - **Prepare to take reasonable actions to address material differences in access to benefits.** The 2024 final rule does not list reasonable actions, but the regulators note that some plans have already increased spending and raised reimbursement rates for MH/SUD benefits, invested in MH/SUD programs and efforts to connect enrollees with MH/SUD services, and developed screening tools to detect at-risk youths. These might be examples of reasonable actions to close the gap in access to MH/SUD

benefits, depending on the facts and circumstances. Regulators continue to focus on network adequacy. When material differences in access to in-network MH/SUD benefits exist, the 2024 final rule lists reasonable actions a plan could take, such as recruiting additional providers, expanding telehealth to mitigate geographic shortages, helping enrollees find in-network providers and updating provider directories.

- **Document efforts.** For plan years starting on or after Jan. 1, 2026, the written comparative analysis must include information related to the evaluation of outcomes data.

Confirm that the plan has completed a written NQTL comparative analysis. The 2021 CAA (Pub. L. No. 116-260) formalized the requirement for health plans to complete and document a comparative analysis of a plan's NQTLs by Feb. 10, 2021. If none exists, prepare one immediately.

- Prepare the analysis before — not after — receiving an agency's or a participant's request.
- Employers sponsoring fully insured plans should be able to rely on the insurer's comparative analyses (since insurers are directly subject to MHPAEA), but confirm this with the carrier.
- Assistance from third-party administrators (TPAs) to self-funded plans varies, since MHPAEA does not directly regulate TPAs or other benefit administrators.
- Plans with multiple vendors 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.

Revise the written comparative analysis to comply with the 2024 final rule. The final rule defines key terms (evidentiary standards, factors, processes, and strategies) and outlines specific content requirements for the NQTL comparative analysis.

- For plan years starting on or after Jan. 1, 2025, the comparative analysis must:
  - Describe each applicable NQTL and benefits subject to it
  - Identify and define the factors and evidentiary standards used to design and/or apply each NQTL
  - Describe how factors are used in the design and/or application of each NQTL
  - Demonstrate that, as written, the NQTL for the MH/SUD benefits is comparable to and no more stringent than it is for the M/S benefits.
  - Demonstrate that in operation, the NQTL for the MH/SUD benefits is comparable to and no more stringent than it is for the M/S benefits
  - Set out findings and conclusions, including a reasoned and detailed discussion about the plan's compliance that details any actions the plan has taken or intends to take to address areas of concern or noncompliance; cites any additional outside information supporting the findings and conclusions; gives the date of analysis completion; identifies the title and credentials of relevant persons who participated in the performance and documentation of the comparative analysis, plus additional

information about any expert reviewer or consultant on whom the plan relied; and supplies a fiduciary certification

- **Prepare the fiduciary certification required of ERISA plans for plan years starting on or after Jan. 1, 2025.** The findings and conclusions must include a certification by one or more named plan fiduciaries that they engaged in a prudent process to (i) select one or more qualified service providers to perform and document the comparative analysis, and (ii) monitor those service providers' performance and documentation of the comparative analysis.
  - ERISA-covered plans will need to identify the named fiduciaries who will sign the certification and retain counsel to draft the certification.
  - The named fiduciary/fiduciaries should review the comparative analysis, ask questions about the analysis and discuss it with service providers to understand its findings and conclusions, and get assurances from those preparing the comparative analysis that, to the best of their ability, the NQTLs and associated comparative analyses comply with MHPAEA.
  - Church plans and state or local government plans do not need to include this certification with their comparative analyses.
- **Prepare to include information on the outcomes data evaluation for plan years starting on or after Jan. 1, 2026.** The comparative analysis will need to include information about the outcomes data evaluation to demonstrate that an NQTL *in operation* is in parity for MH/SUD and M/S benefits. Plans must identify the relevant data collected (or explain the lack of relevant data), evaluate the outcomes data, provide a detailed explanation of any material differences in access and whether these differences are (or are not) attributable to the NQTL, and explain what actions were taken to address any material differences and whether the differences persist despite those actions.

Prepare to produce a comparative analysis on request from a federal or state agency, or a plan participant or representative.

- The comparative analysis must be provided to the federal regulators within 10 business days of a request. If the regulators find the comparative analysis insufficient, additional information must be provided within 10 business days. The comparative analysis must also be produced to any applicable state authority on request, although different time limits may apply.
- After an adverse benefit determination for MH/SUD benefits, a participant or beneficiary — including a provider or another person acting as the authorized representative of the participant or beneficiary — must be provided with the comparative analysis on request.
- An ERISA-covered plan must provide the comparative analysis to participants and beneficiaries within 30 days of a request *at any time*. Failure to do so can potentially trigger penalties of $110 per day. A federal district court recently required a plan to pay more than $32,000 for failing to provide certain medical-necessity criteria and documents identifying the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, even while ruling against the plaintiff on the substance of the MHPAEA claims.

Update the plan's comparative analysis as needed to reflect changes in plan terms, coverage, operations and data outcomes. The comparative analysis should reflect the plan's current terms and coverage, so the analysis may need an update whenever a plan's benefit design, administration or utilization changes, including when the way an NQTL is applied to MH/SUD or M/S benefits changes.

Prepare a list of all NQTLs that apply to MH/SUD benefits. For plan years starting on or after Jan. 1, 2025, ERISA plans must provide this list to the named fiduciaries completing the fiduciary certification. All covered plans must provide this list to regulators on request.

Prepare to satisfy the meaningful benefits standard in 2026. For plan years starting on or after Jan. 1, 2026, a group health plan that offers benefits for a MH/SUD condition in any classification must provide meaningful benefits for that MH/SUD condition in every classification for which M/S benefits are provided.

- **Evaluate whether the plan must cover additional MH/SUD benefits**. Compare the benefits provided for M/S conditions in the same classification to determine if the MH/SUD benefits provided are meaningful.
- **Confirm a core treatment is covered for each MH/SUD condition (if one exists) in each classification in which the plan covers M/S benefits.** A core treatment "is a standard treatment or course of treatment, therapy, service or intervention indicated by generally recognized independent standards of current medical practice." Examples of core treatments include applied behavior analysis (ABA) therapy for autism spectrum disorders (ASDs), nutritional counseling for eating disorders, and counseling, behavioral therapies, plus medications to treat opioid use disorders.

Ensure vendor contracts provide adequate assistance with MHPAEA compliance. While the 2024 final rule doesn't require this step, regulators consider it a best practice.

- Make sure vendor contracts include an agreement to comply with MHPAEA and specify the required level of support to produce a written comparative analysis satisfying existing and any future guidance. For example, consider requiring that the vendor collect relevant data (or explain the lack of relevant data), evaluate outcomes data, provide a detailed explanation of any material differences in access and whether these differences are (or are not) attributable to the NQTL, identify actions taken to address the material differences, and explain whether the differences persist after the actions are taken.
- Require vendors to comply with disclosure requests from federal or state regulators or plan participants.
- Consider negotiating performance guarantees related to MHPAEA compliance, such as a guarantee to timely respond to disclosure requests or a guarantee to conduct periodic self-audits for MHPAEA compliance.
- Require the vendor to inform the plan sponsor of any agency MHPAEA investigation, even one that might occur in the vendor's fully insured business. DOL continues to target vendors that administer plans with impermissible exclusions of MH/SUD treatments, such as ABA therapy to treat ASD, medication-assisted treatment for MH/SUDs, medications for treating opioid use disorders, urine drug testing as part of MH/SUD treatment and nutritional counseling for eating disorders. Self-funded plan sponsors should evaluate whether the investigation implicates a plan term or practice and consider how to respond (such as by removing the provision or ending the practice at issue).

- Require the vendor to inform the employer 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 like eating disorders — would fail to comply with MHPAEA.

Keep track of agency enforcement priorities. Watch for a third report to Congress, and review for additional information about MHPAEA enforcement. Previous reports to Congress have identified NQTLs commonly causing problems and priority enforcement areas. CMS recently posted several final determination letters.

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 or ASD treatments. For example, the 10th US Circuit Court of Appeals held that a plaintiff had properly alleged a MHPAEA violation by contending that the plan used acute-level treatment guidelines for residential treatment, but not for inpatient skilled nursing, which was the "relevant analog" to the MH/SUD service at issue.

- Monitor the *Wit v. United Behavioral Health* litigation in 2025. In *Wit,* the plaintiffs brought a class action seeking reprocessing of more than 67,000 denied behavioral health claims, and the district court initially ruled in favor of the plaintiffs. However, the 9th US Circuit Court of Appeals in 2023 overturned the district court's class certification and reversed the lower court's decision to the extent the ruling required the plans to cover all care consistent with generally accepted standards. The case remanded to the district court is now limited to breach of fiduciary duty issues (*W v. Health Net Life Ins. Co.*, 86 F.4th 1265 (10th Cir. 2023)).

Watch for additional guidance or legislation.

- Regulators intend to update the MHPAEA self-compliance tool and issue additional guidance about the type, form, and manner of data that plans must collect for the outcomes data evaluation. The regulators also must submit a third report to Congress, although the timing of the report is uncertain. The first two reports offered extensive insight into the regulators' enforcement priorities.

- The Biden administration has continued efforts to strengthen the provider workforce, and legislation extending telehealth flexibilities could assist with those efforts. Other proposals, such as adding civil monetary penalties for MHPAEA violations, appear unlikely to gain bipartisan support in the short term.

Related resources

Section 4

Group health plan transparency

Action

Continue to offer the self-service transparency tool (with data available for all items and services), as required by the final transparency-in-coverage (TiC) rule, and ensure data is accurate. Confirm that machine-readable files (MRFs) are updated monthly. Make sure those files have accurate and complete in-network provider rates and out-of-network allowed payments, including facility fees. Include additional data for alternative reimbursement arrangements when applicable. Prepare to post MRFs for prescription drugs once regulators provide more information. Ensure timely 2025 submission of the required gag-clause attestations and prescription drug RxDC reports (see Prescription drugs). Look for analyses of healthcare prices made public under the final transparency regulation for hospitals and by third-party administrators (TPAs) and insurers. Watch for new transparency legislation and guidance — especially on advanced EOBs — and continue good-faith efforts to comply in the interim. Work with vendors to ensure compliance, and update contracts as necessary — most plan sponsors don't have the required information for these disclosures. Consider requesting vendors provide reporting and performance guarantees related to transparency compliance.

Specific steps

Continue complying with the final TiC rule for group health plans and insurers in 2025. For the 2025 plan year, continue providing a self-service transparency tool *for all plan-covered items and services*, including prescription drugs **—** much more than the 500 items and services initially required in 2023. Ensure that all applicable plan service providers will deliver required data. 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. Prepare to post a separate MRF for prescription drugs, and include data for alternative reimbursement arrangements. Confirm that MRFs and the self-service tool include facility fees. Consider these requirements when onboarding new vendors. Continue to communicate the self-service tool to plan participants, and update language in the plan document and summary plan description as necessary.

- **Review the TiC rule and related guidance to ensure compliance for the self-service tool.** The TiC rule 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. The rule requires other group health plans, including self-funded plans and insurers, to take several key actions:
  - **Provide an internet self-service tool for all covered services and items, including prescription drugs.** 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.

- **Include required disclosures** — the Department of Labor (DOL) has provided a draft model notice for the self-service tool.
- **Review ACA implementation FAQs part 65 on how to comply for items and services with low utilization.** 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.)
- **Review proposed rules on contraceptive coverage disclosures.** Under recently proposed rules for plan years beginning on or after Jan. 1, 2026, plans would need to include a new required notice if a participant requests cost-sharing information for any covered contraceptive item or service. The new notice would need to explain that over-the-counter contraceptive items are covered without a prescription and without cost sharing, and give a telephone number and internet link to where a participant or beneficiary can learn more information about the plan's contraceptive coverage. (See Preventive services.)

- **Continue to make accurate and complete MRFs for in- and out-of-network allowed amounts available on a public website, and prepare to add a MRF for prescription drugs.** The final TiC rule requires standardized MRFs, updated monthly, containing the plan's negotiated rates for in-network providers, past allowed payments to out-of-network providers and prescription drug information. The Centers for Medicare & Medicaid Services (CMS) has provided a schema and helpful discussions on GitHub that developers must follow in preparing the MRFs. Ensure the applicable MRF includes all data elements for the negotiated rate and the allowed amounts.
  - **Monitor third-party analyses of MRFs.** For example, the *Journal of the American Medical Association* released research results analyzing small sample of October 2022 prices and found variation even within the same insurer's MRFs.
  - **Watch for guidance on posting MRFs with prescription drug prices.** The regulators rescinded their enforcement delay of the requirement to post MRFs for

prescription drugs, finding “no meaningful conflict” with the RxDC reporting of pharmacy benefits and drug costs mandated by the 2021 CAA. Regulators intend to develop technical requirements and an implementation time line 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 the implementation timeline is announced.

  - **Facility fees.** Guidance confirms that "items and services" includes facility fees. Therefore, plans and issuers must provide facility fee information in MRFs and the self-service tool.

  - **Alternative reimbursement arrangements.** Plans can no longer rely on a safe harbor originally available for certain alternative reimbursement arrangements. If the plan or issuer can demonstrate that compliance would have been extremely difficult or impossible, enforcement is unlikely, but regulators will exercise enforcement discretion on a case-by-case basis. Plans and issuers unable to determine in-network dollar amounts should continue to follow the existing GitHub technical guidance for percentage-of-billed-charges arrangements.

  - **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 addresses recordkeeping. The 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.

- **Review 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.

- **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. The extent to which a healthcare provider, network or association of providers, or other service provider may place reasonable restrictions on the public disclosure of this information or data is unclear.
- **Applicability.** The current gag-clause prohibition and the attestation requirement applies 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).
- **Gag-clause attestation.** Regulators provided detailed ACA and 2021 CAA implementation FAQs part 57 for group health plan sponsors and health insurers before the deadline for the first attestation (due Dec. 31, 2023). The regulators have issued additional compliance FAQs, updated instructions, a user manual and a reporting template for the second attestation, due by Dec. 31, 2024.

  - 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.

  - The annual attestation must be submitted through the CMS Health Insurance Oversight System portal.

  - The first attestation covered the period beginning Dec. 27, 2020, and ending on the date of the attestation. Subsequent attestations are due by every Dec. 31 and cover

the period beginning with the submission date of the last attestation and end on the date of the current submission.

Review and comply with the 2021 CAA's transparency requirements and related enforcement relief. Look for more guidance on several 2021 CAA transparency topics in 2025. The 2021 CAA's requirements, unless otherwise noted, generally took effect for the 2022 plan year and include the following:

- **Price comparison tool.** Plans and insurers must 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. Plans and insurers had to launch the price comparison tool starting with the 2023 plan year. (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. The departments of Health and Human Services (HHS) and 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 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 guidance. A recent 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.
- **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.

- **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 future guidance or regulations, 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.

Examine how annual hospital price disclosures might help plan participants. 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. To make the data more useful and make it easier for hospitals to comply, HHS finalized 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. Work with relevant experts — e.g., data specialists — to understand the hospital data. 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.

Explore new opportunities to negotiate or directly contract rates with individual hospitals or hospital systems if a particular plan currently pays higher rates than what other entities pay. The hospital data and the MRFs should provide unprecedented insights into the rates that participants and plans pay for medical services and items like prescription drugs at hospitals. Be on the lookout for third-party analyses of pricing data, and ask your vendors/insurers how they are analyzing the data.

Review newly released data, including new government reports, when available. Providers and pharmacy benefit managers generally have treated negotiated rates as proprietary information inaccessible to plan sponsors. The TiC rule, the hospital transparency rule and the RxDC reporting requirement (see Prescription drugs) could infuse more competition into the healthcare marketplace, allowing plan sponsors to negotiate better rates, while giving participants upfront estimates of medical expenses from different providers.

Look for more robust hospital disclosures as enforcement efforts increase. Not all hospitals have fully complied with the transparency rule, but that may change as CMS increases enforcement. Effective Jan. 1, 2022, CMS raised the penalties for noncompliance (currently $300 per day) to a maximum of about $2 million per year. Besides sending out numerous warning and corrective letters, CMS has taken 15 enforcement actions imposing civil monetary penalties against hospitals that failed to comply with the rule.

Related resources

Section 5

Data privacy and security

Action

Implement heightened Health Insurance Portability and Accountability Act (HIPAA) privacy standards for reproductive healthcare. Assess how cybersecurity risks change data security priorities for group health plans. Look for updated HIPAA guidance on online tracking technologies, and focus on how to address telehealth and digital solutions for behavioral health and other targeted health conditions. Evaluate vendors, new technologies, and apps to determine whether HIPAA or other data protection and privacy laws apply. Regularly review vendors' compliance with HIPAA and the Department of Labor (DOL)'s cybersecurity measures for ERISA plans. Use compliance tools from regulators to identify and address security vulnerabilities, and monitor federal enforcement.

Specific steps

Implement the heightened HIPAA privacy standards for reproductive healthcare. A new rule from the Department of Health and Human Services (HHS) — the HIPAA Privacy Rule to Support Reproductive Health Care — requires heightened privacy protections for protected health information (PHI) involving reproductive healthcare. The rule bans the use or disclosure of PHI for prohibited purposes (civil, criminal, or administrative investigation or liability, or to identify anyone for such purposes). In certain cases, the rule requires an attestation that the PHI will not be used for a prohibited purpose before it can be disclosed. The rule took effect June 25, 2024, but gave covered entities and business associates until Dec. 23, 2024, to comply with most new obligations. Self-funded group health plans and fully insured group health plans that have access to PHI access must comply.

- **Revise operational workflows to respond to requests for PHI potentially related to reproductive healthcare.** Identify who will determine whether the request is for a prohibited purpose.
  - Develop a process for obtaining (and retaining) a written attestation after receiving a request for PHI potentially related to reproductive healthcare. Determine what vendor will handle the request and when to involve legal counsel. Instructions and a model attestation are available from HHS.
  - Give special attention to the privacy and data-sharing practices of point solutions and mobile apps that handle reproductive health data.
- **Consider developing (or discuss with plan administrators about developing) a procedure for identifying and tracking PHI potentially related to reproductive healthcare**. This could be instrumental in responding to disclosure requests.
- **Revise HIPAA policies and procedures.** Also and provide updated training to relevant workforce members.
- **Review health plan documents**. Determine whether a plan amendment related to the HIPAA privacy rule changes is required.

- **Review plan member communications to ensure HIPAA references are accurate and up to date.**
- **Review and revise business associate agreements (BAA) as needed.** Consider clarifying each party's responsibilities for handling a request for reproductive PHI and/or requiring notice to other parties if one party receives a request for a prohibited purpose.
- **Prepare to update and post the notice of privacy practices (NPP) on the plan's website by Feb. 16, 2026, and thereafter provide the revised information in the plan's annual mailings.** Plans that don't post the notice on their websites must distribute the information within 60 days of the revision (presumably by Apr. 17, 2026). The revised NPP will also have changes related to the heightened confidentiality protections for substance use disorder (SUD) records created by federally assisted SUD treatment providers and programs. Review the HHS fact sheet for more information.
- **Watch for any changed requirements due to litigation over this new HIPAA rule and portions of the 2000 privacy rule.** Texas is challenging the new rule in its entirety and portions of the 2000 rule limiting PHI disclosure to state officials and law enforcement (45 CFR 164.512(f)).

Review the HIPAA security management process, and plan to identify and respond to any cybersecurity incidents. The HIPAA security rule requires covered entities — health plans, providers and clearinghouses — and business associates to ensure the confidentiality, integrity and availability of all electronic protected health information (ePHI). HIPAA regulations (as amended for the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act) prescribe how health plans should secure ePHI and provide notice and remedial action after a breach.

- **Review — and update if needed — policies and procedures to prevent, detect, contain, and correct security incidents.** Of the 626 breaches affecting 500 or more individuals in 2022 reported to Congress by the HHS's Office of Civil Rights (which enforces HIPAA), 13% were from health plans (affecting more than 2.6 million people)..
  - Review HIPAA security resources from the Department of Health and Human Services (HHS), including its risk analysis guidance. Security risk assessment and risk management are two of the primary compliance failures reported in HHS's latest HIPAA breach report to Congress.
  - Conduct a risk analysis, and implement technical, physical, and administrative safeguards to protect PHI. HHS's interactive security risk assessment tool, designed for small and medium healthcare providers, can be instructive for health plans and business associates. The tool highlights the importance of remediating identified risks by addressing and documenting action steps, assigning responsibilities, and tracking completion dates.
  - If not already done, consider adopting a cybersecurity framework (from the National Institute of Standards and Technology (NIST) or the HITRUST Alliance, for example) to assess risks. Review the revised cybersecurity resource guide, created by NIST in collaboration with HHS. Adopt and implement policies, practices, controls, and other measures for protecting data and responding to cyber threats. Remember that a covered entity's security practices matter when a HIPAA audit occurs.

- **Confirm the processes for mitigating the harmful effects of a breach and for documenting incidents and their outcomes.** HIPAA requires notice to affected individuals, HHS and, in some cases, the media in the event of a security breach. In its report to Congress, HHS said regulated entities need to improve breach responses and reporting.
  - Consider forming a security incident response team, and confirm third-party administrators (TPAs) and other business associates have one. Review NIST's recommendations for responding to security incidents.
  - Confirm the security breach terms are in each BAA. The BAA should clearly identify each party's responsibility for determining whether a reportable breach has occurred and, if so, creating and distributing breach notices, among other items.
- **Review authentication standards, then remedy any risk of unauthorized access to ePHI.** A June 2023 OCR cybersecurity newsletter reminds covered entities of their HIPAA obligation "to verify that a person or entity seeking access to [ePHI] is the one claimed." The most commonly reported category of breaches involves hacking, making up 74% of HIPAA breaches in 2022 involving 500 or more individuals (and affecting more than 32 million individuals in total).
  - Consider implementing multifactor authentication solutions, including phishing-resistant multifactor authentication, to improve the security of ePHI and protect systems from cyberattacks.
  - Confirm TPAs and business associates have appropriate authentication standards.
- **Verify that TPAs and other business associates are implementing audit controls and sharing audit results and risk-mitigation measures with the plan sponsor.** For two years in a row, OCR's annual reports have identified regulated entities' audit controls as needing improvement. The 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.
  - Confirm service agreements allow plan sponsors to periodically examine the strength and effectiveness of TPAs' and other plan vendors' cybersecurity practices.
  - Avoid *pro forma* security reviews. Instead use cybersecurity reviews tailored to the plan's particular risk profile.
  - Confirm security awareness and training programs are ongoing for all workers supporting the plan.
- **Evaluate any health plan vendor supplying wellness and transparency tools, mobile apps, and artificial intelligence to determine if HIPAA applies.** Partnerships with app developers, data warehouses or mobile-technology vendors to provide group health plan benefits and information could trigger HIPAA obligations. If any of those functions or activities involve PHI use or disclosure, the partnership may require a BAA. For more information, see the HHS webpages addressing resources for mobile health apps developers and health Information technology.
  - Review the terms of existing BAAs, especially with long-standing TPAs. Make sure the BAAs specify privacy and security features.

  - Consider the need for a separate data-sharing agreement. Confirm that the BAA and data-sharing agreement are consistent with each other and clearly cover the division of responsibilities in the event of a breach.

- **Evaluate HIPAA challenges in telehealth.** Make sure TPAs and carriers (and any point solutions or stand-alone telehealth offerings) have confirmed that their telehealth offerings and in-network providers ensure data security. Confirm the technology meets HIPAA specifications.
  - Assess telehealth point solutions, and compare privacy and security features against telemedicine capabilities already available to employees through in-network providers.
  - Confirm TPAs, carriers and point-solution vendors use a telehealth technology vendor that will enter into a BAA and comply with applicable HIPAA requirements.
  - Conduct — or ensure the vendor conducts — regular security risk assessments of the telecommunications platform, including encryption of ePHI, login standards and authentication requirements. Confirm identified risks are addressed.
  - Focus on digital solutions for behavioral health offered with the health plan or as a stand-alone telehealth offering (if legislation allowing this as an excepted benefit passes). Evaluate vendors to determine whether their PHI use and disclosure meet HIPAA standards and best practices.
- **Review facility access controls against HIPAA security requirements.** A recent OCR cybersecurity newsletter reminds covered entities (and business associates) about their obligations for the physical security of ePHI. The HIPAA security rule requires covered entities to implement policies and procedures limiting physical access to electronic information systems and the facilities housing those systems, while ensuring that properly authorized access is allowed. The facility access control standard lists four specifications to consider when assessing facility access controls: (1) contingency operations, (2) facility security plan, (3) access control and validation procedures, and (4) maintenance records. If a particular specification is not reasonable and appropriate, the covered entity (or business associate) must document why and implement an equivalent alternative if reasonable and appropriate.
- **Watch for new laws enhancing care coordination and cybersecurity under HIPAA.** In early 2021, HHS proposed changes to the HIPAA privacy rule to reduce or remove barriers to coordinated care and case management. More recently, HHS indicated an intention to strengthen requirements for HIPAA covered entities to prevent, detect, contain, mitigate, and recover from cybersecurity threats to ePHI.

Review ERISA fiduciary duties and the need for additional cybersecurity measures. ERISA fiduciary duties may require plan sponsors to implement cybersecurity measures for health plans that go beyond HIPAA security requirements (see ERISA fiduciary issues). In a Sept. 6, 2024, update, DOL confirmed that the April 2021 cybersecurity guidance issued by the Employee Benefits Security Administration (EBSA) 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 EBSA's 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 ERISA health and welfare plan service providers about their cybersecurity practices, past breaches and insurance policies.
  - Review contract terms on an ERISA plan vendor's obligation to comply with cybersecurity and information security standards and to obtain third-party audits of its cybersecurity practices. Ensure the plan sponsor has the right to review audit results. Consider including other terms to enhance protection for the plan and its participants, and avoid provisions limiting the service provider's liability.
  - Review health plan vendor contracts against BAA terms detailing requirements in the event of a HIPAA breach. Reconcile any conflicts between data security provisions and HIPAA breach 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. Among other actions, the FTC uses its enforcement authority against companies that violate their own privacy policies or make false statements about information security. The FTC's health breach notification rule (HBNR) applies specifically to entities (and their third-party service providers) that collect, hold or interact with consumers' personal health records but are not subject to the HIPAA's privacy and security requirements. This historically has covered traditional personal health record vendors and related entities (e.g., billing, data storage, analytics). The rule also applies to health apps and other direct-to-consumer technologies (like fitness trackers, remote blood pressure cuffs, blood glucose monitors, etc.).

- **Review the obligation to 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. Risks could arise from 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.

Review for applicable breach notification rules. Determine if the HBNR applies to any health and wellness apps not already subject to HIPAA's privacy and security rules. 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.

- **Ensure employees know how any vendor uses or discloses their data.** Consider obtaining employee consent to the information use or disclosure.

Screen plan websites, tools, vendor solutions, and other health and wellness apps offered to plan participants and/or employees for tracking technologies that may violate HIPAA's privacy rule, trigger the FTC's HBNR, or create litigation risk. Tracking technologies collect and analyze information about how users interact with websites or mobile applications, some of which may contain personal health information. Disclosure of personal health information without authorization can violate HIPAA or trigger the HBNR.

- **Review OCR's bulletin about online tracking technologies used by HIPAA covered entities and business associates.** HIPAA applies when the information collected through tracking technologies or disclosed to tracking technology vendors includes PHI., For example, mobile apps that help plan members manage their health information or benefits may use tracking technologies. These technologies also may come into play with health plan or point-solution vendor webpages.
  - 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).
  - Confirm tracking technologies do not result in impermissible disclosures of PHI, even inadvertently (for example, for marketing purposes). PHI disclosures to tracking technology vendors must be specifically permitted by the privacy rule, and unless an exception applies, any PHI disclosed must be limited to the minimum necessary to achieve the intended purpose.
  - Consider auditing health apps, online tools, and webpages to limit or eliminate third-party tracking.
  - Verify that a BAA is in place with tracking any technology vendors the plan is using.
  - Confirm the HIPAA security-risk assessment addresses tracking technologies.
- **Review the joint OCR and FTC warning about the privacy and security risks of online tracking technologies integrated into websites and mobile apps.** While directed at hospitals and telehealth providers, the guidance could apply anywhere health information is stored or shared online, including mobile health and wellness apps, health plan websites and cost-comparison tools, and targeted point solutions.
  - General wellness apps or others not connected to the group health plan, TPA or carrier may not be covered by HIPAA but could face FTC scrutiny for any privacy policy misrepresentations or violations.
  - Ensure any tracking technologies that can't be limited or eliminated are disclosed, and consider adopting a process for participants to opt out. Disclosure of personal health information without authorization can, in some cases, trigger the HBNR.
- **Monitor litigation alleging disclosure of PHI to online tracking technologies violates federal and state law.** In the last year, at least three potential class actions have been filed alleging improper use and disclosure of information collected through tracking technologies. In one case, the tracking technology used on a provider's website allegedly resulted in impermissible PHI disclosure for commercial gain in violation of HIPAA and other federal and state laws. In another case, plaintiffs allege an online pharmacy improperly collected and failed to obtain consent before sharing PHI with third parties via tracking technologies. A third case made similar allegations involving a telehealth provider.

Monitor federal enforcement. Enforcement of the HIPAA security rule is a high priority for OCR, as demonstrated by recent settlements and annual reports to Congress. A lack of funding, however, limits OCR's HIPAA enforcement activities despite the substantial growth in cybersecurity attacks. EBSA enforcement of fiduciary obligations related to cybersecurity

is possible. The FTC is enforcing the HBNR when a security breach concerns individually identifiable health information not protected by HIPAA.

- OCR has said that large breaches reported involving ransomware attacks have increased by 264% since 2018. OCR investigations after ransomware attacks often find insufficient security measures and risk assessments, missing BAAs, or insufficient policies and procedures. In the last 12 months, OCR settlements with covered entities have ranged from $40,000 to $4.75 million.
- Headline-making FTC enforcement actions against mobile health apps and other technologies have continued into 2024. These actions included a multimillion-dollar penalty against a telehealth firm for disclosing personal health information and other sensitive data to third parties for advertising purposes. FTC can bring enforcement actions against entities for violating online privacy policies or statements or for unfair privacy practices.

Monitor data interoperability — the ability of plans, providers and patients to exchange data seamlessly in a uniform format — for privacy and security risks. For a number of years, federal policy has improved standards for healthcare data sharing through various channels, including requirements for application programing interfaces (APIs). APIs allow multiple applications to communicate and share information and enable processing data transfers between systems. APIs that patients use to access information may or may not be connected to group health plan benefits.

- **Consider the pros and cons of an maintaining an API for data used by the plan and its TPA.** Evaluate tech offerings for gaps in privacy and security protections, and assess risks. For example, the software used to power the plan's online cost-sharing tool required by the transparency rules may use APIs (see Group health plan transparency).
- **Assess vendors' offerings that use APIs. New apps and tools may require additional entities to access participant data.** The FTC Act and HBNR covers apps that draw information from multiple sources — such as through a combination of consumer inputs and APIs. For example, a blood sugar monitoring app that collects health information from the consumer and pulls nonhealth information from the consumer's mobile phone calendar is covered under the HBNR.
- **Watch for finalization of a proposed HHS rule on health data, technology and interoperability.** The rule is intended to advance interoperability with new standards, public health information technology certifications, expanded use of certified APIs (such as for electronic prior authorization, patient engagement, care management, and coordination), and information sharing under the information-blocking regulations. Complimenting the final HIPAA privacy rule for reproductive healthcare, the proposed rule would provide an exception under the information-blocking rule for reproductive healthcare. Specifically, the exception would allow an actor not to disclose health information when it has a good faith belief that doing so would reduce potential exposure to legal action related to reproductive health are.

Determine the application of state privacy laws to group health plan information and any sensitive information developed, maintained, or shared by health technologies offered apart from the group health plan. 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.

Monitor federal legislation creating HIPAA cybersecurity standards and establishing national data privacy rights and protections. Newly proposed cybersecurity legislation (S 5218) would require HHS to develop and enforce minimum cybersecurity standards (including annual compliance audits) under HIPAA and would remove the existing cap on fines for violators. A bipartisan, bicameral bill (HR 8818) to establish a national data privacy and security standard is pending in Congress. The bill, if enacted, would create a comprehensive federal consumer privacy framework governing how companies use individuals' information.

Monitor civil litigation resulting from cyberattacks. The Federal Bureau of Investigation reports that healthcare and public health organizations experienced more ransomware attacks in 2023 than any other critical infrastructure sector. Class actions often follow cyberattacks, with plaintiffs seeking millions in civil damages. A surge in class actions against healthcare entities related to pixels and other — often third-party — web tracking technologies emerged in 2023. Companies engaging with third-party vendors are not immune from suit when the third party is the object of the ransomware attack. In one case, a company was accused of violating federal and state laws by failing to implement reasonable and adequate security measures and oversight of a third party vendor with sensitive data that suffered a breach by a criminal organization.

Related resources

Section 6

Artificial intelligence in benefits

Artificial intelligence (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) 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. However, much about AI is still unknown or unproven. Because AI presents risks and opportunities, consider setting guardrails encouraging the responsible use of AI. Plan fiduciaries must act prudently in selecting and monitoring service providers, including the use of AI. Also review any internal AI use under the group health plan. In conducting this review, apply current legal and compliance requirements in novel ways. Watch for legislation, regulation, and litigation to unfold, and apply any new requirements to plans.

Specific steps

Ask all third-party service providers about their use of AI for plan design, administration and decision-making purposes. Make the same inquiries within the organization to learn what plan administrative functions are performed using AI. Create an inventory of the plan's use of AI. Third-party administrators (TPAs) and carriers likely are using algorithms to decide many types of claims. Other AI uses might involve advanced analytics, communications, personalized health and wellness, benefit navigation, and customer service. Some healthcare providers are using AI in making medical diagnoses. Plan fiduciaries should be aware of internal and service providers' use of AI, and include AI in reviewing service providers and plan management.

Understand and apply current legal and compliance requirements to any AI used under a group health plan. This may require novel interpretations. 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.
- **Mental Health Parity and Addiction Equity Act (MHPAEA)**. Identify algorithms that may create a nonquantitative treatment limitation (NQTL), examine for compliance and include in the comparative analysis.
- **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.
- **Affordable Care Act (ACA) Section 1557 nondiscrimination rules**. These final rules include a ban on discriminatory patient-care decision support tools, including those using AI or clinical algorithms. Review tools supporting clinical decision-making, such as

assessment of a patient's health risk, prior-authorization requirements or medical-necessity determinations.

- The rules require covered entities to make efforts to identify any tools in health programs or activities that input variables or factors that measure race, color, national origin, sex, age, or disability. Covered entities must 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.

- The Section 1557 nondiscrimination rules don't apply directly to any employer's or group health plan sponsor's employment practices, including providing employee health benefits. However, the rules often apply to TPAs or carriers working with employer group health plans. (See Other ongoing ACA concerns.)

- The rules will take effect by May 1, 2025.

Watch for legislation, regulation and litigation to unfold. President Joe Biden issued an executive order on the safe, secure, and trustworthy development and use of AI, ordering multiple federal regulators to develop strategic plans for the responsible use of AI. In addition, a bipartisan group of US senators developed a road map for AI policy in the Senate. Federal regulators are only just beginning to issue AI regulations and Congress appears to be studying the issue, so states may take the first steps in enacting AI legislation. In the meantime, several AI-related lawsuits have been filed:

- The 9th US Circuit Court of Appeals recently resurrected a class action challenging the use of AI to process mental health and substance use disorder (MH/SUD) claims (*Ryan v. UnitedHealth Group*), 98 F. 4th 965 (2024)). The carrier used an algorithm only for MH/SUD claims to assess progress and refer cases for peer review. Plaintiffs argue this is a more stringent process than what's used for medical/surgical claims, violating the mental health parity rules and constituting a breach of fiduciary duty.

- Other lawsuits are challenging the use of AI in claims administration on other grounds. For example, one lawsuit alleges that an algorithm allows a TPA's doctors to automatically deny payments in large batches that do not match certain preset criteria for treatments, evading the physician review process (*Kisting-Leung v. CIGNA*, Docket No. 2:23-cv-01477 (E.D. CA, filed July 24, 2023)). Other lawsuits accuse two TPAs of using AI (an algorithm) to override doctors' recommendations and deny post-acute care for patients in Medicare Advantage plans (*Barrows v. Humana*, Docket No. 3:23-cv-00654 (W.D. KY, filed Dec. 12, 2023)) and *Lokken v. UnitedHealth Group*, Docket No. 0:23-cv-03514 (D. MN, filed Nov. 14, 2023)).

Review plan documents and processes to determine what updates need to be made to reflect the use of AI.

Related resources

Section 7
Surprise billing

Action

Verify emergency services are covered to the full extent required. Confirm plan administrators are properly administering emergency service and other claims protected by the No Surprises Act (NSA), part of the 2021 Consolidated Appropriations Act (2021 CAA, Pub. L. No. 116-260). Make sure to review whether administrators are complying with provider reimbursement, cost-sharing and external review requirements. Confirm plan administrators are prepared to adjust qualifying payment amount (QPA) methodology to reflect revised rules resulting from legal challenges. Make sure the plan is providing the required NSA notices online and in EOBs. Review the frequency and outcomes of IDR proceedings. Consider the appropriateness of vendor fees related to surprise-billing compliance and/or any shared-savings program charges. Monitor ongoing litigation, and watch for new or revised regulations and other guidance.

Specific steps

Confirm emergency services are covered and administered as the NSA requires. Since Sept. 23, 2010, the Affordable Care Act (ACA) has imposed certain standards on nongrandfathered plans that cover emergency services. The NSA expanded these coverage standards and applied them to both grandfathered and nongrandfathered that begin on or after Jan. 1, 2022.

- If any emergency services are covered, both grandfathered and nongrandfathered plans must cover all emergency services.
  - Emergency services include items and services needed to screen, treat and stabilize someone with an emergency medical condition.
  - Emergency services also include routine ancillary services needed for evaluation, as well as post-stabilization items and services (including outpatient observation or an inpatient/outpatient stay provided with the emergency services).
  - Emergency services provided in hospital emergency departments and independent freestanding emergency centers are covered, along with services provided in urgent-care centers and behavioral health crisis facilities licensed by a state to provide emergency services for an emergency medical condition.
- Verify that coverage is not limited by plan terms or conditions (other than a coordination-of-benefits provision, a permissible waiting period or cost-sharing requirements). The NSA prohibits plans from placing certain limits on emergency services, like imposing preauthorization requirements on in-network (IN) or out-of-network (OON) providers and facilities, or denying claims because of general plan exclusions or based solely on medical record review or diagnosis codes.

- Make sure OON emergency service providers aren't subject to administrative requirements or benefit limitations more restrictive than those applied to IN providers of those services.
- Review plan documents (including summary plan descriptions (SPDs) and summaries of benefits and coverage (SBCs) for coverage terms.
- Confirm that plan administrators are using the "prudent layperson standard" when reviewing emergency room claims and do not use diagnostic codes, medical record reviews, or plan exclusions as the sole basis to deny emergency service claims. A plan may approve a claim relying solely on diagnostic codes or take them into account when considering whether to approve a claim. However, diagnostic codes cannot be the sole basis for a claim denial.

Confirm plan administrators are appropriately calculating cost sharing for NSA-protected services. The NSA protects group health plan participants (except those in retiree-only plans, account-based plans or excepted-benefit arrangements) from balance bills. The law also limits cost sharing for (i) emergency services (including ancillary services) received at a nonparticipating facility or at a participating facility from a nonparticipating provider; (ii) a nonparticipating provider's nonemergency services at a participating healthcare facility (unless the patient gave written consent to the charges); and (iii) air ambulance services from nonparticipating providers. The act prohibits charging more for NSA-protected services than plan participants would pay for services from participating providers. Cost-sharing amounts are typically based on the QPA, which is generally the median of the contracted rates recognized by the plan or issuer on Jan. 31, 2019, increased for inflation, for the same or a similar item or service from a provider in the same or a similar specialty or facility of the same or a similar type and provided in the geographic region in which the item or service is furnished.

- Review plan administrators' QPA methodology in light of a federal court ruling vacating a number of provisions in the July 2021 interim final rules and ACA and 2021 CAA implementation FAQs part 57 (*TX Med. Ass'n v. Dep't of Health and Human Servs.*, No. 6:22-cv-00450 (ED TX Aug. 24, 2023) (TMA III). An unlawful methodology (i.e., one based on the rules before the TMA III decision) could result in a cost-sharing determination that causes a plan member to pay more (or less) than what would be owed using a lawful methodology (i.e., in accordance with the TMA III ruling). Plans are expected to calculate QPAs using a good-faith, reasonable interpretation of the statute and regulations that remain in effect after the TMA III decision. Consider taking the following steps:
  - Confirm third-party administrators (TPAs) are prepared to recalculate QPAs using only the rates for plans offered by the same plan sponsor. The QPA for a self-insured group health plan can no longer be calculated using the contracted rates for all self-insured plans administered by the plan's TPA.
  - Check that "ghost rates" and "out-of-specialty" rates are excluded from the QPA calculation going forward, but risk sharing, bonuses, and other incentive-based payments or adjustments are included.
  - Verify that QPAs for air ambulances include "case-specific" and "single case" agreements, which were previously excluded.

  - Note that enforcement discretion is available for any plan or issuer that uses a QPA calculated in accordance with the regulations overturned by TMA III (see 2021 CAA implementation FAQs part 67) for items and services furnished before Nov. 1, 2024.
  - Confirm plans with no network and no median contracted rate (e.g., reference-based pricing plans) are using an eligible database to determine the QPA for emergency and air ambulance services. (Note that the NSA's surprise-billing protections do not apply to nonparticipating nonemergency services provided at a participating healthcare facility if a plan doesn't have a network of participating healthcare facilities.)

Verify that plan administrators are properly classifying providers and facilities as participating or nonparticipating based on contractual relationships and not network status.

- Make sure that providers, facilities and providers of air ambulance services with which the plan has a contractual relationship (direct or indirect) are treated as participating providers for NSA-purposes, regardless of network status.
- Confirm that providers, facilities or air ambulance service providers considered participating for NSA purposes are also considered IN for purposes of the IN deductible and ACA out-of-pocket maximum (OOPM), and vice versa. (See Other ongoing ACA concerns.)
  - For example, an emergency facility providing emergency services can't be a participating facility/provider for the NSA's cost-sharing (and balance-billing) protections but OON for purposes of the ACA OOPM.
  - In other words, for emergency services, nonemergency services at a participating facility, and air ambulance services, either the NSA's balance-billing and cost-sharing protections apply (because the provider or facility is nonparticipating) or the ACA's OOPM applies (because the provider or facility is IN).
- Confirm that cost-sharing payments made for NSA-protected services count toward any IN deductible and the ACA's IN OOPM.

Confirm plan administrators are providing timely initial payments (or denial notices) with the required disclosures to nonparticipating providers. Plans must send the initial payment with required disclosures or a denial notice within 30 days of receiving the bill for air ambulance services. That deadline also applies on receipt of a "clean claim" for emergency services and nonemergency services performed by nonparticipating providers at participating facilities.

- Confirm that plan administrators have a communications process for obtaining the provider information necessary to adjudicate a claim within the 30-day time frame. If coverage can't be determined within that time frame, a benefit denial notice should be issued and communicated in a manner that doesn't suggest the service has been determined not to be covered.
- Check that the initial payment is intended to be the full payment based on relevant facts, circumstances and plan terms.

- Confirm that plan administrators are including the required elements in the payment (or denial) notice when cost sharing is based on the QPA and when the initial payment is reduced on account of service codes or other modifiers.
  - When cost sharing is based on the QPA, the initial payment (or denial notice) must include (i) the QPA for each item or service; (ii) a certification that the QPA was applied when calculating cost sharing and determined to comply with the rules; (iii) a statement about the opportunity for a 30-day negotiation period, followed by IDR if necessary to determine the total payment; and (iv) contact information to initiate a negotiation period.
  - The certification can be made if a good-faith, reasonable interpretation of the statute and regulations that remain in effect after TMA III was used to determine the QPA. The departments will use enforcement discretion for these disclosures if the plan certifies that the QPA was determined to comply with pre-TMA III guidance. This enforcement discretion only applies to items and services furnished before Nov. 1, 2024, and only if the plan timely discloses it's using a QPA calculated in this way if the provider asks.
  - If the service codes or modifiers on the claim change and result in a lower reimbursement (i.e., down-coding), the initial payment must include (i) a statement indicating whether the QPA is based on the down-coded service code or modifier; (ii) an explanation and a description of the codes and modifiers adjusted; (iii) the QPA without the down-coding.
- Verify that plan administrators are including an explanation with the notice denying payment.
- Check that plan administrators are accepting the standard open-negotiation notice from OON providers and facilities. Plan administrators may encourage the use of an online portal for submission of necessary or supplementary information but cannot require this to initiate the negotiation period.

Make sure plan administrators are making external reviews available for NSA compliance matters. The ACA's external review requirement for adverse benefit determinations applies to all NSA-protected claims, including those handled by grandfathered plans otherwise exempt from this ACA requirement.

- Adverse benefit determinations related to NSA compliance include the cost-sharing and surprise-billing protections for emergency services and care provided by nonparticipating providers at participating facilities, as well as the requirement that claim coding accurately and correctly reflects treatments received and the associated NSA protections.

Confirm the required surprise billing notice is posted on a public website and included with EOBs. The notice must use plain language and contain information about balance-billing restrictions, applicable state and federal protections, and contact information for an appropriate state or federal agency in the event a provider or facility violates the balance-billing restrictions.

- Confirm version 2 of the model notice is being used for good-faith compliance with the disclosure requirement.

- If the plan doesn't have a public website, make sure a written agreement requires the TPA to post the notice on the public website where it normally makes information available to participants, beneficiaries and enrollees on the plan's behalf. Verify that the notice does appear on the TPA's public website.
- Make sure the notice contains information on applicable state laws. However, information on all state balance-billing laws is not required.

Review IDR frequency and outcomes. Consider requesting a TPA report on the number of IDR proceedings initiated for plan claims and the outcome of each. Weigh whether to include performance guarantees related to IDR frequency and outcomes in the TPA agreement.

- Consider asking for and reviewing the TPA's strategy for determining the initial payments to nonparticipating providers.
- Review whether IDR frequency or results are impacting provider reimbursement rates. Are standard reimbursement rates for OON care lower or higher due to IDR awards? One study of IDR public use files reports the prices from IDR averaged 4.0 times Medicare reimbursement for emergency services and 6.6 times Medicare for imaging services, with IDR entities selecting the provider's offer more than 80% of the time.
- Consider the impact on provider networks. Are carriers and TPAs looking to bring providers that initiate IDR into networks or reopening contract negotiations with IN providers in an effort to lower IN reimbursement rates?

Review with claim administrators IDR's cost impact on the plan.

- Determine the cost impact of IDR administrative fees. The IDR administrative fee is $115 per party for disputes initiated on or after Jan. 22, 2024 (an increase from the $50 fee that applied to disputes initiated on or after Aug. 3, 2023). This fee could increase for disputes initiated on or after Jan. 1, 2025.
- Determine how IDR entity fees (paid by the losing party) are managed by the TPA. In 2024, IDR entity fees have ranged from $200 to $840 for single claim determinations and from $268 to $1,173 for batched determinations. These fee ranges will remain in effect until different fee ranges are proposed and finalized by the regulators. Is this cost passed through to the plan?
- Determine whether shared-savings programs and fees related to NSA compliance or pass-through fees from IDR are covering the same claims. Can NSA-covered claims be excluded from shared-savings program fees? Close scrutiny of any overlap is particularly warranted in light of federal agency scrutiny of shared-savings programs (see ERISA fiduciary issues). Do NSA requirements (for providers and payors) reduce the need for shared-savings programs?

Watch for agency guidance, revised regulations and court orders adjusting the IDR process. Ongoing litigation challenging IDR rules and procedures could force more delays and changes. Refer to this Centers for Medicare & Medicaid Services (CMS) webpage for important notices about the IDR portal.

Watch for potential expansion of surprise-billing protections to ground ambulances. The Advisory Committee on Ground Ambulance and Patient Billing (GAPB) recommends using the NSA as a framework for ground ambulance legislation, but with modifications.

- Among the modifications, the committee recommends limiting predeductible cost sharing for ground ambulances to the lesser of $100 or 10% of a congressionally determined rate (if no state law or all-payor model agreement applies). As under the NSA for OON emergency services, the ground ambulance cost sharing would apply to the IN deductible and OOPM.
- The GAPB committee didn't suggest what the payment rate should be (for example, a percentage of Medicare rates) but did recommend specific reimbursement standards. By a narrow margin, the committee decided against recommending an IDR process for payment disputes, instead proposing a tiered payment standard that relies on state and local rate setting.
- The committee's recommendation is to apply the OON payment methodology and cost-sharing limitation to all group health plans and issuers (i.e., self-funded and fully insured). The committee also recommends including emergency ground ambulances in the ACA's definition of emergency services for essential health benefits. Congressional action is required to implement these recommendations.

Ensure that vendor contracts provide for NSA compliance. Plans must be able to rely on vendor partners for proper administration of emergency service claims, adjustments to the QPA methodology and timely initial payments — all of which are key to protecting plan participants and reducing the risks of IDR and agency enforcement. A survey suggests that the NSA prevents more than 1 million surprise bills per month, while provider networks grow. Regulators continue to collect stakeholder comments and consumer complaints and to monitor plans' and issuers' NSA compliance. CMS carrier audits have uncovered incorrect payment determinations, faulty QPA calculations and insufficient disclosures to providers.

- Weigh whether to conduct regular audits of how the plan administers NSA-protected claims.
- Consider requiring reports on IDR costs and outcomes at regular intervals.
- Evaluate including performance guarantees related to compliance with the surprise-billing law, rules and court orders.

Related resources

Section 8

State-mandated paid leave and other state law trends

Action

With every state convening its legislature in 2025, watch for bills impacting paid leave, pharmacy benefit managers (PBMs) (see Prescription drugs), coverage mandates for fully insured plans and telehealth access. Monitor ongoing regulatory activity, particularly in states implementing new paid family and medical leave (PFML) laws. Address necessary changes and available options with leave administrators, while keeping an eye on Congress as it considers a federal PFML mandate that could encourage coordination and harmonization among state laws. Look for guidance on new paid sick and safe leave (PSSL) laws if approved on three states' November 2024 ballots. States' attempts to erode ERISA preemption — via legislation and regulation — will likely continue and deserve employers' ongoing awareness. This issue raises particularly high stakes related to PBMs and prescription (Rx) benefit costs. Stay abreast of ERISA litigation challenging these state laws. New group health plan coverage mandates will be introduced, and reporting will remain an employer obligation in a few states. Address required plan changes with PBMs, insurers and other third-party administrators (TPAs), keeping a cautious eye on costs. Look for the results of another ballot initiative in Washington related to its long-term care (LTC) coverage mandate.

Specific steps

Assess how state mandates related to PFML, paid PSSL and other types of paid leave affect existing employer programs, and make revisions accordingly. Despite common elements, these laws vary in details and require careful review to ensure compliance. For example, Delaware's PFML law has a minimum-hours eligibility standard and a challenging waiver program for part-time and seasonal employees. A TPA's assistance is recommended for multistate employers.

- **Revisit overall paid leave strategy.** Formulate or review a long-term PFML and accrued paid leave strategy, with the goal of multistate parity to the extent achievable. State and local paid leave laws often vary in contribution amounts, wage replacement benefits, duration, eligibility and paid time-off (PTO) accruals. New laws typically define covered family members more broadly than the federal Family and Medical Leave Act (FMLA) to include domestic partners, designated persons considered family members, and grandparents and grandchildren. Prudent employers — even if no state or local mandate applies to their workforce — should conduct this review, weighing the benefits for recruiting, retention and care of employees when they most need time off.
- **Track agency guidance from states launching PFML programs.** Four states are implementing new PFML programs in 2025 and 2026: Delaware, Maine, Maryland and Minnesota. Before contributions and benefits begin, these states will be issuing comprehensive regulations, guidance and notices that employers operating in those

jurisdictions will need to review and implement. Contributions will start in Delaware and Maine on Jan. 1, 2025. Contributions will start in Maryland on July 1, 2025, and benefits will become available on July 1, 2026. Delaware benefits will become available on Jan. 1, 2026; Minnesota contributions will start and benefits will become available on the same date, Jan. 1, 2026. Act by the specified deadlines (often before contributions begin) if you are considering a private equivalent plan. Initial employer registration may be required. Consider signing up for email updates from the state regulators administering these programs.

- **Assess PFML changes in states with revised program requirements.** A PFML law is not a one-and-done proposition. States often revise major aspects of the law, even after it has fully taken effect. For example, Colorado, Connecticut, Oregon, Rhode Island and Washington enacted substantive PFML changes in 2024. States (like Rhode Island) with long-standing programs are trying to bring them up to newly established benchmarks.
- **Be aware of PFML program contribution rate changes.** Adjust systems and payroll deductions to accommodate changes in PFML contributions for 2025. Some states make these adjustments midyear. For example, Washington, DC, increased the employer contribution rate for its universal paid leave program, effective July 1.
- **Monitor states considering new PFML programs.** Look for more state legislatures to introduce and advance PFML bills in 2025, including Hawaii, Illinois, Michigan and Virginia. PFML laws are no longer limited to the Northeast and West Coast.
- **Keep track of more states considering voluntary paid family leave (PFL) insurance.** This year, Kentucky and South Carolina brought the number of states allowing voluntary PFL insurance to eight. This typically takes the form of a separate policy or a rider to an existing disability plan. More states may follow suit, viewing this insurance option as a preliminary step toward a comprehensive mandate. These programs have yet to gain meaningful traction, but times may change.
- **Look for election results in Alaska, Missouri and Nebraska on PSSL ballot initiatives.** On Nov. 5, voters in these three states will decide on PSSL mandates. All three laws, if enacted, would take effect in 2025.
- **Stay up to date on state and local accrued paid leave and supplemental pay mandates.** Monitor state legislation and local ordinances for new or revised PSSL and PTO-related requirements. PTO grabbed national headlines last year with the Illinois Paid Leave for All Workers Act (PLAWA). That law spawned similar changes in Chicago's and Cook County's leave mandates, all now in effect. The requirement to provide paid leave for any reason may spread to other states and localities. In addition, some localities may follow San Francisco's lead by enacting paid leave mandates that supplement a state PFML program.
- **Track other leave laws.** Keep tabs on states that will consider unpaid but job-protected leave for several reasons, including bereavement and organ donation.
- **Follow Uniformed Services Employment and Reemployment Rights Act (USERRA) litigation.** While most state PFML laws cover military-related qualifying exigencies, a noticeable trend is occurring with the federal USERRA. Regulations require employees on military leave to have the same rights and benefits as employees on other, similar leaves. If benefits vary, the employee must be given "the most favorable treatment

according to any comparable form of leave." Compliance with this requirement is increasingly contested in the courts.

Get ready for more discussion and debate of a federal PFML program. Earlier this year, the House Bipartisan Paid Family Leave Working Group (House working group) issued a PFML policy framework. The document included the Interstate Paid Leave Action Network (called I-PLAN), which would harmonize differences between and develop a multistate electronic system for states with existing PFML laws. A national PFML program appears to be a top priority of the Harris-Walz campaign. Former President Donald Trump signed the Federal Employee Paid Leave Act, providing paid parental leave to federal employees, as part of a 2019 defense authorization law.

Keep tabs on the 2025 tax debate, specifically related to the § 45S employer tax credit for offering PFML benefits not required by state or local law. This tax credit — like several other provisions under the 2017 Tax Cuts and Jobs Act (Pub. L. No. 115-97) — expires at the end of the 2025 tax year. A House working group suggested making the tax credit permanent and perhaps even increasing it, especially for small businesses. Employers subject to state paid leave laws and multistate employers with employees in a state mandating paid leave have found the requirements for the tax credit unworkable.

Take action on telehealth developments, particularly related to mental health parity.

- As interstate telehealth access continues to expand, reflect on how to enhance telehealth access, particularly for mental health. All but eight states are part of the Psychology Interjurisdictional Compact (PSYPACT), which enables cross-state use of behavior health services. Other compacts enacted this year included dieticians, occupational therapy and audio-speech pathology. The final federal mental health parity regulations emphasize the important role of telehealth in parity compliance.
- **Keep an eye out for telehealth reimbursement parity mandates for fully insured plans.** A majority of states require insured plans to reimburse telehealth providers at the same rate as in-person providers. The trend may continue.
- **Watch 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 Tennessee in 2024).

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

- **Stay tuned for more coverage mandates for fully insured plans.** Every year, state legislators enact new insurance laws that mandate coverage for specific services. Recent trends have included fertility, *in vitro* fertilization, abortion-related services and gender-affirming care. Prior-authorization practices are another area open to debate in 2025.
- **Understand that some state insurance laws apply on an extraterritorial basis to fully insured plans issued in another state.** Know 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 services.** Several states have restrictions and/or bans on gender-affirming care for minors and

abortion. Participants in these states may need to travel to another state to access services covered under the plan. Changes may come in 2025. Abortion rights are on the Nov. 5 ballots in several states. Lawsuits challenging state bans on gender-affirming care continue through the courts. The US Supreme Court will review a Tennessee law in *US v. Skrmetti* when the justices begin their 2024–-2025 term in October.

Ensure processes for group health plan reporting are in place.

- **Maintain individual-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 ACA deadlines. Submission of Form 1095-C usually satisfies the state reporting obligation. Double-check any reporting changes (albeit unlikely) from prior years. Massachusetts has two requirements: the Health Insurance Responsibility Disclosure (due Dec. 15) and Form MA 1099-HC (due Jan. 31).
- **Comply with other state laws related to group health plan assessments (and related reporting).** Meet 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 the Health Care Accountability Ordinance (applicable to city and county contractors)).
- **Review communications and processes for Washington's LTC law if a Nov. 5 ballot initiative passes.** Washington voters will decide whether the state's LTC coverage mandate — including a 0.58% employee salary-reduction contribution to the WA Cares Fund that started on July 1, 2023 — should have an employee opt-out. If enacted, the ballot provision will necessitate employer communications and payroll system changes. Meanwhile, standard reporting requirements will continue but may change next year if further legislation is passed.

Track PBM developments and ERISA preemption issues in the courts and state legislatures. Pay attention to ERISA-based challenges to state laws (particularly PBM restrictions) extending to self-funded plans. Particularly monitor *Pharmaceutical Care Management. Association v. Mulready*, No. 22-6074 (10th Cir. Aug. 15, 2023) (cert. pending), decided by the 10th Circuit and on petition with the US Supreme Court.

Related resources

Section 9

Preventive services

Action

Confirm nongrandfathered group health plans cover without cost sharing all in-network preventive services that the Affordable Care Act (ACA) requires. Modify 2025 benefits for the latest ACA guidance and any new or updated preventive care recommendations. Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives approved by the Food & Drug Administration (FDA), unless an exemption applies. Monitor a proposed ACA rule that would enhance coverage of prescribed and over-the-counter (OTC) contraceptives without cost sharing, clarify the exceptions process for all ACA-recommended preventive services, and require additional disclosures about contraceptive coverage. Keep an eye on a proposed preventive-services rule that would eliminate the moral exemption and amend the religious exemption from mandated coverage of women's contraceptives. Review guidance addressing coverage pre-exposure prophylaxis (PrEP) and the use of industry-standard coding practices for recommended preventive services. Monitor ongoing litigation that would let all nongrandfathered group health plans and insurers exclude coverage of or impose cost sharing on many ACA-mandated preventive services, plus allow employer plan sponsors with religious objections to exclude coverage of PrEP HIV medications. Review IRS guidance expanding the preventive care benefits that high-deductible health plans (HDHPs) designed to work with health savings accounts (HSAs) can opt to cover on a pre- or no-deductible basis; consider whether to make corresponding plan changes. Review group health coverage of COVID-19 testing and vaccines, and determine whether to change that coverage now that more than a year has elapsed since the public health emergency (PHE) expired in May 2023. Update 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 the US Preventive Services Task Force (USPSTF), the Health Resources & Services Administration (HRSA), and the Advisory Committee on Immunization Practices (ACIP).

- Coverage generally must conform for plan years that begin on or after the one-year anniversary of the date when a 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 when they were 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. 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).

Add or update no-cost in-network coverage of preventive services with a USPSTF A or B recommendation issued in 2023 and effective Jan. 1, 2025, for calendar-year plans. For noncalendar-year plans, the effective date could be the plan year beginning in 2024 or 2025, depending on when the plan year starts relative to the date USPSTF issued the recommendation.

- **Latent tuberculosis infection (LTBI) screening for adults ages 18 or older.** Screen for LTBI in asymptomatic adults ages 18 or older at increased risk for tuberculosis. This recommendation replaces but is consistent with one from 2016. (Issued May 2023)
- **Depression screening for adults ages 19 or older.** Screen for major depressive disorder for adults ages 19 or older, including pregnant and postpartum persons and older adults. This recommendation replaces but is consistent with one from 2016. (Issued June 2023)
- **Anxiety disorder screening for adults ages 64 or younger [NEW].** Screen for anxiety disorders in adults ages 64 or younger, including pregnant and postpartum persons. This is a new recommendation. (Issued June 2023)
- **Folic acid medication for persons planning or capable of pregnancy.** Use a daily supplement containing 0.4 to 0.8 mg (400 to 800 mcg) of folic acid to prevent neural tube defects. This recommendation reaffirms one from 2017. (Issued August 2023)
- **PrEP medication to prevent HIV infection.** Offer PrEP with effective antiretroviral therapy, as well as baseline and follow-up testing and monitoring, to adults and adolescents weighing more than 77 pounds at increased risk of HIV acquisition. A generic PrEP drug is permitted free of cost sharing. While a brand PrEP drug is subject to cost sharing, the plan would need to waive cost sharing if the generic is inappropriate for an individual. This recommendation replaces but is consistent with one from 2019. (Issued August 2023)
- **Screening for hypertensive disorders of pregnancy.** Take blood pressure measurements throughout pregnancy to screen pregnant persons for hypertensive disorders. This recommendation is consistent with one from 2017 (Issued September 2023).

Prepare to 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. For noncalendar-year plans, the effective date could be the plan year beginning in 2025 or 2026, depending on when the plan year starts relative to the date USPSTF issues the recommendation.

- **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 for plan years beginning Jan. 1, 2025–April 30, 2025, that requires coverage of biennial screening mammography for women ages 50–74. The 2016 recommendation individualizes 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. Other types of breast cancer screening (e.g., using ultrasound or magnetic resonance imaging (MRI)) are not included in the recommendation. (Issued April 2024).

  - *Before Jan. 1, 2025 (all plan years).* The 2023 Consolidated Appropriations Act (CAA) (Pub. L. No. 117-328) instructs group health plans to follow the September 2002 USPSTF recommendation that requires no-cost screening mammography, with or without clinical breast examination, every one to two years for women beginning at age 40.
  - HRSA's women's preventive-services guidelines continue to recommend "average-risk women initiate mammography screening no earlier than age 40 and no later than age 50," and then "at least biennially and as frequently as annually."
  - On a related note, regulators recently 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 is 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). (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 weight-loss medications (such as semaglutide) since they are not commonly used for children and teens, and not enough data is available on the potential harms from long-term use of these medications in children and teens. (Issued June 2024)
- **Any additional preventive services recommended during 2024.** If additional preventive service recommendations come out in November or December 2024, ensure noncalendar-year plans comply by the applicable 2025 or 2026 effective date and calendar-year plans comply by Jan. 1, 2026.

Check ACIP's list of vaccines to determine whether the plan must add new vaccines to cover without cost sharing.

- **Respiratory syncytial virus (RSV) vaccine for all adults ages 75 or older and for adults ages 60–74 at increased risk for severe RSV disease.** Provide a single dose of an RSV vaccine, using shared clinical decision-making, for the recommended population. This updated no-cost-sharing coverage requirement is effective for plan years beginning on or after June 26, 2025 (i.e., Jan. 1, 2026, for calendar-year plans).
- **Maternal RSV vaccine or infant receipt of nirsevimab.**
  - *Maternal RSV vaccine for pregnant persons.* Provide maternal RSV vaccine for pregnant persons at 32–36 weeks' gestation using seasonal administration (i.e., September through January in most of the US). This no-cost-sharing coverage

requirement is effective for plan years beginning on or after Sep. 22, 2024 (i.e., Jan. 1, 2025, for calendar-year plans).

- *Nirsevimab for infants and children to 19 months*. Provide nirsevimab for infants younger than 8 months born during or entering their first RSV season, as well as for infants and children ages 8–19 months at increased risk of severe RSV disease entering their second RSV season. This no-cost-sharing coverage requirement is effective for plan years beginning on or after Aug. 25, 2024 (i.e., Jan. 1, 2025, for calendar-year plans).

Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives approved by FDA, unless an exemption applies. Monitor two sets of proposed rules and ongoing litigation.

- **Track the proposed ACA preventive-services coverage rule that would enhance the benefits for prescribed and over-the-counter (OTC) contraceptives without cost sharing, clarify the exceptions process for all recommended ACA preventive services, and require additional disclosures about contraceptive coverage under a proposed amendment to transparency-in-coverage (TiC) rules.** Last year, HHS, Labor and Treasury issued a request for information (RFI) to gather public input on the potential benefits, costs, challenges, and burdens of requiring nongrandfathered group health plans to cover certain OTC drugs without cost sharing *and without a prescription*. The regulators are now proposing to amend the ACA preventive-services rule governing how nongrandfathered group health plans and issuers cover contraceptive products and communicate information about this coverage to participants. This proposed rule would apply for plan years beginning on or after Jan. 1, 2026, except the exceptions process rule would apply beginning on the final rule's effective date. Interested stakeholders can submit comments by Dec. 27, 2024. The proposal comes in response to (i) RFI comments received; (ii) ongoing complaints and public reports about plans and issuers impeding contraceptive coverage (see ACA implementation FAQs parts 51, 54, and 64, and a triagency letter to group health plan sponsors and insurers); (iii) Executive Orders 14076 and 14101; and (iv) the FDA's July 2023 approval of Opill (described below).

  - **Required coverage of OTC contraception without a prescription or cost sharing.** The proposed rule would require nongrandfathered group health plans to cover recommended OTC contraceptive items, such as birth control pills (Opill) and emergency contraception (levonorgestrel), without a prescription or cost sharing.

    - Opill is an OTC progestin-only oral contraceptive — one of the HRSA-recommended contraception methods for women. However, under *existing* ACA guidance, Opill must be prescribed to qualify as an ACA-mandated preventive service without cost sharing. Nevertheless, KFF reports some states already require insured plans to cover some OTC birth control without a prescription.

    - The regulators are taking an incremental approach in implementing this OTC proposal, focusing initially on expanding coverage of contraception. According to the regulators, an incremental approach facilitates implementation for plans, issuers, and other interested parties. The approach also lets regulators gather additional feedback on challenges and benefits of adopting these proposed policies before considering whether and how to propose similar requirements for other ACA-mandated OTC preventive services. The regulators anticipate issuing

another set of proposed rules "in the near future" to address additional issues related to preventive-services coverage in general.

- **Enhanced coverage of prescribed contraceptives without cost sharing.** The proposed rule would enhance what contraceptives nongrandfathered group health plans must cover without cost sharing. Plans currently must cover at least one of each of the contraceptive methods identified in the FDA Birth Control Guide. The proposed rule would expand this mandate by requiring no-cost-sharing coverage of *every* FDA-approved contraceptive that is a drug or drug-led combination product, unless the plan also covers at least one therapeutic equivalent drug or drug-led combination product without cost sharing. For example, plans would need to cover all types of intrauterine devices, since none has a therapeutic equivalent. For this proposed rule, the terms "therapeutic equivalent" and "drug-led combination product" are defined consistent with the FDA definitions of these terms.
  - ACA implementation FAQs — most recently, parts 54 and 64 — continue to make clear that even if not specifically identified in the current FDA Birth Control Guide, all FDA-approved, -cleared or -granted contraceptives that an individual's medical provider determines medically appropriate must be covered without cost sharing. This includes contraceptive products and services not described in the HRSA women's preventive-services guidelines.
- **Exceptions process for all recommended ACA preventive services.** The proposed rule codifies prior guidance (most recently, ACA implementation FAQs parts 54 and 64) on the use of reasonable medical-management techniques by plans and issuers. Plans and issuers using reasonable medical-management techniques for preventive services would have to provide an "easily accessible, transparent, and sufficiently expedient exceptions process." The exceptions process would allow coverage without cost sharing for the preventive service "according to the frequency, method, treatment, or setting that is medically necessary" for the participant, as determined by that person's provider, even if the plan generally does not cover that service.
- **OTC disclosure in online TiC self-service tool search.** The regulators also propose an amendment to the TiC rules to require a new a disclosure for TiC self-service tools that explains that OTC contraceptive items are covered without a prescription and without cost sharing. The disclosure must include a phone number and internet link to where a participant, beneficiary, or enrollee can learn more information about the plan or policy's contraception coverage. (See Group health plan transparency.)

- **Monitor the proposed preventive-services exemption rule that would eliminate the moral exemption and amend the religious exemption from ACA-mandated coverage of women's contraception.**
  - Continue to cover all FDA-approved and ACA-mandated women's contraceptives without cost sharing. Review with counsel before declining or revoking this coverage due to moral or religious objections, as those exemptions are under review.
  - If asserting a religious or moral objection to ACA-mandated women's contraceptive coverage, review with counsel whether to voluntarily adopt an accommodation — or revoke an existing accommodation — allowing participants to obtain women's

contraceptive coverage, if available, directly from the insurer or the third-party administrator (TPA).

- Nongovernmental employers with sincerely held religious or moral objections to contraceptives currently may exclude ACA-mandated coverage of some or all FDA-approved women's contraceptives, under 2018 final regulations upheld by the Supreme Court (*Little Sisters of the Poor v. PA*, 140 S. Ct. 2367 (2020)).
- The religious exemption currently is available to all types of nongovernmental employers, including nonprofit entities, privately held and publicly traded for-profit corporations, churches, and higher education institutions that arrange for student health insurance coverage. The moral exemption currently is available to the same entities, with the exception of publicly traded corporations.

— The proposed preventive-services exemption rule would leave in place the existing religious exemption but rescind the moral exemption for entities and individuals, as well as the optional accommodation for contraceptives. The proposed rule instead would establish a new pathway referred to as an "individual contraceptive arrangement." That arrangement would let individuals enrolled in an objecting entity's plan obtain contraceptive services at no cost directly from a willing provider or facility, with no involvement by the objecting entity. A provider or facility that furnishes contraceptive services under this arrangement could be reimbursed by entering into an arrangement with an issuer on a federally facilitated or a state-based exchange on the federal HealthCare.gov platform. The issuer in turn would seek an exchange user fee adjustment.

— Track ongoing litigation that could change these exemptions.

Review guidance addressing PrEP coverage and the use of industry-standard coding practices for recommended preventive services. ACA and WHCRA implementation FAQs part 68 focuses on PrEP coverage, reiterating the requirement to cover without cost sharing PrEP medication that reduces the risk of HIV infection, plus related baseline and monitoring services. The guidance also responds to reports that some plans and issuers are denying claims or imposing cost sharing for recommended preventive items and services because of how a provider codes for those services. Regulators clarify how plans and issuers can mitigate challenges with coding and processing of claims for recommended preventive services to ensure individuals are not improperly charged for ACA-mandated preventive services.

Monitor ongoing litigation that would let all group health plans and insurers exclude coverage of or impose cost sharing on many ACA-mandated preventive services, and allow employer plan sponsors with religious objections to exclude coverage of PrEP HIV medications.

- The 5th US Circuit Court of Appeals has affirmed a Texas district court decision that USPSTF A and B items and services recommended on/after March 23, 2010, are not constitutional because the USPSTF's power is "unreviewable" rendering its members principal officers of the United States who have not been validly appointed under Article II of the US Constitution (*Braidwood Mgmt. Inc. v. Becerra*, 104 F. 4th 930 (2024)). The appeals court, however, struck down the district court's nationwide injunction (which was on hold during the appeal), instead upholding the district court's decision only as applied to the named plaintiff and remanding the case back to the lower court for further

proceedings. As a result, for now, nongrandfathered group health plans (except named plaintiffs in the case) must continue to cover all USPSTF-recommended items and services without cost sharing while the litigation continues.

  - The district court 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.

- The Justice Department and HHS have filed a petition for a writ of certiorari with the US Supreme Court. As of the date of this article, the court has yet to decide whether it will hear the case (see docket). In the interim, pursuant to a joint motion to stay pending the district court proceedings pending action by the US Supreme Court, nongrandfathered group health plans (except the plaintiffs in the case) must continue to cover all ACA-mandated preventive services without cost sharing. The outcome of this case and the resulting group health plan implications are uncertain.

  - The district court decision, if it stands, removes the requirement — but leaves the option — for group health plans and insurers to provide coverage without cost sharing for preventive items and services USPSTF recommended after March 23, 2010.

  - Regardless of the outcome of this litigation, IRS Notice 2023-37 and ACA and CARES Act implementation FAQs part 59, make clear that items and services that USPSTF recommended with A or B rating 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.

  - States could — and some already do — require fully insured plans to cover the same or a similar set of preventive services without cost sharing.

  - Plans that remove coverage of preventive services without cost sharing must adhere to existing notice requirements.

Review IRS guidance 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.

- **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. This took effect for plan years beginning on or after Dec. 30, 2022. As discussed above, a proposed rule, if finalized, would *require* nongrandfathered group health plans to provide no-cost-sharing coverage of recommended OTC women's contraceptive items, including oral contraceptives, without a prescription.

  - The 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. No. 116-136) permits — but does not require — health reimbursement arrangements and

health flexible spending arrangements 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. This took effect for plan years beginning on or after Dec. 30, 2022. Notice 2024-71 separately provides a safe harbor to treat amounts paid for male condoms as an Internal Revenue Code Section 213(d) medical expense. This notice, as well as the expansion of the 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 MRIs, ultrasounds, and similar screening services. This updates and clarifies the HDHP preventive care safe harbor in Notice 2004-23. The guidance took effect April 12, 2004, the date Notice 2004-23 was published.
- **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. This took effect July 17, 2019, the date Notice 2019-45 was published.
- **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. This took effect for plan years beginning after Dec. 31, 2022.

Review group health plan coverage of COVID-19 testing and vaccines, and determine whether to change coverage

- **COVID-19 tests and related services.** Group health plans no longer have to cover COVID-19 tests and related services (including OTC COVID-19 tests) without cost sharing (i.e., no deductibles, copayments, or coinsurance), prior authorization, or other medical-management requirements.
  - Some plans have voluntarily continued cost-free coverage of COVID-19 tests and related services after May 11, 2023 (the PHE's expiration date). Such plans need to decide whether to continue that coverage, apply cost sharing or other medical-management standards, or eliminate all coverage of COVID-19 tests and related services. The regulators encourage continued coverage of COVID-19 tests and related services without cost sharing or medical-management requirements.

- For HSA-qualifying HDHPs, pandemic relief allowing pre- or no-deductible coverage of COVID-19 testing without affecting HSA eligibility applies only to plan years ending on or before Dec. 31, 2024. Thus, the relief expires Dec. 31, 2024, for calendar-year plans and during 2024 for noncalendar-year plans.
- Review whether plan communications about this coverage clearly indicate whether or when this no-cost coverage ends or changes.

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

Related resources

Section 10

Other ongoing ACA concerns

Action

Confirm compliance with the Affordable Care Act's (ACA's) group health plan benefit mandates and market reforms, and monitor litigation related to the scope of those mandates (see, for example, Preventive services). Make sure hospital and other fixed-indemnity plans qualify as excepted from ACA group health plan mandates and certain other federal laws, and provide the newly required notice. Assess the impact of the 2024 final rule reinterpreting the ACA's Section 1557 nondiscrimination provision, and monitor litigation challenging this rule. Ensure that Health Insurance Portability and Accountability Act (HIPAA) special enrollment practices are up to date, specifically for people losing individual short-term, limited-duration insurance (STLDI) or Medicaid or Children's Health Insurance Program (CHIP) coverage. Make sure to provide the summary of benefits and coverage (SBC) and ACA claims and appeals notices in a culturally and linguistically appropriate manner, consistent with updated guidance effective for the 2025 plan year. Review 2025 group health plan coverage and eligibility terms in light of employer shared-responsibility (ESR) strategy, as well as ESR and minimum essential coverage (MEC) reporting duties. Continue to comply with other ongoing ACA obligations, such as maintaining accurate and timely ESR recordkeeping and reporting, monitoring changes to essential health benefits (EHBs) and state benchmark plans, paying the Patient-Centered Outcomes Research Institute (PCORI) fee for self-funded health plans, and properly handling medical loss ratio (MLR) rebates.

Specific steps

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 EHBs, required first-dollar coverage of specified preventive services (see Preventive services), patient protections for emergency services, and annual in-network out-of-pocket maximums (OOPMs) for EHBs (i.e., $9,200 for self-only and $18,400 for other than self-only coverage in 2025, and $10,150 for self-only and $20,300 for other than self-only coverage in 2026).

- **Drug coupons and cost-sharing definition.** The regulators are expected to propose rules addressing whether drug manufacturer financial assistance is "cost-sharing" that must be counted towards the OOPM and deductible. This rule may impact the viability of "copay accumulator programs" which enable plans to disregard drug manufacture financial assistance (e.g., coupons) rather than apply them to the plan's OOPM and deductible (see Prescription drugs).
- **Prescription drugs as EHBs.** Regulators are expected to propose rules addressing whether large insured and self-funded group health plans must treat all covered prescription drugs as EHBs. A 2024 rule from the US Department of Health and Human Services (HHS) 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. The regulators have

signaled an intent to propose a similar requirement for large insured and self-funded group health plans. In effect, 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 (see Prescription drugs).

- **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. FFCRA and CARES Act implementation FAQs part 42 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.
- **Association health plans (AHPs)**. The Department of Labor (DOL) fully rescinded a 2018 rule that would have allowed working owners and unrelated employers to participate in a Pathway 2 AHP. Pathway 2 AHPs might have offered a route for working owners to avoid compliance with the ACA's EHB and community-rating rules that apply to individual coverage, but the 2018 rule was invalidated by a federal court in 2019. DOL has confirmed that AHPs formed under guidance predating the 2018 rule are still permitted.
- **Ongoing litigation.** Monitor litigation related to ACA benefit mandates that might necessitate plan design or administrative changes. (See Preventive services for a discussion of the lawsuit challenging that ACA mandate.)

Ensure that group hospital indemnity or other fixed-indemnity programs satisfy all requirements to be excepted from certain ERISA and ACA benefit mandates and market reforms. A recent final rule adds the requirement, effective for plan years beginning on or after Jan. 1, 2025, to display a consumer notice distinguishing the program from comprehensive medical coverage on any marketing, application, enrollment and reenrollment materials. Because the notice must be provided at or before enrollment or reenrollment, many plans may have to include the notice with 2025 enrollment materials distributed in 2024. The model notice, which must be used without modification or customization, must be prominently displayed on the first page of the paper or electronic materials (including on a website) in at least 14-point font. Employers should monitor a lawsuit seeking to vacate the notice requirement.

- To qualify as an excepted benefit exempt from certain ERISA and ACA benefit mandates and market reforms — such as the prohibition on annual or lifetime dollar limits on EHBs and the preventive services mandate — a group hospital or other fixed-indemnity program must satisfy each of the following conditions:
  - Is provided under a separate policy, certificate or contract of insurance (i.e., must be fully insured)

  - Pays a fixed dollar amount per day (or other period) of hospitalization or illness, regardless of the amount of expenses incurred
  - Isn't coordinated with exclusions in other group health plan benefits provided by the same employer
  - Pays benefits regardless of whether other coverage provided by the same employer pays for the same event
  - Effective for plan years beginning on or after Jan. 1, 2025, displays a new consumer notice on any marketing, application, enrollment, and reenrollment materials provided to participants at or before enrollment

- **As a best practice, ensure all plan communications adequately inform participants about the limits of fixed-indemnity coverage and could not be construed as misleading**. In particular, employers offering fixed-indemnity coverage and a plan with limited medical benefits (including a MEC-only or a preventive services plan) to the same employees should carefully review all benefit communications to eliminate any suggestion that the fixed-indemnity plan coordinates with exclusions in the limited medical benefit plan or that the two programs together provide comprehensive coverage. Regulators did not finalize an example that would have banned this combination, but they expressed continued concern that this type of benefit "package" is a coordinated arrangement to circumvent federal consumer protections. Regulators also worry that some employees — or employers — might mistake this combination of plans for comprehensive coverage.

Assess the impact of a 2024 final rule interpreting ACA Section 1557's prohibition on discrimination on the basis of race, color, national origin, sex, age, or disability, and prepare to comply with the rule as necessary. The 2024 final rule interprets Section 1557 much more broadly than the Trump administration's 2020 regulations. The 2024 final rule generally went into effect July 5, 2024, with additional time for covered entities to comply with a few provisions, as indicated below. Courts have temporarily stayed portions of the 2024 final rule primarily related to gender identity and gender-affirming care.

- **Determine which employer-sponsored health plans (if any) are "covered entities," directly subject to Section 1557 under the 2024 final rule.** Section 1557 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.
- **Prepare for the likely *indirect* impact on employer-sponsored plans that are insured or self-funded and administered by a covered insurer (i.e., an insurer receiving federal financial assistance from HHS).** 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 on a public exchange). 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.

- TPAs subject to Section 1557 may be liable for a discriminatory plan design in a self-funded plan that they administer, although that liability will depend on whether the TPA or the plan sponsor was responsible for the discriminatory design. HHS intends to determine whether design responsibility lies with the covered TPA or the plan sponsor. HHS will process a complaint against a TPA if the TPA is responsible for developing a discriminatory design feature adopted by an employer. If the design originated with the plan sponsor or the group health plan itself and the TPA played no role in the design, HHS will refer the complaint to the Equal Employment Opportunity Commission (EEOC) or the Justice Department for potential investigation.
- In addition to HHS enforcement, TPAs face private litigation under Section 1557 for *administration* of discriminatory plan designs (along with similar allegations with respect to insured coverage). Recently filed class actions have alleged TPAs violated Section 1557 by administering plans that excluded gender-affirming facial reconstruction surgery and anti-obesity medications for those diagnosed with obesity.
- Given the risk of DOL enforcement and private litigation, some TPAs may be less willing to administer designs that pose any Section 1557 risk (for example, gender-affirming care exclusions). Other TPAs may require additional documentation that plan sponsors accept responsibility for certain design features. Plan sponsors should consult with counsel before entering into such agreements.
- 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 or sex/gender).

- **Understand the new requirements for covered entities under the 2024 final rule.** The 2024 final rule expands and clarifies Section 1557's nondiscrimination protections and adds administrative requirements. Key changes from the 2020 rule include:
  - Discrimination on the basis of sex now includes sex stereotypes; sex characteristics; pregnancy and related conditions (including abortions); sexual orientation; and gender identity. The 2024 final rule includes protections for gender-affirming care and sex discrimination related to marital, parental or family status.
  - Covered entities, including insurers, are prohibited from providing or administering discriminatory health coverage — such as denying, cancelling, limiting or refusing to issue or renew coverage; limiting coverage of a claim; or imposing additional cost sharing or other limitations or restrictions, based on discriminatory factors. Specifically, the 2024 final rule bans:
    - Certain discriminatory coverage exclusions or limits on services related to gender transition or other gender-affirming care
    - Limits or restrictions on coverage based on an individual's sex at birth or gender identity

    - Benefit designs that do not provide or administer coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

  Health coverage newly subject to Section 1557 (i.e., not covered under the prior 2020 rule) has until the first day of the plan year beginning on or after Jan. 1, 2025, to comply. Health coverage previously subject to Section 1557 under the 2020 rule has additional time to comply — again until the first day of the plan year beginning on or after Jan. 1, 2025 — only for the requirement to provide coverage in the most integrated setting appropriate for qualified individuals with disabilities.

- Clarification 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 no later than on/about Nov. 2, 2024 (which is within 120 days of July 5, 2024).
  - No later than on/about July 5, 2025, 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). HHS has posted samples in multiple languages
- A ban on discriminatory patient care decision support tools requires covered entities to look for such tools and mitigate risks by May 1, 2025 (which is within 300 days of July 5, 2024) 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 in benefits.)

- **Monitor court challenges to the 2024 Section 1557 final rule.**
  - States and providers have filed multiple lawsuits challenging the 2024 Section 1557 final rule, focusing on the expansion of sex discrimination to include gender identity discrimination. District courts in Tennessee and Texas have issued preliminary nationwide injunctions limited to parts of the 2024 final rule related to gender identity discrimination. A district court in Florida has issued a similar injunction that applies only within Florida.
  - Additional litigation seems likely.
- **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 a right to administrative appeal of any adverse determination.

Provide a 60-day HIPAA special enrollment opportunity to employees who lose individual STLDI coverage midyear due to recent regulatory changes, and determine whether any relevant plan documentation requires amendment.

- A recent final rule limits the length of an STLDI policy issued on or after Sept. 1, 2024, to three months, with a maximum of one additional month — or four months total — including renewals and extensions. This reverses a 2018 rule that allowed STLDI coverage of up to 12 months — or up to 36 months, including renewals and extensions.
- Employees who purchased individual STLDI coverage may find that coverage expiring sooner than expected because of the final rule — possibly in the middle of the employer's plan year. These individuals may be eligible for a HIPAA special enrollment period to enroll in their employer's group health plan (if they are otherwise eligible to participate). The regulators state that individuals must have 60 days from the date of losing STLDI coverage to enroll in their employer's plan. However, regulators have not explained why this window exceeds the 30-day window available after special enrollment events other than loss of Medicaid or state CHIP coverage. Employers should confirm the 60-day window with their insurers or stop-loss carriers.

Return to standard HIPAA special enrollment time frames for employees losing Medicaid or CHIP coverage, if those time frames were expanded to align with the temporary Medicaid-unwinding special enrollment period (SEP) offered by the ACA federal public exchange.

- Millions of Americans lost Medicaid or CHIP coverage starting in April 1, 2023, as states resumed eligibility determinations paused during the COVID-19 pandemic (referred to as Medicaid unwinding).The Centers for Medicare & Medicaid Services (CMS) announced a temporary unwinding SEP, allowing individuals losing Medicaid or CHIP to enroll in the public exchange anytime between March 31, 2023, and July 31, 2024. Anticipating that many states would need additional months, the CMS extended the unwinding SEP to Nov. 30, 2024.
- Regulators had encouraged but did not require employer group health plans to expand their special enrollment window to align with the unwinding SEP on the public exchanges. (When CMS made this request to employers, the unwinding SEP was set to end July 31, 2024. Plans presumably could, with permission from their insurer or stop-loss carrier, align with unwinding SEP's extension until Nov. 30, 2024, but the guidance doesn't address this issue.) Plans that opted to align with the unwinding SEP should return to standard HIPAA special enrollment time frames (which is at least 60 days after the loss of eligibility for Medicaid or CHIP coverage) by Dec. 1, 2024.

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.

- 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, recent guidance updates the list of counties with language(s) that meet the 10% threshold. The guidance includes sample taglines in each of these languages.

Review planned 2025 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 2025 affordability percentage and the employer affordability safe harbors. For 2025, the ESR required contribution percentage will increase to 9.02%, up from 8.39% in 2024.
  - **2025 calendar-year plans.** The maximum monthly 2025 employee contribution for the lowest-cost, self-only option for employers using the federal poverty line (FPL) affordability safe harbor will increase significantly to $113.20, from $101.94 in 2024.
  - **Noncalendar-year plans beginning in 2025.** Noncalendar-year plans may use the FPL in effect within six months before the first day of the plan year. If the 2025 FPL is issued in January, noncalendar-year plans starting in February to July 2025 may use either the 2024 FPL of $15,060 — resulting in an FPL affordability safe harbor of $113.20 per month — or the 2025 FPL. (If the 2025 FPL is issued in February, noncalendar-year plans starting in March to August 2025 would have that same choice.) These noncalendar-year plans would likely benefit from waiting to use the 2025 FPL since it will probably exceed the 2024 FPL and yield a higher FPL safe harbor contribution limit [(9.02% x 2025 FPL) ÷ 12]. However, depending on when the 2025 plan year starts and the 2025 FPL is issued, waiting for the 2025 FPL may not be practicable. Note: Noncalendar-year plans beginning in 2024 continue to use $105.29 (8.39% x $15,060 FPL in 2024) ÷ 12) as the FPL safe harbor amount until their new 2025 noncalendar-year plan starts.
- **Minimum value.** Employers offering plans that do *not* meet minimum-value standards should consider whether such coverage continues to serve strategic goals. (Examples include plans that cover only preventive services or other “skinny” benefits and do not pass the minimum-value 60% test. A plan also fails these standards if it doesn’t provide substantial coverage of inpatient hospital services and physician services, despite otherwise satisfying the minimum-value 60% test.) These employers should review all plan communications with counsel to ensure that employees and their dependents understand the coverage (and its limits).
  - Public exchange coverage may be a more affordable option for some employees. This is particularly the case for those eligible for expanded subsidies (individuals earning more than 400% of the FPL) and/or enhanced subsidies (fully covering the cost of public exchange coverage for individuals earning up to 150% of the FPL). The current enhanced and expanded subsidies, most recently extended by the Inflation Reduction Act (Pub. L. No. 117-169), are set to expire at the end of 2025. Further

extension of these enhanced and expanded subsidies will be a major issue for the president and Congress in 2025.

  - Regulators have declined to ban employers from offering a fixed-indemnity program and a preventive-services-only MEC plan to the same group of employees. However, the regulators remain concerned that employees might mistake this combination for comprehensive medical coverage. (See discussion of group hospital or other fixed-indemnity plans above.)

- **Assessments.** IRS guidance sets the 2025 ESR assessments as follows:
  - $2,900 (down from $2,970 in 2024) 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 a public exchange; based on CMS guidance, this assessment is projected to reach $3,200 in 2026
  - $4,350 (down from $4,460 in 2024) per ACA full-time employee receiving federally subsidized coverage through a public exchange because the employee wasn't among the 95% of ACA full-time employees offered employer MEC or received an offer of employer MEC that was unaffordable or less than minimum value; based on CMS guidance, this assessment is projected to reach $4,800 in 2026
- **Litigation.** A recent lawsuit challenges the ESR assessment process, specifically the IRS's use of Letter 226-J to satisfy the ACA Section 1411 certification requirement (42 USC § 18081). The plaintiffs seek to set aside an HHS rule allowing IRS to "adopt methods to certify to an employer" that one or more of its employees received a public exchange subsidy. If successful, the lawsuit could modify the ESR rules and/or assessment process.

Ensure the adequacy of ESR recordkeeping and reporting.

- Prepare to furnish individual statements on health coverage and/or offers of coverage to ACA full-time employees (Forms 1095-B and 1095-C) and to file the required forms with IRS. 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 2024 will be due March 3, 2025 (since March 2 falls on a weekend in 2025). IRS will not grant additional extensions. The final regulations also allow an alternative method for furnishing individual MEC statements, as long as the penalty for failing to meet the individual mandate remains zero.
  - Monitor proposed legislation that would expand employers' ability to electronically furnish Forms 1095-C *to all employees* (not just nonemployees and employees not considered full-time under the ACA, as limited under current IRS guidance). This would involve posting a clear and conspicuous notice stating that individuals may receive a paper copy of these forms on request.
- 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.

  - Monitor proposed legislation that would allow substituting any covered individual's date of birth for the taxpayer identification number (TIN) if the reporting entity is unable to collect the individual's TIN. Current IRS rules allow reporting entities to substitute an individual's birthdate for the TIN if they are unable to collect the TIN through "reasonable efforts," which generally include three attempts.

- Comply with IRS regulations (TD 9972, as corrected) requiring electronic filing (due by March 31, 2025, for the 2024 year) for any entity filing 10 or more information returns. This threshold is determined by aggregating Forms 1094, 1095 and W-2, among others.
- Keep the costs of ESR noncompliance in mind as IRS continues to issue ESR assessments. The IRS first began notifying employers in late 2017 about their potential liability for the 2015 calendar year (when the ESR mandate took effect). IRS has actively collected assessments from applicable large employers every year since then. In a December 2019 memorandum, the IRS concluded that no statute of limitations applies to ESR assessments, suggesting assessment letters could come more than three years after the calendar year to which they apply. Monitor proposed legislation that would set a six-year statute of limitations for ESR assessments.
- Check for reporting errors that can result in inaccurate ESR assessments. The Treasury Inspector General for Tax Administration (TIGTA) has 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. Confirm that recordkeeping suffices to respond to any future IRS assessment letters. Look for a possible uptick in employees erroneously receiving subsidized public exchange coverage due to looser CMS rules on verifying an applicant's eligibility for an employer-sponsored health plan. Monitor proposed legislation that would give employers at least 90 days (instead of the current 30 days) to respond to proposed IRS assessments for alleged ESR violations.
- Continue to collect information for 2025 reports due in 2026. Confirm the appropriate measurement method — lookback or monthly — is used to identify ACA full-time employees.

Watch for any changes to EHBs and selected state benchmark plans.

- If using a state benchmark plan to identify which covered benefits are — or are not — EHBs subject to in-network OOPMs and the ban on annual or lifetime dollar limits, review the selected benchmark for any changes applicable in 2025, and consider other states' updates (if any).
- As noted above, the regulators have signaled that they intend to propose rules addressing whether large insured and self-funded group health plans must treat all covered prescription drugs as EHBs (see also Prescription drugs).
- HHS is permitting states to update their benchmark plans to include routine nonpediatric dental services, effective for the 2027 plan year.

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, 2025, for noncalendar-year or short calendar-year plans ending in 2024 before Oct. 1 is $3.22 (up from $3.00 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, 2025, for 2024 calendar-year plans and noncalendar-year plans ending in 2024 on or after Oct. 1 will be announced in the late fall/early winter.

If sponsoring a fully insured group health plan, prepare for continued MLR rebates. 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 HHS 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.

Related resources

Appendix
Related resources

1. Prescription drugs

Non-Mercer resources

- Prescription drug data collection (RxDC) website (CMS, regularly updated)
- Medicare Part D negotiated prices fact sheet (CMS, Aug. 14, 2024)
- The role of PBMs in prescription drug markets Part III: transparency and accountability (House Committee on Oversight and Accountability, July 23, 2024)
- PBMs: The powerful middlemen inflating drug costs and squeezing Main Street pharmacies (FTC, July 9, 2024)
- RxDC reporting instructions (CMS, April 15, 2024)
- RxDC file templates (CMS, Jan. 31, 2024)
- RxDC FAQs (CMS, Dec. 23, 2022)
- Pub. L. No. 117-69, the Inflation Reduction Act of 2022 (Congress, Aug. 16, 2022)
- Field Assistance Bulletin 2021-03 (DOL, Dec. 30, 2021)
- Interim final rules, Prescription drug and healthcare spending (Federal Register, Nov. 23, 2021)
- Section 202 of Pub. L. No. 116-260, the No Surprises Act (NSA) (Congress, Dec. 27, 2020)
- Section 204 of Pub. L. No. 116-260, the 2021 CAA (Congress, Dec. 27, 2020)
- *Pharmaceutical Care Management Association v. Mulready*, No. 22-6074 (10th Cir. Aug. 15, 2023) (cert. pending)
- *Rutledge v. Pharmaceutical Care Management Association*, 140 S. Ct. 812 (2020)

Mercer Law & Policy resources

- Roundup of selected state health developments, second-quarter 2024 (July 26, 2024)
- Roundup of selected state health developments, first-quarter 2024 (April 22, 2024)

Other Mercer resources

- MercerRx
- MercerWell
- Understanding the debate over PBMs (Aug. 1, 2024)

- GLP-1 discontinuation affirms need for holistic weight-loss plan (July 25, 2024)
- SCOTUS rules on the abortion pill: Implications for employers (June 13, 2024)
- Help for opioid addiction: Some progress, much more to do (May 30, 2024)
- Part D enhancements may impact creditable coverage testing (May 23, 2024)
- Addressing obesity requires more than covering GLP-1s for weight loss (May 15, 2024)
- Weight management in the era of GLP-1s (March 28, 2024)
- GLP-1s hit new milestone: Wegovy approved for cardiovascular issues (March 28, 2024)
- New RxDC reporting instructions: Headaches or opportunities? (Feb. 15, 2024)
- The practical impact of Florida drug importation from Canada (Jan. 18, 2024)
- House passes package of PBM, price transparency, billing reforms (Dec. 14, 2023)
- Moving targets: Rx legislative activity to watch in 2024 (Dec. 7, 2023)
- Broad employer coalition urges Senate action on PBM reforms (Nov. 16, 2023)
- Uncertainty persists for bipartisan PBM, transparency reforms (Sept. 28, 2023)
- Drug copay accumulator programs: A many-sided argument (Oct. 26, 2023)

2. ERISA fiduciary issues

Non-Mercer resources

- 29 USC § 1104, Fiduciary duties (US Code)
- 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)
- *Popovchak v. UnitedHealth Grp.,* 22-cv-10756 (SDNY Sept. 19, 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)
- *Su v. UMR Inc.*, No. 3:23-cv-513 (WD WI, filed July 31, 2023); *Su v. MO Bankers Ass'n Inc.*, No. 2:23-cv-4121 (WD MO, filed June 13, 2023)
- *Davis v. United Health Grp. Inc.*, No. 2:2021-cv-01220 (WD WA April 14, 2023)
- Reporting and disclosure guide for employee benefit plans (EBSA, December 2022)
- *Shields v. United of Omaha Life Ins. Co.,* 50 F.4th 236 (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

- What plan sponsors should know about DOL's final fiduciary rule (June 20, 2024)
- What plan sponsors should know about DOL's new fiduciary proposal (Dec. 6, 2023)

Other Mercer resources

- Navigating fiduciary risk in health and welfare benefits (Mercer webinar replay series, Oct. and Nov. 2024)
- ERISA plan sponsors are responding to heightened fiduciary risk (Nov. 22, 2023)

3. 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)
- Self-funded nonfederal governmental plans, procedures and requirements for HIPAA exemption election (CMS)
- Mental Health Parity and Addiction Equity Act (CMS)
- Final rule, Requirements related to the Mental Health Parity and Addiction Equity Act (Federal Register, Sept. 23, 2024)
- New MHPAEA rules: What they mean for participants and beneficiaries (DOL, Sept. 7, 2024)
- New MHPAEA rules: What they mean for providers (DOL, Sept. 7, 2024)
- New MHPAEA rules: What they mean for plans and issuers (DOL, Sept. 7, 2024)
- Fact sheet, Final rules under the MHPAEA (DOL, Sept. 6, 2024)
- *United Behavioral Health v. US District Court for the Northern District of California*, No. 24-242 (9th Cir. Sept. 4, 2024), unpublished opinion
- 2023 MHPAEA report to Congress (DOL, HHS and Treasury, July 24, 2023)
- *Wit v. United Behavioral Health*, Nos. 21-15194, 21-15193, 20-17364 and 20-17363 (9th Cir. Aug. 22, 2023), replacing an earlier version dated Jan. 26, 2023, which replaced an unpublished opinion dated March 22, 2022
- Appendix: MHPAEA guidance compendium (DOL, July 21, 2023)

- Pub. L. No. 117-328, the Consolidated Appropriations Act (CAA), 2023 (Congress, Dec. 29, 2022)
- 2022 MHPAEA report to Congress (DOL, HHS and Treasury, Jan. 21, 2022)
- 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)
- MHPAEA self-compliance tool (DOL, Oct. 20, 2020) (does not cover changes made by the 2021 CAA)

Mercer Law & Policy resources

- 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

- 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)
- Survey: Employers support growing demand for mental health services (Dec. 7, 2023)
- Major mental health parity guidance signals continued enforcement focus for employers (July 27, 2023)
- Big litigation win for UBH, but mental health parity risks continue (April 14, 2022)
- Regulators' first report on mental health parity analysis finds issues (Feb. 3, 2022)
- Time to check your MAT coverage as overdose deaths reach new high (Dec. 2, 2021)
- ABA therapy coverage exclusions raise a red flag (Oct. 6, 2021)
- The DOL increases mental health parity enforcement (Sept. 2, 2021)
- New law aims to improve mental health parity compliance; DOL tool will help (Jan. 7, 2021)

4. Group health plan transparency

Non-Mercer resources

- Hospital price transparency (CMS)

- Technical implementation guide for the triagency price transparency rule (GitHub, updated daily)
- 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)
- Hospital price transparency FAQs (CMS, June 6, 2024)
- Steps for making public hospital standard charges in a machine-readable format (CMS, March 15, 2024)
- CMS makes hospital prices more transparent and expands access to behavioral healthcare (CMS, Nov. 2, 2023)
- 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)
- Overview of TiC MRF requirements (HHS, June 27, 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 resource

- Mercer comments on proposed transparency in coverage rules (Jan. 31, 2020)

Other Mercer resources

- House passes package of PBM, price transparency, billing reforms (Dec. 14, 2023)
- Moving targets: Rx legislative activity to watch in 2024 (Dec. 7, 2023)
- What happened to all that medical price data? (June 22, 2023)
- CMS issues late, breaking guidance on posting machine-readable files (June 22, 2022)

5. Data privacy and security

Non-Mercer resources

- Cybersecurity & Infrastructure Security Agency (CISA)
- Privacy, security and HIPAA (HealthIT.gov)
- Compliance assistance release no. 2024-01 (DOL, Sept. 6, 2024)
- OCR cybersecurity newsletter: HIPAA security rule facility access controls — What are they and how do you implement them? (HHS, Aug. 24, 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)
- Social medial toolkit: HIPAA privacy rule to support reproductive healthcare privacy (HHS, June 27, 2024)
- Use of online tracking technologies by HIPAA covered entities and business associates (OCR, June 26, 2024)
- The American Privacy Rights Act (Congressional Research Service, May 31, 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)
- The NIST cybersecurity framework (CSF) 2.0 (NIST, March 7, 2024)
- Annual report to Congress on breaches of unsecured protected health information for calendar year 2022 (OCR, Feb. 21, 2024)
- Annual report to Congress on HIPAA privacy, security and breach notification rule compliance for calendar year 2022 (OCR, Feb. 20, 2024)
- Cybersecurity resources for HIPAA-regulated entities (NIST, Feb. 14, 2024)

- Implementing the HIPAA security rule: a cybersecurity resources guide (NIST, Feb. 27, 2024)
- Healthcare sector cybersecurity: Introduction to the strategy of the US Department of Health and Human Services (HHS, Dec. 6, 2023)
- OCR cybersecurity newsletter: How sanction policies can support HIPAA compliance (HHS, Oct. 18, 2023)
- HIPAA and telehealth (HHS, Oct. 18, 2023)
- Press release: FTC and HHS warn hospital systems and telehealth providers about privacy and security risks from online tracking technologies (FTC, July 20, 2023)
- OCR cybersecurity newsletter: HIPAA and cybersecurity authentication (HHS, June 29, 2023)
- OCR cybersecurity newsletter: HIPAA security rule security incident procedures (HHS, Oct. 25, 2022)
- FAQ 3013: Does HIPAA require a covered entity or its EHR system developer to enter into a business associate agreement with an app designated by the individual in order to transmit ePHI to the app? (HHS, Sept. 2, 2020)
- FAQ 3009: Does a HIPAA covered entity that fulfills an individual's request to transmit ePHI to an application or other software (collectively "app") bear liability under the HIPAA privacy, security, or breach notification rules (HIPAA rules) for the app's use or disclosure of the health information it received? (HHS, May 9, 2019)
- FAQ 3012: Can a covered entity refuse to disclose ePHI to an app chosen by an individual because of concerns about how the app will use or disclose the ePHI? (HHS, May 9, 2019)
- Final rules, HIPAA privacy, security, enforcement and breach notification (Federal Register, Jan. 25, 2013)

Mercer Law & Policy resources

- HHS adjusts 2024 HIPAA, certain ACA and MSP monetary penalties (Aug. 21, 2024)
- New HIPAA privacy protections for reproductive healthcare (July 30, 2024)
- ERISA Advisory Council delivers download on cyber insurance (May 8, 2023)
- DOL issues cybersecurity guidance for retirement plans (April 26, 2021)
- COVID-19 raises HIPAA privacy, security issues (April 6, 2020)
- CARES Act boosts telehealth, makes other health, paid leave changes (March 27, 2020)
- New California laws affect health insurance, leave, other HR policies (Feb. 19, 2020)

Other Mercer resources

- 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)
- Mercer weighs in as House committee looks to bolster ERISA (March 21, 2024)
- Make cybersecurity part of your 2024 New Year's resolutions (Jan. 4, 2024)
- ERISA plan sponsors are responding to heightened fiduciary risk (Nov. 22, 2023)
- What's working to expand behavioral healthcare access: 5 best practices (Oct. 5, 2023)
- The digital future of men's health — Is there one? (Aug. 17, 2023)
- Technology rushes to fill the ever-widening gap in US pregnancy care (Feb. 16, 2023)
- Two-year renewals of predeductible HDHP telehealth coverage now law (Jan. 11, 2023)
- A new frontier in mental health: Technology (Jan. 5, 2023)
- Survey results: There is more to virtual care than telemedicine (May 11, 2022)
- Virtual care: From "add-on" service to integrated modality (Feb. 24, 2022)
- Privacy in an increasingly connected world (Feb. 3, 2022)
- Telebehavioral healthcare: A post-pandemic view (Jan. 20, 2022)

6. Artificial intelligence in benefits

Non-Mercer resources

- Artificial intelligence: federal contractors compliance obligations (DOL)
- Artificial intelligence and algorithmic fairness initiative (EEOC)
- Artificial intelligence (NIST)
- Copyright and artificial intelligence (US Copyright Office)
- Artificial intelligence and worker well-being: principles for developers and employers (DOL, Oct. 15, 2024)
- Artificial intelligence and machine learning (AI/ML)-enabled medical devices (FDA, Aug. 7, 2024)
- Request for information on uses, opportunities and risks of artificial intelligence in the financial services sector (Federal Register, June 12, 2024)
- A roadmap for artificial intelligence policy in the US Senate (Bipartisan Senate AI Working Group, May 15, 2024)
- FAB 24-01: Artificial intelligence and automated systems in the workplace under the Fair Labor Standards Act and other federal labor standards (CMS, April 29, 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)

- FAQs related to coverage criteria and utilization management requirements in CMS final rule (CMS-4201-F) (CMS, Feb. 6, 2024)
- How generative AI is transforming business and society (Oliver Wyman, Jan. 22, 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 (White House, Oct. 30, 2023)
- Select issues: assessing adverse impact in software, algorithms, and artificial intelligence used in employment selection procedures under Title VII of the Civil Rights Act of 1964 (EEOC, May 18, 2023)
- Medicare Program; contract year 2024 policy and technical changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and programs of all-inclusive care for the elderly (Federal Register, April 12, 2023)
- The Americans with Disabilities Act and the use of software, algorithms, and Artificial Intelligence to assess job applicants and employees (EEOC, May 12, 2022)

Mercer Law & Policy resources

- Roundup: Global employer resources on artificial intelligence (regularly updated)

Other Mercer resources

- The transformative impact of generative AI on HR shared services (2024)
- Demystifying AI for HR: Five ways to address misconceptions (2024)
- States start to take action on AI and insurance (July 25, 2024)
- 3 ways companies can mitigate the risk of AI in the workplace (originally published on the World Economic Forum's agenda blog on Jan. 16, 2024)
- AI reshaping oncology and cardiovascular health (Oct. 5, 2023)
- What is the future of AI in telemedicine? (Sept. 7, 2023)
- Chief People Officer's quick guide to generative artificial intelligence (April 13, 2023)
- AI in Benefits: Managing the Risk to Get to the Rewards (Feb. 11, 2021)

7. Surprise billing

Non-Mercer resources

- No Surprises Act webpage (EBSA)
- Ending surprise medical bills webpage (CMS)
- Independent dispute resolution reports (CMS)
- 2021 CAA implementation FAQs part 67 (DOL, HHS and Treasury, May 1, 2024)
- Report on prevention of out-of-network ground ambulance emergency service balance billing (GAPB, March 29, 2024)
- Final rules, Federal independent dispute resolution (IDR) process administrative fee and certified IDR entity fee ranges (DOL, HHS and Treasury, Dec. 21, 2023)
- Notice 2024-1 (IRS, Dec. 19, 2023)
- Fact sheet, Federal IDR process administrative fee and certified IDR entity fee ranges (CMS, Dec. 15, 2023)
- 2021 CAA implementation FAQs part 62 (DOL, HHS and Treasury, Oct. 6, 2023)
- *TX Med. Ass'n. v. Dep't of Health and Human Servs.*, No. 6:22-cv-00450 (ED TX Aug. 24, 2023)
- ACA and 2021 CAA implementation FAQs part 60 (DOL, HHS and Treasury, July 7, 2023)
- ACA and 2021 CAA implementation FAQs part 55 (DOL, HHS and Treasury, Aug. 19, 2022)
- Guidance for states, plans and issuers on state external review processes regarding requirements in the No Surprises Act (HHS, Feb. 1, 2022)
- Interim final rules, Requirements related to surprise billing; part II (Federal Register, Oct. 7, 2021)
- Interim final rules, Requirements related to surprise billing; part I (Federal Register, July 13, 2021)
- Title I of Div. BB in Pub. L. No. 116-260, the No Surprises Act (Congress, Dec. 27, 2020)

Other Mercer resources

- Prepare to comply with No Surprises Act notice requirements (Dec. 16, 2021)
- Regulators clarify implementation timeline of transparency provisions (Aug. 25, 2021)
- Surprise billing interim final rule released (July 8, 2021)
- Groups urge surprise billing rules that control costs, protect patients (June 24, 2021)

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

Non-Mercer resources

- PSYPACT
- 2019 National Defense Authorization Act (Pub. L. 116-92)
- 2017 Tax Cuts and Jobs Act (Pub. L. 115-97)
- Uniformed Services Employment and Reemployment Rights Act (USERRA) (38 USC § 4301 *et seq.*)
- USERRA regulations

Mercer Law & Policy resources

- Maryland to require wage range and benefit disclosures in job postings (Sept. 23, 2024)
- 2024 state paid family and medical leave contributions and benefits (Sept. 3, 2024)
- Hawaii employee health and leave benefits may need special attention (July 26, 2024)
- Roundup of selected state health developments, second-quarter 2024 (July 26, 2024)
- Massachusetts sets 2025 individual-mandate coverage dollar limits (July 23, 2024)
- Maryland paid family and medical leave overview (May 17, 2024)
- Paid family and medical leave — snapshots across the US (May 15, 2024)
- Maryland revises paid family and medical leave (May 3, 2024)
- Roundup of selected state health developments, first-quarter 2024 (April 22, 2024)
- Illinois paid leave for all workers overview (March 13, 2024)
- Roundup of selected state health developments, fourth-quarter 2023 (Feb. 5, 2024)
- Some states require group health plan sponsor reporting (Dec. 5, 2023)
- Illinois requires paid leave for any reason starting in 2024 (April 11, 2023)
- Congress extends tax credit for paid family and medical leave (Feb. 12, 2021)
- San Francisco aligns paid parental leave law with state family leave (July 21, 2020)

Other Mercer resources

- Life, absence & disability benefits
- MercerRx
- Ballot box ballyhoo: Four benefits-related initiatives to watch (Aug. 22, 2024)
- States start to take action on AI and insurance (July 25, 2024)
- Uncommon state leave laws may be worth broader employer adoption (June 27, 2024)

- Bereavement leave polices present legal considerations for employers (May 30, 2024)
- Litigation update on selected state benefit and leave laws (March 28, 2024)
- Practice of prior authorization draws increased scrutiny (Feb. 29, 2024)
- IVF uncertainty in Alabama: What can employers do? (Feb. 29, 2024)
- What to expect from the states in 2024 (Jan. 25, 2024)
- Mandated paid leave and other state law trends to watch in 2024 (Oct. 26, 2023)

9. Preventive services

Non-Mercer resources

- Preventive health services (Healthcare.gov)
- A and B recommendations (USPSTF)
- Vaccine-specific recommendations (ACIP)
- Women's preventive-services guidelines (HRSA)
- Proposed rule, Enhancing coverage of preventive services under the ACA (Oct. 28, 2024)
- ACA and WHCRA implementation FAQs part 68 (DOL, HHS and Treasury, Oct. 21, 2024)
- Fact sheet, Biden-Harris administration proposes rule to expand coverage of affordable contraception under the ACA (White House, Oct. 21, 2024)
- New release, Biden-Harris administration proposes expanding coverage of birth control and other preventive services (HHS, Oct. 21, 2024)
- Fact sheet, Enhancing coverage of preventive services under the ACA proposed rules (HHS, Oct. 18, 2024)
- Notice 2024-75, Preventive care for purposes of qualifying as a high-deductible health plan under Section 223 (IRS, Oct. 17, 2024)
- Notice 2024-71, Expenses treated as amounts paid for medical care; safe-harbor for amounts paid for condoms (IRS, Oct. 17, 2024)
- Petition for a writ of certiorari in *Braidwood Mgmt. Inc. v. Becerra* (US Supreme Court Sept. 19, 2024)
- State requirements for insurance coverage of contraceptives (KFF, September 2024)
- *Braidwood Mgmt. Inc. v. Becerra*, 104 F. 4th 930 (2024)
- ACA implementation FAQs part 64 (DOL, HHS and Treasury, Jan. 22, 2024)
- Request for information, Coverage of over-the-counter preventive services (Federal Register, Oct. 4, 2023)

- Preventive-services access on the docket in *Braidwood v. Becerra* (Congressional Research Service, Sept. 12, 2023)
- News release, FDA approves first nonprescription daily oral contraceptive (FDA, July 13, 2023)
- Executive Order 14101, Strengthening access to affordable, high-quality contraception and family planning services (Federal Register, June 23, 2023)
- Notice 2023-37, Expenses related to COVID-19 and preventive care for purposes of HDHPs (IRS, June 23, 2023)
- Joint stipulation, proposed order and stay in *Braidwood Mgmt. Inc. v. Becerra*, No. 23-10326 (5th Cir. June 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 (2023)
- Second memorandum opinion and order on remedies in *Braidwood Mgmt. Inc. v. Becerra*, No. 4:20-cv-00283 (ND TX, March 30, 2023)
- FFCRA, CARES Act and HIPAA implementation FAQs part 58 (DOL, HHS and Treasury, March 29, 2023)
- Proposed rule, Coverage of certain preventive services under the ACA (Federal Register, Feb. 2, 2023)
- Fact sheet: COVID-19 public health emergency transition roadmap (HHS, Feb. 9, 2023)
- Pub. L. No. 117-328, the Consolidated Appropriations Act, 2023 (Congress, Dec. 29, 2022)
- ACA implementation FAQs part 54 (DOL, HHS and Treasury, July 28, 2022)
- Executive Order 14076, Protecting access to reproductive healthcare services (Federal Register, July 8, 2022)
- Joint letter to group health plan sponsors and issuers regarding ACA-mandated contraceptive coverage (DOL, HHS and Treasury, June 27, 2022)
- ACA, FFCRA and CARES Act implementation FAQs part 51 (DOL, HHS and Treasury, Jan. 10, 2022)
- *Braidwood Mgmt. Inc. v. Becerra*, 627 F. Supp. 3d 624 (2022)
- ACA, HIPAA and CARES Act implementation FAQs part 50 (DOL, HHS and Treasury, Oct. 4, 2021)
- Pub. L. No. 116-136, the CARES Act (Congress, March 27, 2020)
- Notice 2020-15, HDHPs and expenses related to COVID-19 (IRS, March 11, 2020)
- *Little Sisters of the Poor v. PA*, 140 S. Ct. 2367 (2020)

- Notice 2019-45, Additional preventive care benefits permitted to be provided by a high deductible health plan under § 223 (IRS, July 17, 2019)
- Final rule, Moral exemptions and accommodations for coverage of certain preventive services under the ACA (Federal Register, Nov. 15, 2018)
- Final rule, Religious exemptions and accommodations for coverage of certain preventive services under the ACA (Federal Register, Nov. 15, 2018)
- Notice 2018-12, Notice of transition relief regarding the application of Section 223 to certain health plans providing benefits for male sterilization or male contraceptives (IRS, March 5, 2018)
- Final rule, Coverage of certain preventive services under the ACA (Federal Register, July 14, 2015)

Mercer Law & Policy resource

- IRS expands predeductible preventive care for HSA-qualifying health plans (July 23, 2019)

Other Mercer resources

- ACA preventive-services coverage and litigation continue, for now (June 27, 2024)
- Employers weigh start of RSV immunization coverage (Dec. 14, 2023)
- Employers to decide if OTC birth control will be covered at no cost (July 20, 2023)
- Texas judge pares back ACA preventive-services coverage requirement (March 31, 2023)
- Will a court decision change preventive care coverage? (Sept. 14, 2022)
- Contraceptive coverage: Good for women, good for business (July 12, 2018)

10. Other ongoing ACA concerns

Non-Mercer resources

- 29 CFR § 2590.732(c)(4), Regulation on excepted benefits that are noncoordinated (Code of Federal Regulations (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)
- Summary of benefits and coverage materials (CMS)
- Section 1557 of the Patient Protection and Affordable Care Act (HHS)
- 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)
- Premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage for the 2026 benefit year (CMS, Oct. 8, 2024)
- Rev. Proc. 2024-35 (IRS, Sept. 6, 2024)
- Final rule, Nondiscrimination in health programs and activities (ACA Section 1557) (Federal Register, May 6, 2024)
- Final rule, Definition of "employer" — AHPs (Federal Register, April 30, 2024)
- Final rule, Patient Protection and Affordable Care Act; 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)
- Rev. Proc. 2024-14 (IRS, Feb. 12, 2024)
- Poverty guidelines for 2024 (HHS, Jan. 17, 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)
- Premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing, and required contribution percentage for the 2025 benefit year (CMS, Nov. 15, 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)
- Notice 2023-70, Insured and self-insured health plans adjusted applicable dollar amount for fee imposed by sections 4375 and 4376 (IRS, Nov. 18, 2023)
- ACA and 2021 CAA implementation FAQs part 60 (DOL, HHS and Treasury, July 7, 2023)
- FFCRA, CARES and HIPAA implementation FAQs part 58 (DOL, HHS and Treasury, March 29, 2023)
- Losing Medicaid or CHIP coverage? (EBSA, March 29, 2023)
- Final rule, Electronic-filing requirements for specified returns and other documents (Federal Register, Feb. 23, 2023)

- Temporary SEP for consumers losing Medicaid or CHIP coverage due to unwinding of the Medicaid continuous enrollment condition FAQs (CMS, Jan. 27, 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, the Inflation Reduction Act (Congress, Aug. 16, 2022)
- FFCRA and CARES Act implementation FAQs part 44 (DOL, HHS and Treasury, Feb. 26, 2021)
- 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, Nondiscrimination in health and health education programs or activities (ACA Section 1557) (June 19, 2020)
- FFCRA and CARES Act implementation FAQs part 42 (DOL, HHS and Treasury, April 11, 2020)
- Memorandum 20200801F, Statute of limitations for IRC § 4980H (IRS, Dec. 26, 2019)

Mercer Law & Policy resources

- 2025 affordability percentage for employer health coverage increases (Sept. 9, 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)
- 2025 HSA, HDHP and excepted-benefit HRA figures set (May 10, 2024)
- Summary of 2024 benefit-related cost-of-living adjustments (Feb. 8, 2024)
- 2024 federal poverty levels can impact ESR affordability (Jan. 17, 2024)
- 2024 quick benefit facts (Jan. 15, 2024)
- DOL sets 2024 penalties for health and welfare benefit plan violations (Jan. 11, 2024)
- Agencies propose overhaul of fixed-indemnity plan rules (July 18, 2023)
- Final regulations extend ACA individual statement due dates (Dec. 20, 2022)
- ACA 1557 nondiscrimination rule revised, but what is effective now? (Nov. 5, 2020)
- Employers face ongoing liability for ACA play-or-pay assessments (March 2, 2020)

Other Mercer resources

- Healthcare leftovers pile up for year-end congressional menu (Oct. 3, 2024)
- Drug copay accumulator programs: A many-sided argument (Oct. 26, 2023)

Mercer (US) Inc.
1166 Avenue of the Americas
New York, NY 10036
www.mercer.com