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Law & Policy Group | GRIST

Top 10 health, leave benefit compliance and policy issues in 2024

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Contents

Health and leave benefit compliance issues for 2024

Employer-sponsored health plan compliance issues in 2024 will continue to generate extensive federal and state regulatory activity, legislation, and litigation. Issues in the spotlight include preparing for sweeping new mental health parity rules proposed for 2025, ongoing compliance with numerous group health plan transparency requirements, and efforts to rein in healthcare and prescription drug costs. Employers must also contend with the growing patchwork of state rules, particularly ones targeting prescription drug pricing and paid family/sick leave. Active litigation continues on several key health policy issues, including surprise billing, Affordable Care Act (ACA)-required preventive services and ERISA preemption of state benefit laws, especially those affecting prescription drug benefits. Major reforms in a divided Congress are unlikely, but bipartisan efforts to lower healthcare costs and regulate pharmacy benefit manager (PBM) practices this year could result in some new requirements for 2024 or later.

This GRIST summarizes expected 2024 compliance and policy developments affecting health and leave benefits and suggests action steps for employers. Topics covered include:

- **Congressional outlook.** A significant bipartisan, bicameral drive aims to pass legislation lowering healthcare costs through increased transparency and competition. A broad array of bills would reform PBM practices, add new and expand existing transparency requirements, address provider and hospital billing practices, extend pandemic-related telehealth flexibilities, enhance access to mental healthcare, and ease employers' ACA reporting duties. At the same time, potential legislative threats to ERISA preemption of state laws are emerging. Whether any legislation might become law with 2024 compliance implications for plan sponsors probably will not become clear until the end of this year. Any measure that does pass Congress late in the year would probably delay most effective dates until 2025, though some provisions still could apply in 2024.
- **Regulatory outlook.** Extensive proposed Mental Health Parity and Addiction Equity Act (MHPAEA) regulations and heightened enforcement will remain a major compliance issue in 2024. Federal agencies continue to implement the transparency provisions in the 2021 Consolidated Appropriations Act (2021 CAA, Pub. L. No. 116-260), including the prescription drug data collection (RxDC) reporting — which completed its second round in June — and the surprise billing ban. Plans will also have to continue submitting the annual attestation of compliance — first due by Dec. 31, 2023 — with the 2021 CAA's "gag clause" prohibition. In addition, the required scope of items and services in the consumer-facing cost-sharing tool required under the transparency-in-coverage (TiC) rule will significantly expand in 2024.
- **Litigation outlook.** Litigation will likely continue to limit the Biden administration's efforts to implement and expand healthcare reforms. Legal challenges to existing healthcare reforms target the ACA's preventive services mandate and the 2021 CAA's surprise billing regulations. Ongoing litigation over ERISA preemption of state PBM laws and regulations will have major implications for employers' pharmacy benefit programs.

- **State outlook.** At the state level, employers can expect states to continue implementing paid leave laws and prescription drug pricing reforms, along with health insurance coverage mandates.

Congressional outlook

Numerous bipartisan healthcare proposals have a chance of making their way into an expected major "must pass" year-end bill that ties up a host of legislative loose ends. Examples include measures that would increase the transparency of PBMs' and other providers' business practices, foster greater competition among providers and hospitals (including site-neutral payment reforms), expand access to telehealth and mental healthcare, and ease employers' ACA reporting duties.

The shape of any healthcare legislation included in a larger bill will likely take form first as separate Senate and House measures that may see floor votes this fall. Both packages would incorporate provisions from a spate of bills that have already passed key committees in both chambers, often by wide bipartisan margins. With the exception of legislation to extend the ability to offer excepted-benefit, stand-alone telehealth benefits beyond this year, the effective dates in these bills largely do not apply until after 2024. However, the legislative process is in flux, leaving the chance some requirements could hit next year. Legislation that does not cross the finish line this year will remain on the congressional agenda for 2024.

Outlook for healthcare proposals with bipartisan support

PBM reforms. Reducing drug prices by increasing transparency and reforming how PBMs do business is a top bipartisan priority this year. Reforms in an expected Senate healthcare package will likely draw from provisions in the Pharmacy Benefit Manager Reform Act (S 1339), including:

- Extensive new PBM annual disclosures to plan sponsors about rebates and fees received from drugmakers and other third parties, the amount of prescription drug copayment assistance funded by drug manufacturers, total out-of-pocket spending by plan beneficiaries, formulary placement rationale, a list of covered drugs billed under the health plan, and the total gross and net drug spending by the health plan
- A requirement to pass all rebates, fees, alternative discounts and other remuneration related to utilization through to the health plan
- A broad-based commercial market ban on "spread pricing" (a PBM charging a plan sponsor more than the amount reimbursed to the pharmacy dispensing the drug)

In addition, the measure would direct the Department of Labor (DOL) to conduct a study on whether PBMs should serve as ERISA fiduciaries to plans. Some plan sponsor groups are urging Congress to go further and make PBMs plan fiduciaries without conducting a study. These groups are also pushing back on an attempt by independent pharmacies to add language limiting ERISA preemption of expanding state PBM reforms, which can interfere with multistate employers' ability to design pharmacy benefit programs.

Like S 1339, wide-ranging House legislation — the Lower Costs, More Transparency Act (HR 5378) — could soon see a floor vote. This measure would mandate extensive semiannual PBM reports to plan sponsors 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.

PBM reforms affecting public programs proposed in both chambers would:

- Delink list drug prices and PBM compensation in Medicare
- Increase transparency into PBM business practices related to Part D benefits
- Require a study of how vertical integration in the pharmacy space is affecting Medicare drug costs and spending
- Ban spread pricing in Medicaid

Speeding more generics to market and capping out-of-pocket costs for insulin are also bipartisan priorities in both chambers.

Increased transparency and provider competition. Another major bipartisan theme of bills in both chambers is to lower overall healthcare costs through transparency and competition.

The above-mentioned HR 5378, which combines separate bipartisan bills approved by several House committees, would implement more price and operational transparency in the healthcare industry. Proposals include codifying and strengthening current price transparency rules for hospitals, including enhancing the transparency-in-coverage (TiC) rules and requiring 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 that plan sponsor groups hope lawmakers will eventually extend to the commercial market. Provisions would require that Medicare and Medicare beneficiaries pay the same rates for physician-administered drugs in off-campus hospital outpatient departments and in physician offices. Other provisions would require that each off-campus outpatient department of a Medicare provider obtain and include a unique provider identifier on claims for payment.

The bill also would mandate a slew of new government reports on various topics, including how well current price-transparency requirements are working and whether adding quality-of-care metrics to those requirements would be feasible. Another provision would strengthen the No Surprises Act’s gag clause prohibition by ensuring that employer plan sponsors are not contractually restricted from obtaining cost or quality-of-care data related to their own plans from service providers.

The Senate, meanwhile, is forging its own path on transparency and encouraging more provider competition. A bill passed by the Health, Education, Labor and Pensions Committee (S 2840) would:

- Bar anti-competitive contract provisions that prevent plans from directing employees to higher-value, lower-cost providers
- Require off-campus hospital outpatient departments to provide a unique identifier on all bills, which would help employers determine whether charges are appropriate
- Ban hospital facility fees for telehealth and certain other services

Virtually all these transparency and PBM reforms have strong backing from the plan sponsor community. While drawing fire from PBMs and other providers, the measures have

widespread bipartisan support, as shown in the often-overwhelming approval votes by House and Senate committees. That support suggests that, despite uncertainty about how the two chambers might reach agreement, some proposals could land in any final healthcare package that Congress might pass this year.

Extension of telehealth flexibilities. Bipartisan legislation to make permanent two temporary pandemic-related telehealth provisions have cleared House committees and are expected to see a full House vote this fall. The Senate outlook is clouded, however, by opposition from some Democrats and participant-rights groups.

The Telehealth Benefit Expansion for Workers Act (HR 824) would make permanent the pandemic-related relief that treats 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. The temporary relief, and the permanent extension proposed in HR 824, only extends that treatment to employees ineligible for any other group health plan offered by the same employer (e.g., part-time or seasonal workers). While this temporary policy is tied to the public health emergency (PHE) that ended on May 11, employers now offering this stand-alone telehealth benefit may continue to do so through the end of the plan year that began on or before May 11 (e.g., through Dec. 31, 2023, for calendar-year plans).

Although HR 824 is sponsored by lawmakers from both parties, it passed out of committees over the objections of some Democrats. They expressed concern that continued relief from many ACA and ERISA requirements for stand-alone telehealth could encourage smaller employers to offer telehealth instead of major medical benefits. The practice could create confusion among workers, causing some to think they have more comprehensive coverage.

The bipartisan Telehealth Expansion Act (S 1001, HR 1843) would make permanent the pandemic-related relief that allows high-deductible health plans (HDHPs) qualifying to work with health savings accounts (HSAs) to cover telehealth and other remote care services on a pre- or no-deductible basis. The temporary relief also permits an otherwise HSA-eligible individual to receive pre- or no-deductible telehealth coverage from a stand-alone vendor outside of the HDHP. In both cases, the individual would remain eligible to make or receive HSA contributions. Originally provided in the 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act (Pub. L. No. 116-136) for plan years starting on or before Dec. 31, 2021, this relief was most recently extended by the 2023 CAA (Pub. L. No. 117-328) for plan years beginning after Dec. 31, 2022, and before Jan. 1, 2025. Without a permanent or another temporary extension, the relief will expire on Dec. 31, 2024, for calendar-year plans (and during 2025 for noncalendar-year plans).

Similar legislation has been introduced in the Senate. 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. Those concerns make the prospect of any extension uncertain.

Eased employer ACA reporting duties. Two bipartisan passed by the full House would make some relatively minor but welcome changes to employer reporting requirements under the ACA's employer shared-responsibility (ESR) provisions.

The Paperwork Burden Reduction Act (HR 3797) seeks to codify existing IRS rules allowing the use of the alternative method for furnishing Forms 1095-B and some Forms 1095-C. The bill would also expand those rules to allow the alternative method for furnishing Forms 1095-C to *all* employees (not just nonemployees and employees not considered full-time under the

ACA, as limited under current IRS guidance). The method, implemented by IRS after Congress reduced the ACA's individual mandate penalty to $0, excuses an employer from having to mail paper copies of the forms 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 make other amendments to the ACA's employer reporting rules. Those changes would allow substituting any covered individual's birthdate for the person's taxpayer identification number (TIN) if the reporting entity has been unable to collect that TIN. Current IRS rules allow substituting birthdates for TINs if reporting entities have been unable to collect individuals' TINs through "reasonable efforts," which generally include three attempts. In addition, the bill generally would codify current IRS rules on electronic delivery (which requires individuals' affirmative consent) of Forms 1095-B and C to employees. 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 violations of the ESR rules. Finally, the bill would set a six-year statute of limitations for ESR assessments. IRS's current position is that no statute of limitations applies to ESR assessments.

These noncontroversial ACA reporting changes have a decent chance of becoming part of any House-Senate deal on final healthcare legislation.

Mental health parity and access. Bipartisan legislative efforts on these issues — particularly to strengthen provider networks and extend telehealth flexibilities — are ongoing. However, lawmakers and agencies also will continue to focus on parity enforcement, with DOL's proposed overhaul of MHPAEA regulations set to dominate the policy agenda.

A Senate Finance Committee hearing earlier this year on inaccurate mental health provider directories and network access problems in Medicare and Medicaid suggests employer plans could face the same scrutiny from Democrats. Committee Chair Ron Wyden, D-OR, may reintroduce a new version of "ghost network" legislation from last year. That bill aimed to increase reporting accuracy, strengthen enforcement and create civil monetary penalties for employer plans found out of compliance with parity rules. Like last year's bill, however, a reintroduced measure is unlikely to draw any support from Republicans.

HSA reforms. Bills advanced by the House Ways and Means Committee would expand access to HSAs but are unlikely to be taken up by the Senate. The Bipartisan HSA Improvement Act (HR 5688) would allow using HSA funds to pay for "direct primary care (DPC) service arrangements" and care provided by work site medical clinics, without jeopardizing an individual's HSA eligibility, among other things. Another measure, the HSA Modernization Act (HR 5687), includes proposals to increase contribution limits and broaden the types of services that individuals can use HSAs to reimburse before reaching the deductible.

2024 health and leave benefit planning

The following list highlights 10 top compliance-related priorities for planning 2024 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).** As state and federal regulators continue pushing to rein in PBMs and control Rx costs, expect new PBM legislation to pose challenges for plan

sponsors. Watch for a possible progress report from the Federal Trade Commission (FTC) on its expansive investigation of the PBM industry. Prepare to meet the June 1, 2024, deadline for submitting the third prescription drug data collection (RxDC) reports to the Centers for Medicare & Medicaid Services (CMS). Monitor CMS's Rx price negotiations (and ongoing litigation) under the Inflation Reduction Act of 2022 (Pub. L. No. 117-69) and the downstream impact on group health plan costs. Keep an eye out for potential industry changes that could impact employer plans. Watch for coverage issues concerning new or emerging drugs, and pay attention to new and recent Rx market entrants offering alternative solutions. Keep tabs on any Food & Drug Administration (FDA) news about importing prescription drugs. Track developments from a district court decision related to counting drug manufacturer assistance toward cost sharing and the impact on copay accumulator programs.

2. **Group health plan transparency.** Prepare to offer the self-service cost-comparison tool (with data available for all items and services), as required by the final TiC rule for plan years starting on or after Jan. 1, 2024. 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, since nonenforcement relief is ending. Prepare to post MRFs for prescription drugs, and watch for more agency information on MRFs. Ensure that required gag clause attestations and prescription drug RxDC reports are timely submitted in 2024. 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 explanations of benefits (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 reporting and performance guarantees from vendors related to transparency compliance.

3. **Mental health parity.** Identify plans subject to the MHPAEA and ensure they comply with MHPAEA and current guidance, including the requirement to have a written comparative analysis of nonquantitative treatment limitations (NQTLs). In light of continuing enforcement efforts, verify that the plan's comparative analysis conforms with agency guidance. Update the comparative analysis as necessary so it reflects current plan terms and coverage, as written and in operation. Review proposed MHPAEA rules and recent agency reports. Consider how plan design and operations, as well as the comparative analysis, would be impacted if the rules are finalized as proposed. Consider parity requirements when improving a group health plan's medical or surgical benefits. Watch for new legislation and guidance, and monitor parity and behavioral health coverage litigation.

4. **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. Some of these cases concern service provider fees (including "hidden" fees), cross plan-offsetting and plan failures to obtain data from service providers. Stay on top of recent DOL enforcement priorities. 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. Select and monitor service providers for their qualifications, 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 those costs using the vast amount of newly available 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.

5. **Data privacy and security.** Assess how heightened cybersecurity risks change data security priorities for group health plans. Look for updated Health Insurance Portability and Accountability Act (HIPAA) standards, 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' HIPAA compliance and cybersecurity measures to reduce risk. Use compliance tools from regulating agencies to identify and address security vulnerabilities, and monitor federal enforcement.

6. **Surprise billing.** Verify 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 No Surprises Act (NSA), part of the 2021 CAA. Make sure the plan is providing the required NSA notices online and in explanations of benefits (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.

7. **State-mandated paid leave and other state law trends.** Several states — including Colorado, Delaware, Illinois, Maine, Maryland and Minnesota — have paid family and medical leave (PFML) programs or accrued paid leave laws that take effect in 2024 and 2025. Carefully review these requirements as regulatory guidance comes out. States will continue to focus on paid leave (particularly in the Midwest), PBM limitations, caps on insulin cost sharing and telehealth expansion. Monitor the progress of these laws. ERISA preemption of state PBM laws continues to generate debate, but a pending appellate court decision could provide clarity.

8. **Preventive services.** Confirm nongrandfathered group health plans cover without cost sharing all ACA-required in-network preventive services. Modify 2024 benefits for the latest ACA guidance and any new or updated recommendations from the United States Preventive Services Taskforce (USPSTF), the Health Resources & Services Administration (HRSA), and the Advisory Committee on Immunization Practices (ACIP). Review group health coverage of COVID-19 testing and vaccines, and determine whether coverage will change now that the PHE has expired. Determine the starting age for mandated cost-free coverage of breast cancer screening. Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives, unless an exemption applies. Monitor proposed rules that, if finalized, would eliminate the moral exemption and amend the religious exemption from mandated coverage of women's contraception. Watch ongoing litigation that would allow employer plan sponsors with religious objections to exclude coverage of preexposure prophylaxis (PrEP) HIV medications. Also track the legal challenge to ACA-mandated in-network cost-free coverage of many USPSTF-recommended preventive services. Decide whether to cover over-the-counter (OTC) oral contraceptives (i.e., Opill) under the group health plan. Ensure the group

health plan covers — without cost sharing — instruction in fertility awareness-based methods of family planning. Update plan documents, summary plan descriptions (SPDs), summaries of benefits and coverage (SBCs), and other materials as needed.

9. **Other ongoing ACA concerns.** Review 2024 group health plan coverage and eligibility terms pertaining to ESR strategy, and ESR and minimum essential coverage (MEC) reporting duties. Confirm compliance with ACA benefit mandates, and monitor litigation over the scope of such mandates (see, for example, Preventive services). Make sure that certain benefits, such as hospital and other fixed-indemnity plans, stand-alone telehealth and employee assistance programs, satisfy the requirements for exception from certain ERISA and ACA market reforms. Consider the plan impact (if any) now that the "family glitch" for affordable coverage is fixed. Continue to calculate the Patient-Centered Outcomes Research Institute fee for self-funded health plans, and prepare for medical loss ratio (MLR) rebates. Watch for final rules and monitor litigation involving the scope of ACA Section 1557's nondiscrimination protections.

10. **Health savings account (HSA), health reimbursement arrangement (HRA) and flexible spending arrangement (FSA) developments.** Prepare to discontinue temporary COVID-19 relief (unless further extended or made permanent) that lets HDHPs qualifying to work with HSAs provide pre- or no-deductible coverage of (i) telehealth and other remote care services, and (ii) COVID-19 testing and treatment. Update HSA-qualifying HDHPs and account-based health plans for indexed dollar limits. Identify pre- or no-deductible health benefits, programs, or point solutions that could jeopardize an individual's eligibility for HSA contributions, and confirm strategy. Consider whether pending IRS regulations on individual-coverage health reimbursement arrangements (ICHRAs) or direct primary-care (DPC) arrangements will impact benefit strategies and compliance efforts. Review future IRS guidance on the definition of a tax dependent for any impact on account-based health plans.

Section 1

Prescription drugs

Action

Expect more federal and state pharmacy benefit manager (PBM) reforms, and track state efforts to control Rx costs, primarily by imposing PBM restrictions and insulin cost-sharing caps. Watch for state PBM legislation targeting self-funded ERISA plans, despite a recent pro-ERISA preemption ruling involving an Oklahoma law (*Pharm. Care Mgmt. Ass'n v. Mulready* (No. 22-6074 (10th Cir. Aug. 15, 2023)). Stay alert to Federal Trade Commission (FTC) activity after the agency rescinded prior pro-PBM guidance and expanded its industry probe to include three PBM-affiliated group purchasing organizations (GPOs). Look for updated RxDC reporting instructions and more webinars from the Centers for Medicare & Medicaid Services (CMS). Stay abreast of Medicare Rx price negotiations and ongoing litigation, and analyze the potential impact on employer-sponsored coverage. As new or emerging drugs and biologics enter the market and high-use drugs (like Adderall, Ozempic and Wegovy) encounter shortages, watch for Rx coverage issues. Assess potential cost savings from alternatives offered by new and recent market entrants (like Amazon Prime Rx and Mark Cuban Cost Plus Drug Co.). Monitor possible FTC action on drug importation (mainly from Canada); a few states have authorized Rx importation, pending approval by the Food & Drug Administration (FDA). Track developments from a district court decision related to counting drug manufacturer assistance toward cost sharing and the impact on copay accumulator programs.

Specific steps

Stay on top of the potential need for plan design changes due to federal PBM legislation enacted later this year and effective in 2024 (or later).

- **Monitor federal PBM legislation for the rest of 2023.** Current proposals would impose additional oversight on PBMs; require new government reports on prescription drugs; mandate pass-through of all discounts and rebates to group health plans; ban PBM "spread pricing" (a PBM charging a plan sponsor more than the amount reimbursed the pharmacy for the drug); cap out-of-pocket insulin costs; and extend the broker/consultant disclosure requirements in Section 202 of the No Surprises Act (NSA) to PBMs. See the Congressional outlook section for details.
- **Discuss with PBMs, other vendors and actuaries the ramifications of any enacted legislation.** Depending on when a plan year starts, some new requirements may have a delayed effective date. However, other provisions may take effect sooner.

Follow state Rx and PBM legislation that affects plan design and costs for fully insured and self-funded ERISA plans.

- **Track state bills restricting PBM activities.** Keep an eye on proposals that would restrict common practices like spread pricing, mail-order and specialty pharmacy steerage, and other price-saving programs for fully insured and self-funded plans. Increased PBM transparency and initial licensing are also on many state legislatures'

slates. In particular, Arkansas, Colorado, Florida, North Dakota, South Carolina, South Dakota, Virginia and Washington passed such laws in 2023. North Carolina and Texas had sweeping PBM bills that ultimately failed to pass this year but could return next year.

- **Pay attention to renewed state efforts to narrow the scope of ERISA preemption.** Determine to what extent new state PBM laws affect self-funded ERISA plans. In the recent *Mulready* decision, the 10th Circuit found ERISA preempts several provisions of an Oklahoma law. However, the Supreme Court's ruling in *Rutledge v. Pharmaceutical Care Management Association* (140 S. Ct. 812 (2020)) holding that only state laws regulating rates avoid ERISA preemption is still controlling.
- **Review PBM contracts and processes.** Examine compliance with applicable state PBM laws and regulations, particularly any legislative changes enacted in the past year. Stay abreast of PBMs' potential unwinding of previous program changes triggered by state laws now ruled as preempted by ERISA; such changes may prove difficult to implement.
- **Monitor state efforts to cap insulin costs.** In particular, Montana and Nebraska implemented insulin cost-sharing limits in 2023. Other states — like Minnesota, Montana and New Mexico — this year passed laws addressing other diabetes-management issues. In August, Kentucky became the latest state to sue drug manufacturers and PBMs for an alleged insulin price-fixing scheme. More states may do the same.

Address any aftermath from FTC's PBM investigations. Three key events on the FTC front have occurred in the past 18 months. First, in June 2022, FTC announced an inquiry into the business practices of the six largest PBMs. Later, FTC expanded the probe to include three GPOs. In July 2023, FTC withdrew its prior policy discouraging efforts to increase PBM oversight and transparency.

- **Check with PBMs.** Follow up with PBMs on any impact the FTC investigation could have on plan design and costs. The probe's focus so far is wide-ranging and includes fees and clawbacks, patient steering, pharmacy reimbursements, and specialty drug practices.
- **Track similar state developments.** Stay abreast of any state investigations similar to the FTC inquiry.

Revise RxDC processes as needed. The next RxDC reporting deadline under NSA Section 204 is June 1, 2024.

- **Prepare early to ensure timely filing.** CMS extended reporting deadlines for the first two cycles, given the volume of questions and operational challenges. However, deadline extensions may not continue. Reconfirm which entities will submit data through the Health Insurance Oversight System (HIOS). Monitor each reporting entity's compliance.
- **Stay on top of any updated instructions** or other guidance that may require changes.
- **Review insurer, third-party administrator (TPA), PBM and other vendor agreements.** Ensure that relevant contracts include an obligation to disclose plan-level data and any relevant narrative response, without any restriction on using the disclosed RxDC data for other permitted purposes. Examine whether the agreement identifies the RxDC reporting entity and include adequate protections (for example, indemnification and performance guarantees).

Stay up to date on the progress of Medicare Rx price negotiations (including litigation) with manufacturers and the potential financial impact on group health plans.

- **Keep tabs on CMS's Medicare Rx price negotiations.** The Inflation Reduction Act authorizes CMS to negotiate drug prices, starting in 2026. The law also makes changes to the standard Medicare Part D benefit ($35 monthly insulin cost-sharing cap and $2,000 out-of-pocket maximum (OOPM)) that will take effect in 2025. On Aug. 29, CMS published the first 10 Medicare drugs subject to negotiations. Even before 2026, these price negotiations could have a collateral impact on employer-provided coverage.
- **Watch for developments in litigation related to Medicare Rx price negotiations.** Drug manufacturers (and the US Chamber of Commerce) have strongly objected to the price negotiation provision. As of the publication of this GRIST, lawsuits alleging various violations of the US Constitution are pending in several federal district courts, including Illinois, New Jersey, Ohio, Texas, and Washington, DC.

Pay attention to Rx trends, particularly those involving new and evolving drugs, biosimilars, and specialty drugs like Adderall (for attention-deficit/hyperactivity disorders) and Ozempic and Wegovy (for weight loss). A recent clinical trial concluded that Ozempic and Wegovy can reduce heart disease risks by as much as 20% for overweight but nondiabetic patients. Monitor shortages of key drugs in high demand or experiencing manufacturing challenges. Pay attention to high-cost drugs and biosimilars coming into the market. Work with PBMs to understand and address the cost impact.

Watch for innovations and new market trends as plans continue to search for cost savings. Blue Shield of California recently announced that it will diversify Rx benefit administration, a multibillion-dollar move that could shake up the PBM industry. In hopes of achieving a better integrated, coordinated and holistic model, the large insurer in 2025 will go from using one of the big three PBMs to a group of five entities to provide Rx coverage. Assess whether a similar initiative will achieve better, cost-effective results for your plan. Review your current PBM/Rx delivery model to see if vendors offering alternatives or niche services can reduce costs and/or improve efficiency. A new CVS venture with Sandoz called Cordavis will market a new Humira biosimilar — a significant development involving a major PBM's move into the manufacturing space. Competitors may follow suit, as happened with GPOs a few years ago. However, these ventures will likely attract scrutiny from regulators concerned about market concentration.

Stay alert to any FDA developments related to Rx importation, as well as state legislation authorizing importation. Texas became the latest state to enact a law authorizing drug importation, pending the issuance of FDA standards. FDA continues to work on a pathway for Rx importation. However, supply issues in Canada may further complicate the issue.

Monitor *HIV and Hepatitis Policy Inst. v. Dep't of Health and Human Servs.* (No. 22-2604 (DC Dist. Sept. 29, 2023)) and related regulatory developments. The recent ruling vacated a regulation allowing (but not requiring) fully insured and self-funded group health plans to disregard drug manufacturers' copay assistance (typically coupons) from accumulating to a plan's deductible and OOPM. This now-vacated rule allowed insurers and plans to adopt copay accumulator programs that exclude copay assistance, even if the drug had no available and medically appropriate generic equivalent. The decision called the rule "inadequately supported" and directed the departments of Labor, Treasury, and Health and Human Services to rewrite the regulation. As of now, the circumstances under which plans

and insurers may still use copay accumulators, if at all, are unclear. About 20 states currently ban copay accumulators for fully insured plans. Counting third-party financial assistance toward deductibles creates an issue for high-deductible health plans designed to work with health savings accounts, as the agencies acknowledged in 2021 regulations.

Related resources

Section 2

Group health plan transparency

Action

Prepare 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 for plan years starting on or after Jan. 1, 2024. 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, since nonenforcement relief is ending. Prepare to post MRFs for prescription drugs, and watch for more agency information on these MRFs. Ensure that required gag clause attestations and prescription drug RxDC reports are timely submitted in 2024 (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 explanations of benefits (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 reporting and performance guarantees from vendors related to transparency compliance.

Specific steps

Continue complying with the final TiC rule for group health plans and insurers in 2024. For the 2024 plan year, provide a self-service transparency tool *for all plan-covered items and services* — much more than the 500 items and services required for 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. Continue to comply with MRF requirements, including recordkeeping and monthly updates. Prepare to post a separate MRF for prescription drugs and include data for alternative reimbursement arrangements, since nonenforcement relief is ending. Confirm that facility fees are included in MRFs and the self-service tool. Consider these requirements when onboarding new vendors. Communicate the rollout of the self-service tool to plan participants, and update language in the plan document and summary plan description (SPD) as necessary.

Review TiC rule to ensure compliance. 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 two key actions:

- **Provide a self-service cost-transparency tool for all covered services and items for plan years beginning on or after January 2024, including prescription drugs.** As discussed later, the 2021 Consolidated Appropriations Act (CAA) requires a price comparison tool, but regulators have delayed enforcement to align this requirement with

the self-service cost-transparency tool required under the TiC rule. The internet 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).

- **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.

Watch for guidance on posting MRFs with prescription drug prices. The agencies recently 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 timeline that sufficiently accounts for plans' and issuers' reliance on the temporary enforcement delay. Plans and issuers should work with vendors to ensure they are ready to post MRFs with prescription drug prices when the implementation timeline is announced.

Confirm that MRFs are updated monthly with accurate and complete data for in-network provider negotiated rates and out-of-network allowed payments, and make sure to include facility fees. 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 all data elements for the negotiated rate and the allowed amounts files are included in the applicable MRF.

- **Facility fees.** Recent 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.** Regulators recently rescinded an enforcement safe harbor for plans and issuers that use certain alternative reimbursement arrangements. The safe harbor applied when plans and issuers using an alternative reimbursement arrangement could not derive accurate and specific contracted dollar amounts for covered items and services or disclose specific dollar amounts using the technical implementation schema on GitHub. Regulators clarified that they did not intend to provide a categorical "safe harbor" and, going forward, will exercise enforcement

discretion on a case-by-case basis. Enforcement is unlikely if a plan or issuer can demonstrate that compliance would have been extremely difficult or impossible. 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: https://github.com/CMSgov/price-transparency-guide/tree/master/schemas/in-network-rates#negotiated-price-object.

- **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 with the TiC rule. 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 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 no gag clauses on price or quality information in plan-related contracts and submit gag clause attestations 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 (HIPAA), consistent with federal privacy regulations. The extent to which a health care 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 apply 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), HRAs, or other account-based plans (like health flexible spending arrangements (FSAs)). Retiree-only plans apparently are not subject to the gag clause prohibition and thus won't need to make the attestation.

- **Gag clause attestation.** Regulators provided detailed FAQs for group health plan sponsors and health insurers needing to attest for the first time by Dec. 31, 2023, that their plan agreements comply with the gag clause ban.
  - 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 (HIOS) portal. Regulators have issued instructions, a user manual and an Excel reporting template that plans and insurers can use.
  - The first attestation, due by Dec. 31, 2023, will cover the period beginning December 27, 2020, and ending on the date of the attestation. Subsequent attestations are due by every Dec. 31.

Review and comply with the 2021 CAA's transparency requirements and related enforcement relief. Look for further guidance on several 2021 CAA transparency topics in 2024. 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. Originally required for the 2022 plan year, the 2021 CAA's price comparison tool is "largely duplicative" with TiC requirements, according to regulators. They delayed enforcement until the 2023 plan year to align the 2021 CAA and the TiC tools, but have yet to issue guidance doing this.

- **Air ambulance reporting.** 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.
- **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 will have to 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 price disclosures might help plan participants. Review the final hospital transparency rule to understand what rates hospitals had to begin disclosing in 2021. Work with relevant experts — e.g., data specialists or clinicians — to understand the hospital data. Look for additional hospital disclosures as enforcement against noncompliant hospitals increases; a recent fact sheet outlines CMS efforts to increase compliance. 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. CMS recently proposed requiring hospitals to 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 would 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 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 14 enforcement actions imposing civil monetary penalties against hospitals that failed to comply with the rule.

Related resources

Section 3

Mental health parity

Action

Identify plans subject to the Mental Health Parity and Addiction Equity Act (MHPAEA). Ensure they comply with MHPAEA and current guidance, including the requirement to have a written comparative analysis of nonquantitative treatment limitations (NQTLs). In light of continuing enforcement efforts, verify that the plan's comparative analysis conforms with agency guidance. Update the comparative analysis as necessary to reflect current plan terms and coverage, as written and in operation. Review proposed MHPAEA rules and recent agency reports. Consider how plan design and operations, as well as the comparative analysis, would be impacted if the rules are finalized as proposed. Consider parity requirements when improving a group health plan's medical or surgical benefits. Watch for new legislation and 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 mental health and substance use disorder (MH/SUD) benefits.

- The act does not apply to retiree-only plans, excepted-benefit plans 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).

Prepare to comply with MHPAEA when the opt-out for self-funded state or local government plans expires. Sponsors of self-funded state or local government plans that have relied on the MHPAEA opt-out in the past should identify when their opt-out expires and work to comply with MHPAEA by that date. The 2023 CAA eliminated the opt-out option as of Dec. 29, 2022. Opt-out elections that expire on or after June 27, 2023, cannot be renewed, so all local and state government plans are or soon will be subject to MHPAEA.

Ensure covered plans' MH/SUD benefits are in parity with covered medical/surgical (M/S) benefits.

- Confirm plan terms and operations don't impose financial requirements or treatment limitations (quantitative or nonquantitative) on MH/SUD benefits that are more restrictive than those imposed on the same classification of M/S benefits.

- Confirm the plan has completed a written NQTL comparative analysis, as required by the 2021 CAA (Pub. L. No. 116-260). If none exists, prepare one immediately.

  – 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 and clinical experts) to demonstrate that NQTLs are applied comparably to M/S and MH/SUD benefits. A comparative analysis that doesn't actually compare the NQTLs for MH/SUD benefits with the same NQTLs for M/S benefits isn't compliant.

Review the plan's NQTL comparative analysis against information in the agencies' 2023 report to Congress, and revise as necessary.

- List and analyze all of the plan's NQTLs.
  - Identifying all NQTLs in a group health plan may require assistance from legal counsel or other experts since regulators have not provided an exhaustive list of NQTLs.
- Make sure the comparative analysis is sufficiently detailed. Review the nine data elements required for each NQTL in FAQ 2 of the 2021 MH/SUD and CAA implementation FAQs, part 45.
- Avoid common comparative analysis failures, including:
  - Failure to identify and adequately describe the factors used to determine if an NQTL would apply or how those factors were applied
  - Failure to demonstrate how or whether the factors were comparably applied to MH/SUD benefits and M/S benefits
  - Failure to explain how the plan, in operation, applied each NQTL
  - Failure to demonstrate that the plan, in operation, applied each NQTL comparably to both MH/SUD and M/S benefits
- Review the list of NQTLs commonly causing problems.
- Review the priority enforcement areas listed in the 2023 MHPAEA report to Congress, which added two new enforcement priorities to the four identified in the 2022 report:
  - **New:** Impermissible exclusions of key MH/SUD treatments (such as applied behavioral analysis (ABA) therapy for autism spectrum disorder (ASD), medication-assisted treatment (MAT), nutritional counseling for eating disorders or urine drug testing as part of treating a MH/SUD condition)
  - **New:** Network adequacy standards for MH/SUD providers
  - Prior authorization requirements for in-network and out-of-network inpatient services
  - Concurrent care review for in-network and out-of-network inpatient and outpatient services
  - Standards for provider admission to a network, including reimbursement rates
  - Out-of-network reimbursement rates (including methods for determining usual, customary and reasonable charges)

- Include data demonstrating that each NQTL was comparably applied in operation to MH/SUD and M/S benefits.

Be prepared to produce a comparative analysis on request from either an agency or a plan participant (or a participant's representative).

- Prepare the analysis in advance, not after receiving an agency's or participant's request.
- Prepare to produce a comparative analysis within 10 days of an agency request. Time extensions are limited and only available on a case-by-case basis. The Department of Labor (DOL) describes making "extraordinary efforts" during investigations to let plans cure deficiencies in comparative analyses. However, the agency expects to receive more complete comparative analyses on initial request in coming years.
- Make the comparative analysis available to participants and beneficiaries within 30 days of a request.

Update the plan's comparative analysis as needed to reflect current plan terms, coverage and operations. An update may be required whenever a plan's benefit design, administration or utilization changes.

Review proposed MHPAEA rules and consider how plan design and operations would be impacted if the rules are finalized as proposed. The proposed rules would amend the existing MHPAEA regulations and create new requirements for the NQTL comparative analysis. The proposed rules are sweeping and emphasize improving in-network access to MH/SUD benefits. The agencies have asked for comments on wide-ranging topics, so the final version may differ from the proposal. Nevertheless, since the agencies expect that the new MHPAEA rules, if finalized, would take effect for the 2025 plan year, plan sponsors may want to prepare to comply with the major proposed changes by taking some or all of the steps below:

- Understand the proposed three-part test that each NQTL would have to satisfy:
  - **"No more restrictive" test.** Each NQTL on MH/SUD benefits can be no more restrictive, as written or in operation, than the predominant limit applied to substantially all M/S benefits in the same classification. This test uses numerical testing similar to the testing of financial and quantitative limits.
  - **"Design/application" test.** Any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits in a classification must be comparable to and applied no more stringently than those applied to M/S benefits in the same classification. The factors and evidentiary standards used can't discriminate against MH/SUD benefits relative to M/S benefits.
  - **"Outcomes data" test.** Plans must collect and evaluate relevant data to assess the impact of each NQTL on MH/SUD and M/S benefits, then act to address any material differences. The proposed rules require additional data for network composition NQTLs, including provider reimbursement rates, utilization rates, and network adequacy metrics (including data on time and distance to providers and the number accepting new patients). The proposed rules also would prohibit material differences in network composition NQTL outcomes.

- Explore whether any NQTLs would — or could be modified to — meet either of the two exceptions for NQTLs, although the proposed rules do not detail how a plan would satisfy either exception. A plan applying an NQTL that satisfies either exception would not have to meet the "no more restrictive" test and would not be considered to use discriminatory standards under the "design/application" test. The plan would still need to comply with the design/application test. A plan using the second exception would also need to comply with the "outcomes data" test. To qualify for an exception, the plan must apply an NQTL that either:
  - Impartially applies generally recognized, independent professional medical or clinical standards (consistent with generally accepted standards of care) to M/S and MH/SUD benefits, without deviating from the standards in any way
  - Is reasonably designed to detect or prevent and prove fraud, waste, and abuse by using indicators established through objective and unbiased data, and be narrowly designed to minimize impact on access to MH/SUD benefits
- Review whether the plan offers "meaningful benefits" in each classification for all covered MH/SUD conditions, as the proposed rule would require.
- Review the additional content requirements for NQTL comparative analyses, such as:
  - Certification by one or more named fiduciaries that the comparative analysis complies with content requirements
  - Information supporting the new "no more restrictive" test, such as the predominant NQTL applied to substantially all M/S benefits in each classification, along with information about how the predominant limit was determined
  - Information supporting the new "outcomes data" test, including identification and evaluation of the data collected, a detailed explanation of material differences in outcomes, and the basis for concluding that any material difference is not attributable to differences in the comparability or relative stringency of how the NQTL is applied
  - Actions the plan has taken or intends to take to address potential areas of concern or noncompliance

Evaluate the plan's network of behavioral health providers, and consider how to make improvements, if necessary, in anticipation of revised MHPAEA rules.

- Confirm that the plan's MH/SUD provider network composition and participation standards are in parity with those for M/S provider networks. Evaluate how the plan sets its provider reimbursement rates and monitors the adequacy of provider networks.
- Avoid "phantom networks" by ensuring providers in the network directory are actually in network and taking new patients.
- Plan for future network improvements that may be required if the proposed rules are finalized, and document all efforts to expand the network of behavioral health providers. These efforts could include expanding telehealth, improving reimbursement rates or modifying network requirements.

  - Under the proposed rules, a plan would be noncompliant if outcomes data show material differences in access to in-network MH/SUD benefits compared with M/S benefits in the same classification. Future guidance is expected to specify the type, form, and manner of data on NQTLs related to network composition that plans would have to collect, and the agencies intend to create a nonenforcement safe harbor.

  - A plan would not be faulted for failing the outcomes test due to provider shortages that the plan cannot effectively address, as long as the plan's actions are well documented and demonstrate that the disparities are not due to network composition NQTLs.

Ensure that vendor contracts provide adequate assistance with MHPAEA compliance.

- Make sure that vendor contracts specify the level of support required to produce a written comparative analysis that satisfies existing guidance and any future guidance, including final MHPAEA rules.

- Require vendors to comply with disclosure requests from regulating agencies and plan participants.

- Consider negotiating performance guarantees related to MHPAEA compliance, such as a guarantee to timely respond to agencies' or participants' 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 related 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 disorder, 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 plan provision or ending the plan 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 be noncompliant.

Monitor ongoing and emerging parity and behavioral health coverage litigation against employer-sponsored health plans and TPAs, and watch for additional guidance or legislation.

- Court challenges often involve coverage denials for residential treatment, wilderness therapy or ASD treatments. For example, plan beneficiaries challenged a plan's denial of speech therapy as a treatment for ASD under a habilitative services exclusion, even though the plan covered the same service to restore a member's ability to speak.
- The ultimate impact of the closely watched *Wit v. United Behavioral Health* lawsuit (Nos. 20-17363, 21-15193, 20-17364 and 21-15194 (9th Cir. Aug. 22, 2023)) remains unclear. This class action seeks reprocessing of more than 67,000 denied behavioral health claims under generally accepted standards of care. In its most recent opinion, the 9th US Circuit Court of Appeals overturned the district court's class certification for certain denied benefit claims because the lower court had not accounted for different circumstances among claimants. The 9th Circuit clarified that claim reprocessing is sometimes appropriate if the administrator used the wrong standard, but only with a showing that the plaintiff would be entitled to benefits had the administrator applied the correct standard. The appeals court also reversed the lower court's decision to the extent it required the plans to cover all care consistent with generally accepted standards. However, the 9th Circuit allowed the parties to request a rehearing and remanded the case to the district court to consider the remaining class action claims of fiduciary breach.
- The agencies are expected to issue revised final MHPAEA regulations after reviewing relevant comments, which are due Oct. 17. Regulators also intend to release a revised MHPAEA self-compliance tool, probably after the proposed regulations are finalized.
- Bipartisan efforts to pass legislation strengthening the provider workforce and extending telehealth flexibilities are ongoing. Other legislative proposals, such as adding civil monetary penalties for MHPAEA violations or reducing "ghost networks," appear unlikely to gain bipartisan support. (For more on mental health parity and access legislation, see Congressional outlook).

Related resources

Section 4

ERISA fiduciary issues

Action

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. Some of these cases concern service provider fees (including "hidden" fees), cross plan-offsetting and plan failures to obtain data from service providers. Stay on top of recent US Department of Labor (DOL) enforcement priorities. 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) and RxDC submissions (see Prescription drugs). Select and monitor service providers for their qualifications, 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 those costs using the vast amount of newly available 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.

Specific steps

Reassess with legal counsel relevant fiduciary roles, responsibilities, delegations, processes and insurance coverage. 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."
  - **Operate in accordance with written plan documents.** Comply with plan document terms, to the extent consistent with ERISA.
  - **Duty to diversify plan assets.** Diversify plan assets to minimize the risk of large losses.
    - This fiduciary duty is not usually relevant to most health and welfare plan fiduciaries unless they are responsible for a plan with a trust or a voluntary employee beneficiary association (VEBA). A group health and welfare plan's

funds are often held in the employer's general assets — rather than in a trust or a VEBA — because of a long-standing DOL nonenforcement policy for cafeteria plans and other contributory welfare plans. If the conditions in the nonenforcement relief are satisfied, plan fiduciaries do not have an ERISA obligation to treat those funds as plan assets until participant contributions can reasonably be segregated from the employer's general assets.

- **Determine who is acting as a plan fiduciary and what their responsibilities are.** Every ERISA plan must have one or more ***named fiduciaries*** authorized to control and manage the operation and administration of the plan. A person can also be a ***functional fiduciary*** under ERISA for an employee benefit plan to the extent that person exercises any discretionary authority or control over the 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.
- **Ensure any delegation of fiduciary responsibility is properly documented.** A named fiduciary may delegate fiduciary responsibility to another fiduciary or a third-party vendor if the plan document includes a procedure for doing this. For example, a plan sponsor may delegate fiduciary responsibility for claims and appeals to its third-party administrator (TPA), if the TPA agrees to take on that responsibility. Some plans establish committees to act as the plan's fiduciary. The delegation of fiduciary responsibility does ***not*** end the related responsibility for delegating fiduciary, who may 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 inquiries, lawsuits or investigations as quickly as possible.
- **Ensure that insurance coverage is adequate.** Plans cannot indemnify fiduciaries for liability. 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 equitable relief a court deems appropriate 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. Recent lawsuits raise issues about service provider fees (including "hidden" fees), cross plan-offsetting and lack of access to plan data from service providers. Here are some examples:

- In one recent case (*Kraft Heinz Co. Emp. Benefits Admin. Bd. v. Aetna*), a plan sponsor sued its TPA, alleging breaches of fiduciary duty because the TPA:
  - Approved false, fraudulent, improper and duplicative claims
  - Refused to turn over claims data for employer to audit
  - Reprocessed claims to pay providers less than in-network contracted rates and kept the difference between what the plan pays and what the providers receive

  - Engaged in cross-plan offsetting, which benefits TPA and its insured plans at the expense of self-funded plans
  - Comingled the plan's funds with the funds of TPA and other plans

- Another case, *Popovchak v. UnitedHealth Group Inc.,* involves a group of employer plan members challenging their TPA's use of a "shared savings" program for out-of-network claims. The plaintiffs allege that the TPA breached its fiduciary duty of loyalty by artificially reducing the calculation of some eligible expenses by using repricer data. This meant the TPA could profit from purported "savings" fees, even though it never reached agreements with the particular out-of-network providers that would generate those savings. The shared savings arrangement, according to plaintiffs, injured individual plan members who received lower reimbursement from the plan and were balance-billed by the provider. A similar case about a TPA's shared savings program, *Davis v. United Health Group Inc.*, is also working its way through the courts.
- In *Shields v. United of Omaha Life Insurance Co.*, an appellate court recently held that an insurer acted as a functional fiduciary with the discretion to make eligibility and life insurance coverage determinations. The court found the insurer breached its fiduciary duty to make those determinations within a reasonable period after accepting premiums for the coverage.
- DOL just reached a settlement to end a TPA's practice of cross-plan offsetting. The agency is also suing another TPA, alleging its emergency claims procedures do not comply with the required "prudent layperson" standard. DOL is seeking reimbursement for plan participants for denied claims and an injunction to prevent the TPA from improperly denying claims in the future. Specific violations alleged in this case include:
  - The TPA relied solely on diagnostic codes for emergency claims.
  - The TPA denied nearly all urinary drug screening (UDS) claims without reviewing for medical necessity (as required by plan document).
  - Explanations of benefits (EOBs) for denied emergency and UDS claims were deficient.

Stay on top of other DOL enforcement priorities. Recent DOL enforcement priorities include reviews of parity comparative analyses (see Mental health parity) and cybersecurity audits (see Data privacy and security). 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.)

Timely meet all ERISA reporting and disclosure requirements for group health plans. These requirements include but are not limited to long-standing obligations like filing the Form 5500, as well as newer requirements such as disclosing the comparative analysis of nonquantitative treatment limitations (NQTLs) in response to authorized requests (see Mental health parity) and satisfying the transparency requirements, including submitting gag clause attestations (see Group health plan transparency) and RxDC reports to the Centers for Medicare & Medicaid Services (CMS) (see Prescription drugs).

Comply with ERISA requirements, such as the duty-of-care standard, when selecting and monitoring service providers. Consider their qualifications, quality of services and reasonableness of compensation.

- Work with legal counsel and other experts, as needed, to review service agreements and plan operations. This assessment involves a wide variety of tasks, including some new ones like:
  - Mitigate cybersecurity issues.
  - Collect and review broker and consultant compensation disclosures.
  - Ensure that service providers don't have gag clauses in their contracts and make plan data available on request, as required 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.
- Take these other steps when reviewing service provider agreements:
  - Identify and understand service agreement terms related to fees (direct or indirect), and look carefully at any terms, including shared-savings arrangements, that create potential risks.
  - Review indemnification provisions and liability limits.
  - Verify service agreements have provisions that allow for ongoing monitoring (e.g., audits or market checks) and termination if needed.
  - Review with counsel potential plan asset/prohibited transaction concerns relating to any cross-plan offsetting provisions (see the discussion above about DOL's settlement ending a TPA's practice of cross-plan offsetting). If retaining these provisions, make sure they are clearly disclosed in the plan document and summary plan description (SPD).
  - Confirm the service provider agrees to follow fiduciary standards — including avoidance of self-dealing and conflicts of interest — and comply with claims procedure requirements under ERISA and the Affordable Care Act (ACA).
  - Review legal responsibilities assigned to service providers versus the plan sponsor for compliance with ACA, ERISA, the Mental Health Parity and Addiction Equity Act (MHPAEA), and other laws.
- In selecting service providers:
  - Elicit information to assess the provider's qualifications, quality of services and reasonableness of fees paid from plan assets.
  - Consider soliciting bids from service providers via requests for proposals (RFPs), and decide whether to include desired contract terms in RFPs.
  - Review the scope, adequacy and quality of provider networks.

- In monitoring current service providers:
  - Review direct and indirect fees paid to a provider against prevailing rates for similar services. 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. Ensure providers avoid self-dealing, conflicts of interest or other improper influence.
  - Modify or terminate service agreements as needed.

Prepare to use the newly available transparency data to assess plan operations. Although the transparency data currently is not easy to analyze, Mercer believes the data will become more useful over time. Plan sponsors should begin to explore their own data and evaluate companies or organizations who are in the midst of summarizing and validating this new data. (For more details, see Group health plan transparency.)

Review all other applicable fiduciary matters for compliance. Many other fiduciary issues could arise for group health plan fiduciaries (for example, ERISA's plan asset or bonding requirements), some of which may be very complex. In addition, future guidance (for example, on ERISA's fiduciary rule) may revise existing or impose additional requirements. As a result, consult with legal counsel and other experts as needed to review potential fiduciary issues related to the plan.

Update plan documents, SPDs and other communications to ensure they are current. Consider including protective provisions in plan documents and SPDs. Consult counsel about desirability of clauses addressing matters like anti-assignment, forum selection and contractual statute of limitations. Review terms against case law developments.

Related resources

Section 5

Data privacy and security

Action

Assess how heightened cybersecurity risks change data security priorities for group health plans. Look for updated Health Insurance Portability and Accountability Act (HIPAA) standards, 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' HIPAA compliance and cybersecurity measures to reduce risk. Use compliance tools from regulating agencies to identify and address security vulnerabilities, and monitor federal enforcement.

Specific steps

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 as needed policies and procedures for the prevention, detection, containment, and correction of security incidents.** In a December 2022 report to the Department of Labor (DOL) about cybersecurity issues affecting health plans, the ERISA Advisory Council stated that health plans and insurers have experienced some of the largest US data breaches, including 38 hacking/information technology (IT) incidents involving nearly 1.9 million people in the first 10 months of 2022.
  - Review HIPAA security resources from the Department of Health and Human Services (HHS), including its risk analysis guidance. Security risk assessment and management is one of the primary compliance failures reported in HHS's latest HIPAA breach report to Congress.
  - Conduct risk analyses, and implement technical, physical, and administrative safeguards to protect PHI. HHS's interactive security risk assessment (SRA) tool, designed for small and medium healthcare providers, can be instructive for health plans and business associates. The tool highlights the importance of remediating risks identified in a risk assessment by addressing and documenting action steps, assigning responsibilities, and tracking completion dates.
  - If not already doing so, consider adopting a cybersecurity framework (from the National Institute of Standards and Technology (NIST) or the HITRUST Alliance, for example) to assess risks. 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.
  - Consider forming a security incident response team, and confirm third-party administrators (TPAs) and other business associates have one. Review NIST's security incident response team recommendations. HHS's Office for Civil Rights (OCR), which enforces HIPAA. has endorsed those recommendations.
  - Confirm the terms of a security breach are in each business associate agreement. Responsibility for determining whether a reportable breach has occurred, and if so, creating and distributing breach notices, among other items, should be allocated between the parties in the business associate agreement.

Review authentication standards, then identify and remedy 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." OCR reports that "hacking is now the greatest threat to the privacy and security of [ePHI]" and 74% of HIPAA breaches reported in 2021 involved hacking/IT incidents.

- 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 results and risk-mitigation measures with the plan sponsor. 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 be covered by HIPAA. If any of those functions or activities involve PHI use or disclosure, those partnerships may require a business associate agreement. For more information, see the HHS webpages addressing resources for mobile health apps developers and health Information technology.

- Review terms of existing business associate agreements, especially with long-standing TPAs. Make sure privacy and security features are specified.

- Consider the need for a separate data-sharing agreement. Confirm that the business associate and data-sharing agreements 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 have confirmed that their telehealth offerings and in-network providers ensure data security. Confirm the technology meets HIPAA specifications. OCR enforcement discretion for certain HIPAA noncompliance by telehealth providers during the pandemic expired on Aug. 9, 2023, 90 days after the end of the COVID-19 public health emergency. If Congress makes permanent the temporary relief that allowed stand-alone telehealth to be treated like an excepted benefit (see the telehealth discussion in the introduction), evaluate privacy and security measures for stand-alone telehealth offerings.

- Reconsider current telehealth options. 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 business associate agreement 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 and authentication requirements. Ensure 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 use and disclosure of PHI meet HIPAA standards and best practices.
- Watch for finalization of the proposed rule amending the privacy and security standards for substance use disorder (SUD) patient records (the “Part 2 rule”) to align with HIPAA. While the Part 2 rule does not directly apply to group health plans, the proposal, if finalized, may ease interactions between group health plans and certain SUD providers.

Identify the need for cybersecurity measures beyond HIPAA requirements. ERISA fiduciary duties may require plan sponsors to implement cybersecurity measures for health and welfare plans that go beyond HIPAA security requirements (see ERISA fiduciary issues). For mobile technologies — particularly the ever-increasing behavioral health apps — the Federal Trade Commission (FTC) may require cybersecurity measures beyond HIPAA’s requirements.

- Review DOL cybersecurity guidance from 2021. According to DOL, ERISA requires plan fiduciaries to prudently select service providers with strong cybersecurity practices and monitor providers’ activities. In April 2021, DOL published tips for retirement plans to hire service providers with strong security practices, cybersecurity best practices for ERISA fiduciaries and online security tips for retirement plan beneficiaries. This guidance, while aimed at retirement plans, could apply equally to ERISA health and welfare plans.
  - Review cybersecurity measures for ERISA-covered plans, such as accident, disability, life and on-site clinics that aren’t subject to HIPAA’s privacy and security rules. These plans also face heightened cybersecurity risks and may fall within DOL’s 2021 guidance. Update measures to comply with DOL’s best practices.

  - Consider asking all ERISA health and welfare plan service providers for details on their cybersecurity practices, past breaches and insurance policies.
  - Review contract terms for an ERISA plan vendor's obligation to protect data and obtain third-party audits of its cybersecurity practices. Ensure the plan sponsor has the right to review audit results.
  - Review the plan sponsor's data security provisions in vendor contracts against DOL's cybersecurity best practices. Then review business associate agreement terms detailing requirements in the event of a HIPAA breach. Reconcile any conflicts between data security provisions and HIPAA breach requirements.

- Review the obligation to protect against impermissible disclosures of personal health information under the FTC Act and its health breach notification rule (HBNR). The FTC Act's obligations and the HBNR apply to HIPAA covered entities and business associates, as well as other companies that collect, use, or share health information but aren't HPAA covered entities. Whether digital solutions are made available through a health plan or directly from the plan sponsor but separately from the health plan, the privacy and security risks to personal health information should be assessed.
  - Evaluate digital solutions for health information generated in apps and other health technology settings. This could include websites, mobile health apps, and other technologies used to track diseases, diagnoses, treatments, medications, fitness, fertility, sleep, mental health, and diet, among other health concerns.
    - A 2021 FTC policy statement confirms that the HBNR — originally designed to protect personal health records maintained by entities not covered by HIPAA — applies to any online service that provides health-related tracking, which encompasses nearly any health and wellness app. The policy statement also clarifies that a "breach" for purposes of the HBNR is not limited to cyberattacks but includes any use or disclosure of personal health information without user authorization.
    - A June 2023 proposed update to the HBNR rule suggests FTC has the authority to regulate any health app or similar technology not covered by HIPAA.
  - Review mental health apps for privacy and security measures. The use of digital behavioral health services like mobile mental health apps offering clinical and nonclinical support increased during the pandemic when in-person healthcare visits were avoided or unavailable. Many of these apps have been criticized for their weak privacy and security practices.
  - Ensure employees know how any vendor uses or discloses their data. Consider obtaining employee consent to the information use or disclosure.

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; these programs are intermediaries that process 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. APIs may be in use, for example, with the software used to power the plan's online cost-sharing tool required by the transparency rules (see Group health plan transparency).
- Assess vendors' offerings that use APIs. New apps and tools may require additional entities to access participant data. FTC considers the HBNR to cover 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.

Screen plan websites, tools, vendor solutions, and other health and wellness apps made available to plan participants and/or employees for tracking technologies that may violate HIPAA's privacy rule or the FTC Act. 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, the FTC Act or the FTC's HBNR.

- Review the OCR's 2022 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. Tracking technologies may be in use, for example, when mobile apps help plan members manage their health information or benefits. 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 or apps, and other health-related technologies (e.g., cookies, fingerprinting, web beacons and tracking pixels).
  - Confirm tracking technologies are not resulting 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.
  - Confirm a business associate agreement is in place with tracking any technology vendors the plan is using.
  - Confirm tracking technologies are addressed in the HIPAA security-risk assessment.
- 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 to 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 that operate online.

  - 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, violate the FTC Act and the HBNR.

Give special attention to the privacy and data-sharing practices of plans, TPAs, point solutions, and mobile apps that handle reproductive health data. A White House fact sheet and a 2022 executive order illustrate the importance of protecting sensitive health records, including reproductive healthcare information.

- Review the proposed rule that would strengthen HIPAA's privacy protections for reproductive healthcare information and bolster patient-provider confidentiality.
  - If finalized, the rule would require an attestation that the use or disclosure of requested reproductive healthcare information is not for a prohibited purpose (civil, criminal or administrative investigation).
  - The rule would require an updated HIPAA privacy notice explaining the added protections for reproductive healthcare information.
- Review the OCR guidance explaining that the existing HIPAA privacy rule permits, but does not require, certain PHI disclosures to law enforcement and others, subject to specific conditions.

Watch for revised HIPAA guidance and confirmation of ERISA's fiduciary duty with respect to cybersecurity for health and welfare plans. HHS is expecting to finalize proposed modifications to the HIPAA privacy and security rules, which would require changes to HIPAA policies, notices, and business associate agreements. Multiple stakeholders noted in the 2022 ERISA Advisory Council report have requested that DOL clarify how the 2021 cybersecurity guidance applies to group health plans. The council supported this request and recommended that DOL regularly review and update its cybersecurity guidance to stay current with evolving technology and cybersecurity risks.

- Stay informed about new or revised HIPAA rules that may require updating or changing policies, procedures, security standards, notices, disclosure forms, and business associate agreements. Consider how to implement changes, particularly when using third-party vendors for matters like supplying the notice of privacy practices or maintaining PHI.
- Look for DOL response to stakeholder advocacy for expanding HIPAA rules to protect individually identifiable PHI, even when not created or maintained by covered entities.
- Evaluate how new or revised ERISA fiduciary cybersecurity guidance would affect the plan, its sponsor, and existing or planned vendor initiatives.

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. In addition,

FTC is enforcing the HBNR rule, for the first time since its publication in 2009, when a security breach concerns individually identifiable health information not protected by HIPAA.

- Note that OCR's latest breach report to Congress identified an ongoing need for covered entities to improve compliance with the HIPAA security rule, particularly in risk assessment and management, information system activity review, audit controls, and access controls. In calendar year 2021, hacking/IT incidents accounted for the largest category of breaches reported to OCR, affecting the most individuals.
  - Annual penalties for HIPAA security and privacy violations can total more than $2 million. These civil penalties are separate from any sums HHS can collect from settlements. (For more information on HIPAA penalties, see HHS adjusts 2022 HIPAA, certain ACA and MSP monetary penalties.)
- Keep in mind that OCR enforcement actions in 2023 often involve insufficient security measures and risk assessments. Consider these examples:
  - Failure to perform periodic security testing and regularly review information system activity led, in part, to a $1.3 million settlement with a health plan after member ID information was vulnerable to unauthorized online disclosure for two days.
  - Failure to properly secure a network server containing ePHI led to a $75,000 settlement agreement with a business associate.
  - Failure to implement an authentication process to safeguard and securely transmit ePHI resulted in $1.25 million settlement agreement with a health system.
- EBSA investigations into health and welfare plans have reportedly included cybersecurity questions and document requests.
- Follow FTC enforcement actions against mobile health apps and other technologies that inadequately secure personal health records. FTC can bring enforcement actions against entities for violating online privacy policies or statements or for unfair privacy practices. So far in 2023, vendors and apps — like those providing mental health support, prescription drug benefits, women's reproductive assistance and diagnostic testing — have entered FTC settlement agreements totaling nearly $10 million for alleged improper disclosures to third-party advertising platforms without authorization, among other concerns.
- In a joint letter about the use of online tracking technologies, OCR and FTC announced their continuing commitment to ensuring the privacy of individuals' health information.

Determine the application of state privacy laws to group health plan information and sensitive information developed, maintained, or shared by health technologies offered apart from the group health plan. HIPAA only preempts state law to the extent that complying with both the federal and state laws would be impossible. State laws can be more protective of sensitive information and apply in addition to HIPAA.

Keep up with federal legislation to improve consumer interoperability protections, with heightened awareness of healthcare cybersecurity risks. Senate efforts to address health data privacy risks related to new technologies will likely continue in 2024.

- Earlier this year, a Senate committee's request for information sought input on a number of topics, including HIPAA rules, the collection and sharing of health data and location data, and the challenges of complying with state and international privacy frameworks.
- Legislation introduced earlier this year (SB 631) would ban the use of personally identifiable health data for commercial advertising, create additional data minimization and disclosure restrictions for health data disclosed without consent, and prohibit the sale of location data.

Related resources

Section 6
Surprise billing

Action

Verify 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 No Surprises Act (NSA), part of the 2021 Consolidated Appropriations Act (2021 CAA, Pub. L. No. 116-260). Make sure the plan is providing the required NSA notices online and in explanations of benefits (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.

Specific steps

Determine which plans are subject to the NSA's surprise billing rules. The NSA protects health plan participants from balance bills and limits cost sharing for (i) emergency care (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 rules apply broadly to grandfathered and nongrandfathered group health plans, as well as federal and nonfederal governmental plans, certain church plans, so-called "grandmothered" or transitional plans, and individual policies (including student health insurance).
- The rules don't apply to excepted benefits, retiree-only plans, short-term limited-duration insurance, or health reimbursement arrangements (HRAs) and other account-based plans.

Confirm emergency services are covered and administered as required by the NSA. 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. This includes 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). Services provided in hospital emergency departments and independent free-standing 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 or denying claims because of general plan exclusions or based solely on medical record review or diagnosis codes.

- Make sure out-of-network (OON) emergency service providers aren't subject to administrative requirements or benefit limitations more restrictive than those applied to in-network providers of those services.
- Confirm post-stabilization services are covered as emergency services, unless the patient consents to the OON care and agrees to balance billing after proper notice, among other requirements.
- Confirm coverage of emergency services without prior authorization for in-network and OON providers and facilities.
- 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 amounts for NSA-protected services. The law 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 qualifying payment amount (QPA), which is generally the plan's or issuer's median contracted rate as of Jan. 1, 2019, adjusted for inflation. The July 2021 interim final rules (July 2021 IFRs) provide details for calculating the QPA.

- Review plan administrators' QPA methodology in light of a federal court ruling vacating a number of provisions in the July 2021 IFRs and August 2022 FAQs (*TX Med. Ass'n v. Dep't of Health and Human Servs.*, No. 6:22-cv-00450 (Aug. 24, 2023)) ("TMA III"). An unlawful methodology (i.e., one based on the rules prior to 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 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.

- Determine whether and when to implement a new QPA methodology to comply with TMA III. The departments intend to appeal the decision and will exercise enforcement discretion for any plan or issuer that uses a QPA calculated in accordance with the regulations overturned by TMA III for items and services furnished before May 1, 2024. The agencies will consider extending the May 1 date until Nov. 1, 2024, if necessary (see 2021 CAA implementation FAQs part 62).
- 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-network for purposes of the in-network 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 participating 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-network).
- Confirm that cost-sharing payments made for NSA-protected services count toward any in-network deductible and the ACA's in-network OOPM.

Confirm plan administrators are timely providing initial payments (or denial notices) with the required disclosures to nonparticipating providers. The NSA requires that plans send the initial payment with required disclosures or a denial notice within 30 days of receiving the bill. The Aug. 24, 2023, TMA III ruling vacated the July 2021 IFR's "clean-claim" provision relating to air ambulance bills, which had started the 30-day clock when a plan had received all information necessary to decide the claim. The same clean-claim provisions relating to emergency services and nonemergency services performed by nonparticipating providers at participating facilities were not challenged and thus not vacated by TMA III (see 2021 CAA implementation FAQs part 62).

- Verify that plan administrators are prepared to send the initial payment for air ambulance claims with the required disclosures within 30 days of receiving a provider's bill and within 30 days of receiving a clean claim for all other NSA-protected claims.

- 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 timeframe, 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 and circumstances and plan terms. The initial payment doesn't have to be equivalent to the QPA.
- 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 was determined in compliance with the rules; (iii) a statement about the opportunity for a 30-day negotiation period, followed by IDR to determine the total payment, if necessary; 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 in compliance with pre-TMA III guidance. This enforcement discretion only applies to items and services furnished before May 24, 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 the TPA 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 to the TPA agreement.

- The agencies reported significantly more disputes than expected were initiated in the first year of the IDR system, but only a fraction have resulted in payment determinations, partly due to the complexity of eligibility determinations. The report also indicated that of the payment determinations rendered, the initiating party (typically providers) prevailed in approximately 71% of the disputes.
- 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 inflated IDR awards?
- 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-network providers in an effort to lower in-network reimbursement rates?

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

- Determine the cost impact of IDR administrative fees. At the start of 2023, the IDR administrative fee increased from $50 to $350, partly due to the unexpectedly large number of disputes. However, disputes initiated on or after Aug. 3, 2023, are subject to the lower $50 fee resulting from a court order invalidating the increase (see *TX Med. Ass'n. v. Dep't of Health and Human Servs.*, No. 6:23-cv-00059 (ED TX Aug 3, 2023); "TMA IV" ruling). In response to that court order, the agencies propose new rules that would increase the IDR administrative fee to $150 per party for disputes initiated on or after the date the regulation is finalized or Jan. 1, 2024, whichever is later.
- Determine how IDR entity fees (paid by the losing party) are managed by the TPA. In 2023, IDR entity fees have ranged from $200 to $700 for single claim determinations and from $268 to $938 for batched determinations. Under the proposed rule, the ranges would increase in 2024 to as much as $840 and $1,173 for single and batch determinations, respectively. 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? 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. CMS has repeatedly paused the IDR process to make changes required by federal court decisions. Ongoing litigation challenging IDR rules and procedures could force more delays and changes.

- Multiple court rulings have vacated certain provisions of the IDR regulations pertaining to weighting of the QPA, the QPA calculation methodology, administrative fees and batching requirements.
- Court rulings have repeatedly caused a suspension of the IDR portal, slowing the process and invariably contributing to the backlog that began when the volume of cases far exceeded expectations.
- Watch this CMS webpage for important notices about the IDR portal. New guidance for the IDR operations could create some stabilization if opposing parties are satisfied with changes made in response to the district court rulings.

Watch for potential expansion of surprise billing protections to ground ambulances and urgent care centers. The Advisory Committee on Ground Ambulance and Patient Billing (GAPB) has collected public comment on a number of topics related to the expansion of NSA protections to ground ambulances. A report with recommendations is expected before year-end. NSA protections currently do not extend to urgent care centers unless licensed by a state to provide emergency services. If quantitative data demonstrates balance billing is increasing at urgent care centers, the agencies may reconsider the regulatory approach to care received at those centers.

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-payment administration — all of which are key to reducing the risks of IDR and agency enforcement. Agencies continue to collect stakeholder comments and consumer complaints and to monitor plans' and issuers' NSA compliance.

- 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 7

State-mandated paid leave and other state law trends

Action

Monitor state legislation and regulations affecting employer-provided benefits, including paid leaves, pharmacy benefit manager (PBM) limitations (see Prescription drugs) and telehealth access. Discuss changes and available options with leave administrators, PBMs, insurers, and other third-party vendors, then evaluate and budget for cost increases. Watch whether any states follow the lead of Washington, where mandatory employee contributions for long-term care (LTC) coverage started in mid-2023. Expect to see new health insurance coverage mandates enacted. Track state bans on certain medical care, particularly restrictions related to abortion and gender-affirming care for minors, and evaluate the impact on access to covered benefits and the need for medical-related travel benefits. Look for more state proposals related to universal healthcare, although a recent state legislative report predicts belt-tightening may curtail legislation requiring significant funding. Stay abreast of ERISA litigation on state laws affecting self-funded plans, which is currently an issue primarily affecting Rx benefits. Keep an eye on emerging state initiatives to ensure pay and benefit equity for temporary workers.

Specific steps

Determine whether current state paid family and medical leave (PFML) programs, accrued paid leave mandates, and other leave laws necessitate revisions to employer-provided leave benefits, and amend those plans and policies as needed. These laws vary by state and require extensive coordination and communication (likely with third-party administrator (TPA) assistance) for multistate employers to ensure compliance.

- **Examine overall leave strategy.** Consider a long-term PFML and accrued paid leave strategy to achieve parity across multiple states and local jurisdictions. State and local leave laws typically vary in contribution amounts, wage replacement benefits, job-protected leave duration, eligibility and paid time-off (PTO) accruals. Most new laws broadly define a covered family member to include, for example, domestic partners and designated persons equivalent to a legal or biological family member, neither of which are included in the federal Family and Medical Leave Act (FMLA) and its regulations.

- **Watch for PFML guidance in states with new programs.** Watch for implementing regulations and other guidance in states where benefits and/or contributions are starting in 2024 or 2025. Colorado benefits become available on Jan. 1, 2024; Maryland contributions start on Oct. 1, 2024. In 2025, contributions begin in Delaware and Maine. Consider subscribing to email updates from state agencies administering these programs.

- **Review PFML guidance in jurisdictions where program requirements have changed.** Even when a PFML program has fully taken effect, states often make changes to address administration gaps, inefficiencies, solvency and other issues. Monitor any

updates to the existing programs in California, Colorado, Connecticut, Delaware, Massachusetts, New Jersey, Oregon, Washington, and Washington, DC, and revise policies to comply.

- **Account for PFML program contribution rate changes.** Adjust systems and payroll deductions to accommodate any changes in PFML contributions for 2024. Rhode Island (July 1) and Maryland (Oct. 1) are among the few states updating contributions on a noncalendar-year schedule.
- **Keep an eye on states considering establishing PFML programs.** Maine and Minnesota joined the list of states with PFML mandates in 2023. Track states deliberating PFML programs in 2024, including Hawaii, Illinois, Louisiana, North Carolina, Vermont and Virginia.
- **Follow the trend of states allowing optional paid family leave insurance policies.** This year, Alabama, Arkansas, Florida, Tennessee, and Texas added paid family leave as an insurable benefit through life and disability insurers. More states — including the above states considering PFML programs — may follow suit. Assess whether an insured policy in these states is financially preferable to an employer-funded family leave benefit. Rates may improve as these markets mature.
- **Monitor state and local accrued paid leave and supplemental pay mandates.** Monitor state and local jurisdictions adopting requirements related to accrued paid sick leave, sick and safe leave, or PTO available to use for any reason. Employers in Illinois and Minnesota will have to coordinate those states' new accrued paid leave laws with local mandates in 2024. Other localities may follow the example of San Francisco, where the 2023 Military Leave Pay Protection Act requires supplemental pay for employees absent from work for military duty.
- **Pay attention to the continuing COVID-19 wind-down of supplemental paid leaves.** With end of the COVID-19 public health emergency (PHE) and national emergency, most (but not all) states and localities have ended mandated leaves for COVID-19 reasons. Make needed adjustments when COVID-19 leave mandates end on Dec. 31, 2023, in Philadelphia, Nevada (vaccines only), New York (vaccines only) and Seattle (gig workers only). As of this writing, paid leave mandates in Oakland, CA, and Chicago/Cook County, IL (vaccines only) continue. Several jurisdictions (like Arizona, Colorado and San Francisco) have broadened the qualifying reasons under existing paid leave laws to include PHE-related reasons.
- **Track bereavement and organ donation leave laws.** Watch for more states to consider unpaid but job-protected bereavement leave requirements that go beyond many employers' traditional programs or policies. Illinois this year expanded the qualifying reasons under its bereavement leave law. Unpaid organ donation leave laws are also a trend to watch. Keep in mind that some PFML laws already cover bereavement and/or organ donation leave.

As states expand telehealth access, consider increasing telehealth benefits, particularly for mental health.

- **Pay attention to states joining interstate compacts.** Use of telehealth for behavioral health services continues to expand, with at least 80% of all states joining the Psychology Interjurisdictional Compact (PSYPACT). The compact facilitates the cross-state practice of telepsychology and temporary in-person, face-to-face psychology. Other compacts for

interstate telehealth services like occupational therapy and professional counseling are also gaining traction. The proposed federal mental health parity regulations emphasize access to mental healthcare and, if finalized, will shine a spotlight on telehealth compacts.

- **Watch for telehealth developments.** States are on dual tracks. On the one hand, many are looking to ease requirements for establishing a provider-patient relationship via telehealth. On the other hand, some are restricting telehealth services, particularly for prescribing medications, as Utah did in a 2023 law, or are specifically banning the use of telehealth for certain care (like medication abortion and certain transgender care for minors).

Ensure processes for group health plan reporting (including LTC coverage in Washington) are in place.

- **Continue individual-mandate reporting.** California, Massachusetts, New Jersey, Rhode Island, and Washington, DC, require individual-mandate reporting, while Vermont simply requires employees to maintain copies of IRS Form 1095 and submit to the state if requested. State reporting deadlines typically (but not always) mirror the ACA deadlines, and submission of Form 1095-C usually satisfies the state reporting obligation. Stay abreast of 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).
- **Adhere 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.** Employee salary-reduction contributions to the WA Cares Fund started as of July 1. Individual employee exemptions are available but require documentation. Employers should communicate the contribution requirement and exemption availability to new hires. Quarterly payments and reports are due to employers' SecureAccess Washington accounts by the last day of the month after each calendar quarter ends. While no state has seriously considered a program similar to WA Cares in 2023, future legislation is possible, given the financial stress on Medicaid programs due to the lack of LTC coverage.

Clarify with insurers how state coverage mandates affect fully insured policies, and consider the healthcare access implications (for fully insured and self-funded plan participants) of state laws restricting or banning certain medical care covered by the group health plan.

- **Consider the effect on premium rates.** Address the premium cost impact (if any) of new or expanded coverage requirements, such mandated coverage of fertility treatments, gender-affirming care or abortion-related services, as well as insulin cost-sharing caps.
- **Bear in mind the extraterritorial application of some insurance laws.** Know your plan's state of issue (situs). Review with your insurer how other states' insurance laws may apply to participants who reside in another state. For example, some states restrict abortion coverage, and other states require abortion coverage and/or gender-affirming

care in fully insured plans. In some cases, these laws apply to residents of the state covered by an insured plan issued from another state.

- **Be aware of access issues related to abortion and gender-affirming services.** Some states have restrictions and/or bans on gender-affirming care for minors and abortion services. As a result, participants in those states may need to travel to another state to access services covered under the plan.

Track PBM developments in the courts and statehouses.

- **Follow ERISA preemption cases.** Pay attention to ERISA-based challenges to state laws (particularly to PBM restrictions) extending to self-funded plans, particularly the *Mulready* case recently decided by the 10th Circuit.
- **Monitor PBM legislation that could affect plan costs.** Assess the potential cost impact of legislation regulating PBMs, especially in light of states' increased willingness to include self-funded plans within the scope of these laws. Specific cost concerns include "any willing pharmacy" provisions, spread-pricing bans and prohibitions on pharmacy steering.

Watch for bills requiring equal pay and equivalent benefits for temporary employees.

- **Track legislation related to temporary employees.** Illinois (2023 Pub. Act 103-0437, HB 2862) and New Jersey (2023 Ch. 10, AB 1474) this year enacted laws requiring staffing agencies to compensate temporary workers in parity with employees at the client company. More states may follow with similar legislation.

Related resources

Section 8

Preventive services

Action

Confirm nongrandfathered group health plans cover without cost sharing all in-network preventive services required by the Affordable Care Act (ACA). Modify 2024 benefits for the latest ACA guidance and any new or updated recommendations from the United States Preventive Services Taskforce (USPSTF), the Health Resources & Services Administration (HRSA). and the Advisory Committee on Immunization Practices (ACIP). Review group health coverage of COVID-19 testing and vaccines, and determine whether coverage will change now that the public health emergency (PHE) has expired. Determine the starting age for mandated cost-free coverage of breast cancer screening. Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives, unless an exemption applies. Monitor proposed rules that, if finalized, would eliminate the moral exemption and amend the religious exemption with respect to mandated coverage of women's contraception. Watch ongoing litigation that would allow employer plan sponsors with religious objections to exclude coverage of preexposure prophylaxis (PrEP) HIV medications. Also track the legal challenge to ACA-mandated in-network cost-free coverage of many USPSTF-recommended preventive services. Decide whether to cover over-the-counter (OTC) oral contraceptives (i.e., Opill) under the group health plan. Ensure the group health plan covers without cost sharing instruction in fertility awareness-based methods of family planning. 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 USPSTF, HRSA, and ACIP recommendations.

- 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. As discussed later, 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 to be 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 Centers for Disease Control and Prevention (CDC) director. A HRSA recommendation or guideline is deemed to be issued once accepted by the HRSA administrator or, if applicable, adopted by the secretary of the Department of Health and Human Services (HHS).

Review group health plan coverage of COVID-19 testing and vaccines, and determine whether coverage will change now that the PHE has expired.

- **COVID-19 tests and related services.** Since the PHE ended on May 11, 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 (e.g., through 2023 plan year-end). Such plans need to decide whether to continue that coverage in 2024, apply cost sharing or other medical-management standards, or eliminate all coverage of COVID-19 tests and related services. Regulators encourage continued coverage of COVID-19 tests and related services without cost sharing or medical-management requirements.
  - With respect to health savings account (HSA)-qualifying high-deductible health plans (HDHPs), the pandemic relief allowing pre- or no-deductible coverage of COVID-19 testing without affecting HSA eligibility applies only with respect 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. (See Health savings account (HSA), health reimbursement arrangement (HRA) and flexible spending arrangement (FSA) developments.)
  - Review whether plan communications about this coverage clearly indicate whether or when this no-cost coverage ends or is modified.
- **COVID-19 vaccines and administration costs.** Nongrandfathered group health plans still must "immediately" cover any new *in-network* COVID-19 vaccine and associated administration costs without any cost sharing (including no deductibles, copayments and coinsurance). This requirement applies once the vaccine is authorized under an emergency use authorization (EUA) or approved under a biologics license application (BLA). The coverage requirement is part of the ACA preventive services mandate and did not expire with the end of the PHE. Coverage of a particular vaccine must be consistent with the scope of the EUA or BLA (including amendments) and allow for (i) administering an additional dose to certain individuals, (ii) administering booster doses, or (iii) expanding the age range of individuals for whom the vaccine is authorized or approved.
  - During the PHE, this cost-sharing ban also applied to *out-of-network* COVID-19 vaccines. Now that that the PHE has expired, group health plans should determine whether to continue covering out-of-network COVID-19 vaccines and associated administration costs or limit the coverage to in-network providers.
  - To promote workplace health and safety, grandfathered group health plans should consider covering these vaccines free of cost sharing as well.

Add or update no-cost in-network coverage of preventive services with a USPSTF "A" or "B" recommendation issued in 2022 and effective Jan. 1, 2024, for calendar-year plans. For noncalendar-year plans, the effective date could be the plan year beginning in 2023 or 2024, depending on when the plan year starts relative to the date USPSTF issued the recommendation.

- **Statin preventive medication for adults ages 40–75 who have at least one cardiovascular disease (CVD) risk factor and an estimated 10% or greater risk of**

experiencing a cardiovascular event in the next 10 years. Prescribe a statin for the primary prevention of CVD for adults ages 40–75 who have one or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension or smoking) and an estimated 10% or greater risk of experiencing a cardiovascular event over the next 10 years. USPSTF finds insufficient evidence on the benefits and harms of initiating a statin for primary prevention of CVD events and mortality in adults ages 76 or older. This recommendation is consistent with one from 2016. (Issued August 2022)

- **Syphilis infection screening for nonpregnant adolescents and adults.** Screen for syphilis infection in sexually active adolescents and adults who have an increased infection risk. This recommendation reaffirms one from 2016. (Issued September 2022)
- **Depression screening for adolescents ages 12–18.** Screen for major depressive disorder (MDD) in adolescents ages 12–18 years. This recommendation replaces but is consistent with one from 2016. (Issued October 2022)
- **Anxiety screening for children and adolescents ages 8–18 [NEW].** Screen children and adolescents ages 8–18 for anxiety. This is a new recommendation. (Issued October 2022)

Prepare to 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 issues the recommendation.

- **Latent tuberculosis infection (LTBI) screening for adults ages 18 years or older.** Screen for LTBI in asymptomatic adults ages 18 years 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 years or older.** Screen for major depressive disorder (MDD) 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 µg) 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 to adults and adolescents weighing more than 77 pounds at increased risk of HIV acquisition. 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. (Issued September 2023).

- **Any additional preventive services recommended during 2023.** If additional preventive service recommendations come out in 2023 (after the date of this article), ensure noncalendar-year plans comply by the applicable 2024 or 2025 effective date and calendar-year plans comply by Jan. 1, 2025.

Determine the starting age for mandated coverage of breast cancer screening without cost sharing.

- **Until Jan. 1, 2025**, the 2023 CAA 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.
- **On/after Jan. 1, 2025**, the starting age for biennial screening mammography is unclear. The January 2016 USPSTF recommendation requiring coverage of biennial screening mammography without cost sharing for women ages 50 to 74 presumably will go back into effect on Jan. 1, 2025. That could change if a draft recommendation is finalized during 2023 (as discussed below), or legislation further extends reliance on the September 2002 recommendation.
  - Under 2016 (and 2009) USPSTF recommendations with a "C" rating, the decision to screen average-risk women in their 40s must be individualized, balancing the benefits and harms. Therefore, plans may but are not required to cover this screening without cost sharing before age 50.
  - However, USPSTF announced a draft recommendation in May 2023 that would require continued cost-free coverage of biennial screening mammography for women beginning at age 40. This recommendation, if finalized, would take effect for plan years starting on or after the one-year anniversary of the final recommendation's issuance.
- HRSA-supported 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."

Check ACIP's list of vaccines to determine whether the plan must add new vaccines to cover free of cost sharing.

Ensure continued coverage without cost sharing of ACA-mandated women's contraceptives approved by the US Food & Drug Administration (FDA), unless an exemption applies. Monitor proposed rules that, if finalized, would eliminate the moral exemption and amend the religious exemption with respect to mandated coverage of women's contraception. Also track ongoing litigation that could change these exemptions.

- Continue to cover all FDA-approved women's contraceptives without cost sharing. Review with counsel before declining or revoking this coverage due to moral or religious objections, as the status of those exemptions are under review (see discussion below).
- HHS, Labor, and Treasury guidance (ACA implementation FAQs parts 51 and 54) and a joint letter to group health plan sponsors and insurers cite complaints and public reports about potential violations of the contraceptive coverage mandate. The FAQs 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-supported Women's Preventive Services Guidelines. Part 54 of the ACA implementation FAQs clarify how the contraceptive coverage requirements apply to fertility awareness-based methods and emergency contraceptives. Part 54 also confirms the federal requirement preempts any conflicting state law.

- If asserting a religious or moral objection to mandated women's contraceptive coverage, review with counsel. Decide 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.
- **Proposed rules**, if finalized, would leave in place the existing religious exemption but rescind the moral exemption for entities and individuals, as well as the optional accommodation for contraception. The proposed rules 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 from 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.

Decide whether to cover OTC oral contraceptives (i.e., Opill) under the group health plan.

- **Opill.** The FDA recently approved Opill, the first daily oral contraceptive for sale in the US without a prescription. Opill is a progestin-only oral contraceptive — one of the HRSA-recommended contraception methods for women. However, under existing ACA guidance, Opill, unless prescribed, will not qualify as an ACA-mandated preventive service.
  - HHS, Labor, and Treasury recently issued a request for information to gather public input on the potential benefits, costs, challenges, and burdens associated with requiring nongrandfathered group health plan to cover certain OTC drugs without cost sharing and without a prescription. These OTC preventive items and services include certain types of tobacco-cessation pharmacotherapy, folic acid supplements during pregnancy, breastfeeding supplies, and certain contraceptives, such as Opill.
  - Even though ACA currently doesn't mandate coverage of Opill without a prescription, group health plans should still decide whether to cover Opill without a prescription

and whether to impose cost sharing. KFF reports some states already require insured plans to cover some OTC birth control without a prescription.

- The 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act permits — but does not require — HRAs and health FSAs to reimburse costs for OTC drugs without a prescription. HSAs likewise may reimburse OTC drugs without a prescription, such as Opill, on a tax-free basis. While not entirely clear, the broad scope of IRS Notice 2013-57 arguably allows HSA-qualifying HDHPs to provide pre- or no-deductible coverage for Opill, without jeopardizing an individual's eligibility to make or receive HSA contributions.

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

- A federal district court in Texas held that USPSTF does not have constitutional authority to make coverage recommendations about preventive services. In addition, the court held the requirement that group health plans and insurers cover PrEP HIV medication without cost sharing violates a private employer's rights under the Religious Freedom Restoration Act (RFRA). In particular, the court ruled:
  - Requiring plans to cover USPSTF A and B items and services recommended on/after March 23, 2010, is unconstitutional, and the mandatory coverage of these items and services without cost sharing cannot be enforced.
  - Mandatory cost-free coverage of ACIP- and HRSA-recommended preventive services recommendations (which include women's contraception) is constitutional and can be enforced.
  - Mandatory coverage of PrEP HIV medications without cost sharing cannot be enforced on some plaintiffs if this requirement violates their RFRA rights.
- However, the 5th US Circuit Court of Appeals has stayed the district court's decision and final judgment. For now, nongrandfathered plans (except plaintiffs in the case) must continue to cover all USPSTF-recommended items and services. The case is currently on appeal before the 5th Circuit and will likely end up before the Supreme Court. The outcome of this case and the resulting group health plan implications are uncertain.
  - This 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 items and services USPSTF recommended after March 23, 2010.
  - Regardless of the outcome of this litigation, IRS Notice 2023-37 and FAQs part 59, Q&A-7, make clear that items and services recommended with a USPSTF 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 cost-free group health coverage for instruction in fertility awareness-based methods.

- Pursuant to a stipulation, final order and settlement of claims, HRSA agreed to restore its 2021 contraception recommendation to include "instruction in fertility awareness-based methods, including the lactation amenorrhea method" for women seeking alternatives to FDA-approved contraceptives. HRSA had deleted the sentence in December 2021; however, litigation challenging that sentence's removal proved successful (*Tice- Harouff v. Johnson*, No. 6:22-cv-00201 (ED TX Dec. 5, 2022)).
- Group health plans and issuers should review whether they cover without cost sharing instruction in fertility awareness-based methods for women who want an alternative to FDA-approved contraceptives.

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

Related resources

Section 9

Other ongoing ACA concerns

Action

Review 2024 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. Confirm compliance with the Affordable Care Act's (ACA's) benefit mandates, and monitor litigation related to the scope of such mandates (see, for example, Preventive services). Make sure that certain benefits, such as hospital and other fixed-indemnity plans, stand-alone telehealth and employee assistance programs (EAPs), satisfy the requirements to be excepted from the certain ERISA and ACA market reforms. Consider the plan impact (if any) now that the "family glitch" for affordable coverage is fixed. Continue to calculate the Patient-Centered Outcomes Research Institute (PCORI) fee for self-funded health plans, and prepare for medical loss ratio (MLR) rebates. Watch for final rules and monitor litigation involving the scope of ACA Section 1557's nondiscrimination protections.

Specific steps

Review planned 2024 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 2024 affordability percentage and the employer affordability safe harbors. For 2024, the ESR required contribution percentage will drop significantly to 8.39%, down from 9.12% in 2023.
  - **2024 calendar-year plans.** The maximum monthly 2024 employee contribution for the lowest-cost, self-only option for employers using the federal poverty line (FPL) affordability safe harbor will decrease to $101.94, from $103.28 in 2023. This marks the second decrease in three years (after a 2022 decline from 2021) to the FPL safe-harbor dollar amount for calendar-year plans. As a result, employers that use the exact safe harbor dollar amount to set employee contributions will need to reduce the currently required employee contribution for the lowest-cost, self-only option for the 2024 plan year. The same is possible for noncalendar-year plans beginning in 2024, depending on the 2024 FPL amounts issued in late January 2024.
  - **Noncalendar-year plans beginning in 2024.** Noncalendar-year plans may use the FPL in effect within six months before the first day of the plan year. If the 2024 FPL is issued in January, noncalendar-year plans starting in February to July 2024 may use either the 2023 FPL of $14,580 — resulting in a FPL affordability safe harbor of $101.94 per month — or the 2024 FPL. (If the 2024 FPL is issued in February, noncalendar-year plans starting in March to August 2024 would have that same choice.) These noncalendar-year plans would likely benefit from waiting to use the 2024 FPL since it will probably exceed the 2023 FPL and yield a higher FPL safe harbor contribution limit [(8.39% x 2024 FPL) ÷ 12]. However, depending on when the 2024 plan year starts and the 2024 FPL is issued, waiting for the 2024 FPL may not be practicable. Note: Noncalendar-year plans beginning in 2023 continue to use

$110.81 (9.12% x $14,580 FPL in 2023) ÷ 12) as the FPL safe harbor amount until their new 2024 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 of such plans include ones that cover only preventive services or other "skinny" benefits and do not pass the minimum-value 60% test or that don't provide substantial coverage of inpatient hospital services and physician services, even if otherwise satisfying the minimum value 60% test.) These employers also should review all plan communications with counsel to ensure that employees and their dependents understand the coverage (and its limits).
  - A proposed rule, if finalized, would effectively prohibit employers from offering a fixed-indemnity program and a preventive-services-only MEC plan to the same group of employees. The proposed rule does not directly regulate or prohibit preventive-services-only plans, but a footnote states that regulators discourage such limited coverage.
  - Public exchange coverage may be a more affordable option for some employees, since the Inflation Reduction Act (Pub. L. No. 117-169) extended the American Rescue Plan Act's temporary increase in subsidies through 2025.
- **Assessments.** IRS guidance sets the 2024 ESR assessments as follows:
  - $2,970 (up from $2,880 in 2023) 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
  - $4,460 (up from $4,320 in 2023) 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

Review plan design for compliance with ACA benefit mandates.

- **ACA benefit mandates.** Continue to comply with ACA benefit mandates, such as the ban on lifetime and annual dollar limits for essential health benefits (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., $9,450 for self-only and $18,900 for other than self-only coverage in 2024).
  - Ensure compliance with recent agency guidance requiring plans to align their treatment of a particular item or service as in-network or out-of-network for purposes of the ACA OOPM and the surprise billing ban. For example, if an item or service is treated as provided by a *participating* provider for the surprise billing ban (and thus not protected by the No Surprises Act), the item or service must be treated as *in-network* for the OOPM (see Surprise billing).
  - Determine whether litigation related to various ACA benefit mandates necessitates any plan design or administrative changes. See Preventive services for a discussion of the lawsuit challenging the ACA preventive services mandate.

- **Grandfathered plans.** Grandfathered plans do not have to meet a number of ACA benefit mandates (such as the annual in-network OOPM and the required first-dollar coverage of preventive services). Employers that want to continue sponsoring grandfathered plans should ensure compliance with the requirements for preserving grandfathered status. Agency FAQs confirm that reversing required COVID-19 testing coverage enhancements — or other benefit enhancements related to COVID-19 diagnosis or treatment or expanded telehealth and other remote care services — after the COVID-19 emergencies ended in 2023 (April 10 for the national emergency (NE) and May 11 for the public health emergency (PHE)) does not jeopardize a plan's grandfathered status. Plans continuing such enhancements beyond the emergency periods should also be able to reverse course later without losing grandfathered status — if the reversal doesn't affect the benefits and cost sharing in place in 2010.

Confirm that any group hospital indemnity or other fixed-indemnity program satisfies all requirements to be "excepted" from certain ERISA and ACA market reforms under *existing* regulations. Regulators have stated that they intend to "closely examine" whether group fixed-indemnity excepted-benefit coverage is actually paying per service or item rather than on a per day (or other period) basis.

- Group hospital indemnity or other fixed-indemnity insurance is considered an "excepted benefit" exempt from certain ERISA and ACA market reforms — such as the ACA's prohibition on annual or lifetime dollar limits on EHBs and the preventive services mandate — as long as the policy meets all of these 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

Consider what (if any) modifications to group hospital indemnity or other fixed-indemnity programs would be required if proposed amendments to the excepted-benefit requirements are finalized.

- **New standards for "fixed" benefits.** The proposed rules include new standards describing how group hospital or other fixed-indemnity excepted-benefit coverage can provide benefits in a "fixed" amount (i.e., per period). The dollar amount would remain fixed, regardless of the services or items received, actual or estimated amount of expenses incurred, severity of the illness or injury, or other characteristics particular to a covered participant's or beneficiary's course of treatment. The dollar amount also would not vary on any other basis (such as a per-item or per-service basis).
- **Informal coordination with another group health plan prohibited.** Group fixed-indemnity excepted-benefit coverage can't coordinate with an exclusion under a group health plan sponsored by the same plan sponsor. The departments propose to broadly interpret prohibited "coordination" to include informal coordination with an employer's group health plan. In particular, if the proposed rules are finalized, employers could no

longer offer a preventive services-only MEC plan and a group hospital fixed-indemnity plan to the same group of employees.

- **Effective date.** The proposed rules, if finalized, would apply to new fixed-indemnity insurance sold or issued on or after the effective date of the final rules with respect to plan years beginning on or after that date. Group hospital indemnity or other fixed-indemnity coverage sold or issued before the final rules' effective date would have until the plan year beginning on or after Jan. 1, 2027, to comply, but those plans would have to display a new notice starting with the plan year after the rules are finalized.

Wind down stand-alone telehealth and other remote care programs offered to benefit-ineligible employees. Such programs are unlikely to satisfy either certain ERISA and ACA market reforms or excepted-benefit standards.

- Agency FAQs allowing stand-alone telehealth and other remote care programs for employees ineligible for any other group health plan offered by the same employer expire at the end of the plan year beginning on or before May 11, 2023 (i.e., Dec. 31, 2023, for calendar-year plans). Monitor federal legislation that would make this relief permanent.

Confirm that EAPs meet excepted-benefit requirements now that temporary COVID-19 relief has expired.

- Agency FAQs that temporarily permitted an excepted-benefit EAP to cover COVID-19 *diagnostic and testing* services expired with the end of the COVID-19 emergencies. If an EAP provides *testing* after May 11, 2023, evaluate whether doing so provides "significant benefits in the nature of medical care" that jeopardize the EAP's excepted-benefit status. However, agency FAQs allow coverage of COVID-19 *vaccines* after May 11, 2023, without jeopardizing an EAP's excepted-benefit status.

Assess the impact of the 2022 end of the "family glitch" on the plan or employees and their dependents. Consider sending additional employee communications or allowing impacted employees to change their benefit elections midyear to enroll in the public exchange.

- Final rules allow family members of employees offered affordable self-only but unaffordable family coverage to receive premium tax credits (PTCs) for public exchange coverage beginning in 2023. Under the prior rule, the lowest-cost employee-only coverage determined the affordability of employer-provided coverage for employees' family members. Importantly, the family glitch fix did not affect ESR assessments or compliance strategies, which continue to be based solely on the lowest-cost, self-only coverage providing minimum value.
- IRS guidance permits, but does not require, employers to amend cafeteria plans to allow a participant to revoke an election for other than self-only group health coverage (e.g., family coverage) so one or more family members can enroll in public exchange coverage and receive PTCs.
  - Plan amendments must be made by the end of the first plan year in which the plan permits this new type of midyear election change. Employers that permitted midyear changes during the 2023 plan year must amend the plan at any time on or before the last day of the plan year that begins in 2024 (Dec. 31, 2024, for calendar-year plans). Employers that adopt this change beginning in the 2024 plan year must amend their

plan on or before the last day of the plan year that begins in 2025 (Dec. 31, 2025, for calendar-year plans).

- Requirements for the new type of midyear election change include the following:
  - One or more family members must be eligible for a special enrollment period (SEP) (e.g., due to a change in residence) or the open enrollment period for public exchange coverage.
  - The revocation of group health coverage must correspond to intended enrollment for public exchange coverage that takes effect by the day after the last day of group health coverage.
  - The employee either must revoke his or her own coverage or elect self-only coverage (or family coverage for individuals other than the family member(s) seeking public exchange coverage).
  - The cafeteria plan may rely on the employee's reasonable representation that the employee and/or related individuals have timely enrolled or intend to enroll in a qualified health plan through a public exchange.

Consider aligning the Health Insurance Portability and Accountability Act's (HIPAA's) SEP with the temporary Medicaid "unwinding" SEP offered by the ACA federal public marketplace.

- Millions of Americans are expected to lose Medicaid or Children's Health Insurance Program (CHIP) coverage during the 12- to 14-month period that began April 1, 2023 (referred to as Medicaid unwinding), as states resume eligibility determinations paused during the COVID-19 pandemic. The Centers for Medicare & Medicaid Services (CMS) announced a temporary unwinding SEP, allowing individuals losing Medicaid or CHIP to enroll anytime between March 31, 2023, and July 31, 2024. Regulators have encouraged, but don't require, employer group health plans do the same. Employers that want to expand their special enrollment window (either through July 31, 2024, or for some lesser period of time) should analyze the potential impact on the plan. Employers deciding to implement an extended SEP should obtain permission from their insurer (if insured) or stop-loss carrier (if self-funded), confirm with counsel that the expansion complies with applicable laws and regulations, amend plan documents as needed, and communicate this change to participants and beneficiaries.
- Regulators suggest additional steps that employers may take to help employees and dependents impacted by Medicaid unwinding, including educating employees. The Department of Labor (DOL) has posted a sample notice that employers may use.

Ensure the adequacy of ESR recordkeeping and reporting.

- Prepare to furnish individual statements and file 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 on health coverage and/or offers of coverage to ACA full-time employees (Forms 1095-B and 1095-C) This means that reporting for 2023 will be due March 1, 2024. 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 codify *and expand* employers' ability to furnish Forms 1095-B *and 1095-C* by 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. IRS reiterated that transitional relief would end after 2020 for filings that, despite good-faith efforts to comply, have "missing and inaccurate taxpayer identification numbers and dates of birth, as well as other information required on the return or statement."

  - 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 new IRS regulations requiring electronic filing for any entity filing 10 or more information returns (determined by aggregating Forms 1094, 1095 and W-2s, among others). This requirement goes into effect for filings due in 2024. The previous threshold for mandatory e-filing Forms 1094 and 1095 was 250 or more forms, applied separately to each type of form filed.

- Keep in mind the costs of ESR noncompliance as IRS continues to issue ESR assessments. The agency 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. In a December 2019 memorandum, the agency 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 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 assessment 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.

- Plan for 2023 reports due in 2024, and continue to collect information for 2024 reports due in 2025. Confirm the appropriate measurement method — lookback or monthly — is used to identify ACA full-time employees.

Confirm use of the most recent summary of benefits and coverage (SBC) templates during open enrollment.

- Use the most recent models — issued for plan years starting on or after Jan. 1, 2021 — to prepare SBCs for open enrollment. Materials include an SBC template, a uniform glossary, a sample completed SBC, instructions and guides for coverage example calculations — each in multiple languages. Changes to the coverage calculator may result in different values for coverage examples, even when the plan design has not changed. Review updated instructional guides for specific instructions on how to account for health reimbursement arrangements (HRAs), health savings accounts (HSAs) and other healthcare accounts, along with health plan features like wellness programs.

Review any proposed changes to 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 2024, and consider other states' updates (if any).
- In December 2022, the Department of Health and Human Services (HHS) asked for information about EHBs, including whether the benefits provided under a "typical employer plan" have changed since 2014.

Continue to calculate and pay the PCORI fee for self-funded group health plans, including certain HRAs 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, 2024, for noncalendar-year or short calendar-year plans ending in 2023 before Oct. 1 is $3.00 (up from $2.79 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, 2024, for 2023 calendar-year plans and noncalendar-year plans ending in 2023 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.

Consider whether ACA Section 1557's prohibition on discrimination on the basis of race, color, national origin, sex, age, or disability applies, and — if it does — whether any benefit changes are required.

- While the 2020 Section 1557 regulations significantly reduced the impact of Section 1557 on insurers and employers, rules proposed in 2022 would, if finalized, apply Section 1557 to *all* operations of any health insurer or third-party administrator (TPA) that receives HHS funds. Each iteration of the Section 1557 rules has been challenged in court. Moreover, a federal district court recently disregarded agency rules and held that Section 1557 applies to all TPA activities of an insurer that receives certain federal financial assistance based on the statute itself (*C.P. v. Blue Cross Blue Shield of IL*, No. 3:20-cv-06145-RJB (WD WA Dec. 19. 2022)).
- If Section 1557 applies, plan sponsors should review their plans for any potentially discriminatory terms, and assess the risk of such terms with counsel. Section 1557 litigation has involved gender-affirming care, fertility coverage and same-sex spouse exclusions. TPAs may be unwilling to administer potentially discriminatory provisions since a federal district court recently found a TPA liable for a self-funded plan's discriminatory plan provision.
- Churches and employers with religious objections to covering same-sex spouses or transgender services should consult with counsel. The proposed Section 1557 rules would, if finalized, permit recipients of HHS financial assistance to raise conscience and religious freedom objections with HHS's Office of Civil Rights. That office must promptly consider the objection and stay enforcement efforts during such consideration. Courts have reached different conclusions about whether a religious organization should be exempt from Section 1557.

Related resources

Section 10

Health savings account (HSA), health reimbursement arrangement (HRA) and health flexible spending arrangement (FSA) developments

Action

Prepare to discontinue temporary COVID-19 relief (unless further extended or made permanent) that lets high-deductible health plans (HDHPs) qualifying to work with HSAs provide pre- or no-deductible coverage of (i) telehealth and other remote care services, and (ii) COVID-19 testing and treatment. Update HSA-qualifying HDHPs and account-based health plans for indexed dollar limits. Identify pre- or no-deductible health benefits, programs, or point solutions that could jeopardize an individual's eligibility for HSA contributions, and confirm strategy. Consider whether pending IRS regulations on individual-coverage health reimbursement arrangements (ICHRAs) or direct primary-care (DPC) arrangements will impact benefit strategies and compliance efforts. Review future IRS guidance on the definition of a tax dependent for any impact on account-based health plans.

Specific steps

Prepare to discontinue temporary COVID-19 relief (unless further extended or made permanent) that lets HSA-qualifying HDHPs provide pre- or no-deductible coverage of (i) telehealth and other remote care services, and (ii) COVID-19 testing and treatment.

- **HSA-qualifying HDHP pre- or no-deductible coverage of telehealth and other remote care services relief expires on Dec. 31, 2024, for calendar-year plans (and during 2025 for noncalendar-year plans), unless the current relief is further extended or made permanent.** Temporary relief lets HSA-qualifying HDHPs cover telehealth and other remote care services on a pre- or no-deductible basis. In addition, an otherwise HSA-eligible individual can receive pre- or no-deductible coverage for telehealth and other remote care services from a stand-alone vendor outside of the HDHP. In both cases, the pre- or no-deductible telehealth coverage doesn't jeopardize an individual's eligibility to make or receive HSA contributions. Originally provided in the 2020 Coronavirus Aid, Relief and Economic Security (CARES) Act for plan years starting on or before Dec. 31, 2021, this relief was most recently extended by the 2023 Consolidated Appropriations Act for plan years beginning after Dec. 31, 2022, and before Jan. 1, 2025. Unless this relief is further extended or made permanent, HDHP/HSA participants should pay for the fair-market value of any predeductible telehealth and remote care services that are not HSA-compatible preventive care, beginning Jan. 1, 2025 (later for noncalendar-year plans). Review whether plan communications about

telehealth coverage clearly indicate the relief's expiration date. Monitor whether future legislation (e.g., S 1001, HR 1843) further extends this relief or makes it permanent.

- **HSA-qualifying HDHP pre- or no-deductible coverage of COVID-19 *testing and treatment* expires on Dec. 31, 2024, for calendar-year plans (and during 2024 for noncalendar-year plans).** IRS Notice 2020-15 let HSA-qualifying HDHPs cover COVID-19 testing and treatment before individuals have met the deductible, without jeopardizing their eligibility to make or receive HSA contributions. However, that relief applied only "until further guidance is issued". IRS Notice 2023-37 modifies that guidance and provides that relief applies only for plan years ending on or before Dec. 31, 2024. Thus, the relief expires Dec. 31, 2024, for calendar-year plans, but ends earlier in 2024 for noncalendar-year plans. Review whether plan communications about this coverage clearly indicate the relief's expiration date. As a reminder, group health plans, including HDHPs, were *required* to cover COVID-19 *testing* without cost sharing during the COVID-19 public health emergency, which ended on May 11, 2023. However, coverage for COVID-19 *treatment* without cost sharing was always *optional*. Finally, nongrandfathered group health plans, including HSA-qualifying HDHPs, must continue covering in-network COVID-19 *vaccinations* without cost sharing (see Preventive services).

Update HSA, HDHP and excepted-benefit HRA limits for 2024 amounts announced in Rev. Proc. 2023-23 and 2024 health flexible spending arrangement (FSA) limits based on Mercer's projections.

- **HSA annual contribution limits.** The 2024 contribution limits will increase to $4,150 (self-only) and $8,300 (family) — up from $3,850 and $7,700 in 2023. The annual catch-up contribution for individuals ages 55 and older remains $1,000 (not indexed).
- **HDHP in-network out-of-pocket maximums (OOPMs).** The 2024 OOPM will increase to $8,050 (self only) and $16,100 (family) — up from $7,500 and $15,000 in 2023. HDHPs may set lower — but not higher — caps on in-network OOP expenses. The Affordable Care Act's (ACA's) higher OOPMs ($9,450 for self and $18,900 for family coverage in 2024) for nongrandfathered group health plans apply only when an HDHP must embed an ACA individual in-network OOP limit into family HDHP coverage.
- **HDHP minimum annual deductible.** The 2024 minimum deductibles will increase to $1,600 (self-only) and $3,200 (family) — up from $1,500 and $3,000 in 2023.
- **Excepted-benefit HRA annual maximum contribution.** The 2024 maximum annual employer contribution to an excepted-benefit HRA will increase to $2,100, up from $1,950 in 2023.
- **Health FSA annual salary-reduction contribution limit (based on Mercer projections).** Mercer projects the 2024 salary reduction contribution limit to increase to $3,200, up from $3,050 in 2023.
- **Health FSA carryover limit (based on Mercer projections).** IRS Notice 2020-33 permits — but does not require — a health FSA to increase the carryover limit into the next plan year to 20% of the current year's salary-reduction contribution limit. So, for health FSA plan years starting in 2023, the maximum carryover to the 2024 plan year is $610 (20% of the 2023 salary-reduction contribution limit of $3,050). For health FSA plan years starting in 2024, Mercer projects the maximum carryover to the 2025 plan year to be $640 (20% of the projected 2024 salary-reduction contribution limit of $3,200). IRS announces these benefit limits for the coming year in October or November.

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

- Look broadly at telehealth services (unless temporary relief is extended for plan years beginning in 2025 and after), on-site medical clinics, wellness programs, expert medical-opinion services, executive supplemental health benefits, international and travel health plans, coupons for prescription drugs or manufacturer cost-sharing assistance, or specialized care or disease-management programs. Examples of such programs include diabetes control, genetic tests, sleep apnea treatment, maternity support, fertility and infertility services, and behavioral health support. Long-standing IRS guidance permits HSA-qualifying HDHPs to cover pre- or no-deductible preventive care and health benefits that do "not provide significant benefits in the nature of medical care or treatment," such as certain on-site clinics, disease-management programs, wellness programs, or employee assistance programs (EAPs).
- Regardless of the outcome of the *Braidwood* case challenging ACA's preventive services mandate (see the discussion in Preventive services), IRS Notice 2023-37 and ACA/CARES Act FAQs part 59, Q&A-7, make clear that items and services recommended with an "A" or a "B" rating by the United States Preventive Services Task Force (USPSTF) on or after March 23, 2010, are treated as preventive care for HSA/HDHP purposes, regardless of whether these items must be covered free of cost sharing under the ACA.

Decide whether over-the-counter (OTC) oral contraceptives (e.g., Opill) will be a reimbursable expense under an HRA or a health FSA.

- **Opill.** The US Food & Drug Administration (FDA) recently approved Opill, the first daily oral contraceptive to be sold OTC in the US without a prescription. The CARES Act permits — but does not require — HRAs and health FSAs to reimburse costs for OTC drugs without a prescription. HSAs likewise may reimburse OTC drugs without a prescription on a tax-free basis. This would include Opill, once available in the US. While not entirely clear, the broad scope of IRS Notice 2013-57 arguably allows HSA-qualifying HDHPs to provide pre- or no-deductible coverage for Opill without jeopardizing an individual's eligibility to make or receive HSA contributions. Opill is a progestin-only oral contraceptive — one of the contraception methods for women recommended by the Health Resources & Services Administration (HRSA). However, Opill, unless prescribed, will not qualify as an ACA-mandated preventive service.

Consider whether pending proposed IRS regulations on ICHRAs or DPC arrangements and future anticipated regulations on tax dependents will influence benefit strategy and compliance efforts.

- **ICHRAs.** IRS anticipates issuing by the end of 2023 final regulations detailing how ICHRAs interact with ACA's employer shared-responsibility (ESR) requirements and the nondiscrimination rules for self-funded group plans under Section 105(h) of the tax code. For now, employers may rely on the 2019 proposed regulations. Employers offering or considering ICHRAs should monitor whether IRS issues new final rules on how an employer offering ICHRAs can avoid ESR assessments.
- **DPC arrangements.** A DPC arrangement is a contract between an individual and one or more primary care physicians who agree to provide medical care for a fixed annual or periodic fee without billing a third party. Proposed 2020 IRS regulations would allow

HRAs to reimburse all types of DPC arrangement fees, but health FSA and HSA reimbursements are likely limited to DPC arrangement charges for medical care (but not membership fees, which might be viewed as akin to insurance premiums). The latest semiannual regulatory agenda indicates IRS may finalize these rules by the end of 2023. Employers whose benefit strategy includes DPC arrangements should monitor whether IRS pursues a different course under the Biden administration. Finally, as long as a DPC arrangement is considered a health plan or medical insurance, an individual covered by the DPC arrangement cannot make or receive HSA contributions. Monitor legislation (HR 3029, HR 5688 and S 1158) that would allow HSA-eligible individuals covered by DPC arrangements to make or receive HSA contributions.

- **Tax dependents.** The latest semiannual regulatory agenda called for finalizing by June 2023 IRS rules (proposed in 2017) clarifying the definition of tax dependent under Section 152. Review these rules once issued for any impact on HRA, HSA or health FSA reimbursements.

Related resources

Appendix A
Related resources

1. Prescription drugs

Non-Mercer resources

- Prescription drug data collection (RxDC) website (CMS)
- RxDC FAQs (CMS, Dec. 23, 2022)
- Press release, Blue Shield of California unveils first-of-its-kind model to transform prescription drug care; save up to $500 million on medications annually (Aug. 17, 2023)
- Press release, FTC votes to issue statement withdrawing prior PBM advocacy (FTC, July 20, 2023)
- Press release, CMS releases revised guidance for historic Medicare drug price negotiation program (June 30, 2023)
- Press release, FTC further expands inquiry into prescription drug middlemen industry practices (FTC, June 8, 2023)
- RxDC file templates (CMS, March 16, 2023)
- RxDC reporting instructions (CMS, March 3, 2023)
- Press release, FTC launches inquiry into prescription drug middlemen industry (FTC, June 7, 2022)
- Interim final rules, Prescription drug and healthcare spending (Federal Register, Nov. 23, 2021)
- NSA Section 202 in the 2021 CAA (Congress, Dec. 27, 2020)
- NSA Section 204 in the 2021 CAA (Congress, Dec. 27, 2020)
- *Rutledge v. Pharmaceutical Care Management Association*, 140 S. Ct. 812 (2020)

Mercer Law & Policy resources

- Drug reporting rules present challenges for many (Nov. 30, 2022)

Other Mercer resources

- MercerRx
- Insurer teams with Amazon, Mark Cuban, CVS and more on new Rx model (Aug. 24, 2023)
- Consultant talking points: Florida's Prescription Drug Reform Act, Senate Bill 1550 (Aug. 11, 2023) (internal use only)

- Congress leaves for August as clock ticks down on health policy bills (Aug. 3, 2023)
- Are Humira biosimilars about to make a financial impact? (July 20, 2023)
- State legislatures continue to focus on Rx (June 29, 2023)
- Are drug shortages leading to a distracted workforce? (May 11, 2023)
- States target prescription drug costs, the impact of common legislative provisions (slide deck) (May 4, 2023) (internal use only)
- New RxDC reporting instructions: Good/bad news ahead of June 1 deadline (April 13, 2023)
- #Ozempic: TikTok fad or weight management disruptor? (March 16, 2023)
- Amazon offers Prime members a deal on generic prescription drugs (Jan. 26, 2023)
- Agencies issue prescription drug reporting relief for 2020 and 2021 (Dec. 27, 2022)

2. Group health plan transparency

Non-Mercer resources

- Hospital price transparency (CMS)
- Technical implementation guide for the triagency price transparency rule (GitHub, updated daily)
- Gag clause prohibition compliance attestation (CMS, Sept. 6, 2023)
- CMS technical clarification Q&As (CMS, Sept. 6, 2023)
- ACA and CAA 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 CAA implementation FAQs part 60 (DOL, IRS and HHS, July 7, 2023)
- Hospital price transparency FAQs (CMS, June 27, 2023)
- Press release, Hospital price transparency enforcement updates (CMS, April 26, 2023)
- ACA and CAA implementation FAQs part 57 (DOL, IRS and HHS, Feb. 23, 2023)
- 8 steps to a machine-readable file of all items & services (CMS, Nov. 8, 2022)
- 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 CAA implementation FAQs part 49 (DOL, HHS and Treasury, Aug. 20, 2021)
- Pub. L. No. 116-260, the 2021 CAA (Congress, Dec. 27, 2020)
- Final rule, Transparency in coverage (Federal Register, Nov. 12, 2020)
- Final rule, Transparency requirements for hospitals (Federal Register, Nov. 27, 2019)

Mercer Law & Policy resources

- Mercer suggests array of healthcare policy improvements to Congress (March 11, 2022)
- Health plans face new liabilities for inaccurate provider directories (Jan. 4, 2022)
- Healthcare cost transparency and MLR changes finalized (Dec. 2, 2020)
- Mercer comments on proposed transparency-in-coverage rules (Jan. 31, 2020)

Other Mercer resources

- Healthcare quality: Be careful what you measure for (Aug. 30, 2023)
- What happened to all that medical price data? (June 22, 2023)
- Plans and issuers will need to submit ‘gag clause’ attestations by Dec. 31, 2023 (March 8, 2023)
- CMS issues late-breaking guidance on posting machine-readable files (June 22, 2022)
- Regulators clarify implementation timeline of transparency provisions (Aug. 25, 2021)
- Healthcare transparency rules (March 4, 2021)
- Transparency rules: 5 considerations for employers (Nov. 12, 2020)

3. Mental health parity

Non-Mercer resources

- 29 CFR § 2590.712, Parity in mental health and substance use disorder benefits (Code of Federal Regulations)
- 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)

- Extension of comment period for MHPAEA proposed rule (Federal Register, Sept. 28, 2023)
- *Wit v. United Behavioral Health*, Nos. 20-17363, 21-15193, 20-17364 and 21-15194 (9th Cir. Aug. 22, 2023), replacing an earlier version dated Jan. 26, 2023, which replaced an unpublished opinion dated March 22, 2022)
- Proposed rule, Requirements related to the Mental Health Parity and Addiction Equity Act (Federal Register, Aug. 3, 2023)
- News release announcing proposed MHPAEA rules (DOL, HHS and IRS, July 25, 2023)
- Fact sheet: Biden-Harris administration takes action to make it easier to access in-network mental healthcare (White House, July 25, 2023)
- 2023 MHPAEA report to Congress (DOL, HHS and Treasury, July 25, 2023)
- Technical release 2023-01P (DOL, July 25, 2023)
- Appendix: MHPAEA guidance compendium (DOL, July 21, 2023
- Fact sheet: FY 2022 MHPAEA enforcement (DOL, July 21, 2023)
- CMS insurance bulletin, Sunset of MHPAEA opt-out provision for self-funded, nonfederal governmental group health plans (June 7, 2023)
- Pub. L. No. 117-328, the 2023 CAA (Congress, Dec. 29, 2022)
- 2022 MHPAEA report to Congress (DOL, HHS and Treasury, Jan. 25, 2022)
- MH/SUD parity implementation and CAA, 2021 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

- 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)

Other Mercer resources

- 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. 7, 2021)

- House Democrats reveal health, paid leave policies in budget package (Sept. 9, 2021)
- The DOL increases mental health parity enforcement (Sept. 3, 2021)
- New law aims to improve mental health parity compliance; DOL tool will help (Jan. 7, 2021)

4. ERISA fiduciary issues

Non-Mercer resources

- 29 USC 1104, Fiduciary duties (US Code)
- 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)
- *Kraft Heinz Co. Emp. Benefits Admin. Bd. v. Aetna* (complaint filed June 30, 2023)
- *Su v. UMR Inc.*, No. 3:23-cv-513 (WD WI, complaint filed July 31, 2023); *Su v. MO Bankers Ass'n Inc.*, No. 2:23-cv-4121 (WD MO, complaint filed June 13, 2023)
- *Davis v. United Health Grp. Inc.*, No. 2:2021-cv-01220 (WD WA April 14, 2023)
- *Shields v. United of Omaha Life Ins. Co.,* 50 F.4th 236 (2022)
- Multiple employer welfare arrangements under the Employee Retirement Income Security Act (ERISA): A guide to federal and state regulation (EBSA, April 2022)
- Understanding your fiduciary responsibilities under a group health plan (EBSA, Feb. 20, 2020)
- Reporting and disclosure guide for employee benefit plans (EBSA, September 2017)
- *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)

5. Data privacy and security

Non-Mercer resources

- Cybersecurity & Infrastructure Security Agency (CISA)
- Privacy, security and HIPAA (HealthIT.gov)
- Annual civil monetary penalties inflation adjustment (HHS, Oct. 6, 2023)

- Collecting, using, or sharing consumer health information? Look to HIPAA, the FTC Act, and the health breach notification rule (FTC, Sept. 14, 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)
- June 2023 OCR Cybersecurity Newsletter (HHS, June 29, 2023)
- Proposed rule, Health breach notification (Federal Register, June 9, 2023)
- Proposed rule, HIPAA privacy rule to support reproductive healthcare privacy (Federal Register, April 17, 2023)
- HIPAA and telehealth (HHS, April 13, 2023)
- Notice, Expiration of certain notifications of enforcement discretion issued in response to the COVID-19 nationwide public health emergency (Federal Register, April 13, 2023)
- Annual Report to Congress on Breaches of Unsecured Protected Health Information for Calendar Year 2021 (OCR, Feb. 17, 2023)
- Annual Report to Congress on HIPAA Privacy, Security and Breach Notification Rule Compliance for Calendar Year 2021 (OCR, Feb. 17, 2023)
- Use of online tracking technologies by HIPAA covered entities and business associates (OCR, Dec. 1, 2022)
- Mobile health app interactive tool (FTC, Office of the National Coordinator for Health Information Technology (ONC), OCR and the US Food & Drug Administration, December 2022)
- Cybersecurity issues affecting health benefit plans (Advisory Council on Employee Welfare and Pension Benefit Plans, December 2022)
- October 2022 OCR Cybersecurity Newsletter (HHS, Oct. 25, 2022)
- Protecting access to reproductive healthcare services (Executive Order No. 14076, July 8, 2022)
- HIPAA privacy rule and disclosures of information relating to reproductive healthcare (OCR, June 29, 2022)
- Statement of the commission on breaches by health apps and other connected devices (FTC, Sept. 15, 2021)
- Tips for hiring a service provider with strong cybersecurity practices (DOL, April 14, 2021)

- Cybersecurity program best practices (DOL, April 14, 2021)
- Online security tips (DOL, April 1, 2021)
- Proposed modifications to the HIPAA privacy rule to support, and remove barriers to, coordinated care and individual engagement (Federal Register, Jan. 21, 2021)
- 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 the software bear liability for the app's use or disclosure of that information? (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 HIPAA privacy, security, enforcement and breach notification rules (Federal Register, Jan. 25, 2013)
- Computer security incident handling guide (NIST, August 2012)
- Health breach notification rule (Federal Register, Aug. 25, 2009)

Mercer Law & Policy resources

- HHS adjusts 2022 HIPAA, certain ACA and MSP monetary penalties (March 23, 2022)
- 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

- 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. Surprise billing

Non-Mercer resources

- No Surprises Act webpage (EBSA)
- Ending surprise medical bills webpage (CMS)
- 2021 CAA implementation FAQs part 62 (DOL, HHS and Treasury, Oct. 6, 2023)
- IDR partial reopening of dispute initiation guidance (CMS, Oct. 6, 2023)
- Proposed rule, IDR administrative process fee and certified IDR entity fee ranges (DOL, HHS and Treasury, Sept. 26, 2023)
- *TX Med. Ass’n. v. Dep’t of Health and Human Servs.* , No. 6:22-cv-00450 (ED TX Aug. 24, 2023)
- IDR process administrative fee FAQs (DOL, HHS and Treasury, Aug. 11, 2023)
- News release, DOL sues Wisconsin-based third-party claims administrator for denying medical claims for thousands of participants (DOL, Aug. 4, 2023)
- *TX Med’l Ass’n. v. Dep’t of Health and Human Servs.*, No. 6:23-cv-00059 (ED TX Aug. 3, 2023)
- ACA and 2021 CAA implementation FAQs part 60 (DOL, HHS and Treasury, July 7, 2023)
- Federal IDR process — status update (CMS, April 27, 2023)
- Partial report on the IDR process, Oct. 1–Dec. 31, 2022 (DOL, HHS and Treasury, April 26, 2023)
- IRS Notice 2023-4 (Dec. 20, 2022)
- Final rules, Requirements related to surprise billing (Federal Register, Aug. 26, 2022)
- ACA and CAA 2021 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)
- Tit. 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)
- Key transparency & surprise billing deadlines (Dec. 7, 2021) (client-ready slide)
- 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)

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

Non-Mercer resources

- PSYPACT
- San Francisco Military Leave Pay Protection Act (Jan. 20, 2023)

Mercer Law & Policy resources

- Maine law requires paid family and medical leave (Sept. 11, 2023)
- Roundup of selected state health developments, second-quarter 2023 (Aug. 14, 2023)
- Domestic partner benefits remain popular but present challenges (July 11, 2023)
- Minnesota passes paid family and medical leave law (July 10, 2023)
- Maryland revises paid family and medical leave (May 25, 2023)
- Roundup of selected state health developments, first-quarter 2023 (May 19, 2023)
- Illinois requires paid leave for any reason starting in 2024 (April 11, 2023)
- States, cities tackle COVID-19 paid leave (Feb. 15, 2023)
- 2023 state paid family and medical leave contributions and benefits (Feb. 1, 2023)
- States update group health plan sponsor reporting obligations (Dec. 15, 2022)
- Roundup: State accrued paid leave mandates (April 29, 2022)

Other Mercer resources

- Life, absence & disability benefits
- California forecast: Benefit, insurance laws may soon be pouring (Aug. 30, 2023)
- New PFML laws in Maine and Minnesota (July 27, 2023)

- State legislatures continue to focus on Rx (June 29, 2023)
- What we're seeing with state telehealth legislation in 2023 (June 1, 2023)
- Universal coverage debate heating up in several states (April 28, 2023)
- Is ERISA preemption at risk of being preempted? (Feb. 23, 2023)

8. Preventive services

Non-Mercer resources

- Preventive health services (Healthcare.gov)
- A and B recommendations (USPSTF)
- Vaccine recommendations and guidelines (ACIP)
- Women's preventive services guidelines (HRSA)
- 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)
- 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*, No. 4:20-cv-00283 (ND TX March 30, 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)
- *Tice-Harouff v. Johnson,* No. 6:22-cv-00201 (ED TX Dec. 5, 2022)

- *Braidwood Mgmt. Inc. v. Becerra*, No. 4:20-cv-00283 (ND TX Sept. 27, 2022)
- ACA implementation FAQs part 54 (DOL, HHS and Treasury, July 28, 2022)
- State requirements for insurance coverage of contraceptives (KFF, May 1, 2022)
- ACA, FFCRA and CARES Act implementation FAQs part 51 (DOL, HHS and Treasury, Jan. 10, 2022)
- ACA, HIPAA and CARES Act implementation FAQs part 50 (DOL, HHS and Treasury, Oct. 4, 2021)
- Pub. L. No. 116-136, the Coronavirus Aid, Relief and Economic Security (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)
- 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)
- 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

- 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. 15, 2022)
- Contraceptive coverage: Good for women, good for business (July 12, 2018)

9. Other ongoing ACA concerns

Non-Mercer resources

- 29 CFR § 2590.732(c)(4), Regulation on excepted benefits that are noncoordinated (Code of Federal Regulations)
- 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)
- Rev. Proc. 2023-29, 2024 employer shared-responsibility affordability percentage (IRS, Aug. 23, 2023)
- Letter to employers and plan sponsors on Medicaid unwinding (DOL, CMS and Treasury, July 20, 2023)
- Proposed rule, Short-term, limited-duration insurance; independent, noncoordinated excepted-benefit coverage; level-funded plan arrangements; and tax treatment of certain accident and health insurance Proposed regulations (Federal Register, July 12, 2023)
- ACA and 2021 CAA implementation FAQs part 60 (DOL, HHS and Treasury, July 7, 2023)
- Have an employee who's losing Medicaid coverage? (CMS, April 11, 2023)
- FFCRA, CARES and HIPAA implementation FAQs part 58 (DOL, HHS and Treasury, March 29, 2023)
- Medicaid-CHIP SEP options flyer (DOL, March 29, 2023)
- Rev. Proc. 2023-17, 2024 employer shared-responsibility indexed assessments (IRS, March 9, 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)
- Poverty guidelines for 2023 (HHS, Jan. 19, 2023)
- *C.P. v. Blue Cross Blue Shield of IL*, No. 3:20-cv-06145-RJB (WD WA Dec. 19. 2022)
- Final rule, Information reporting of health insurance coverage and other issues under Sections 5000A, 6055, and 6056 (Federal Register, Dec. 15, 2022)
- Premium adjustment percentage, maximum annual limitation on cost sharing, reduced maximum annual limitation on cost sharing and required contribution percentage for the 2024 benefit year (CMS, Dec. 12, 2022)
- Request for information, Essential health benefits (Federal Register, Dec. 2, 2022)
- Notice 2022-59, Insured and self-insured health plans adjusted applicable dollar amount for fee imposed by sections 4375 and 4376 (IRS, Nov. 14, 2022)

- Notice 2022-41, Additional permitted election changes for health coverage under section 125 cafeteria plans (IRS, Nov. 8, 2022)
- Final rule, Affordability of employer coverage for family members of employees (Federal Register, Oct. 13, 2022)
- Pub. L. No. 117-169, the Inflation Reduction Act (Congress, Aug. 16, 2022)
- Proposed rule, Nondiscrimination in health programs and activities (ACA Section 1557) (Federal Register, Aug. 4, 2022)
- Final rule, Patient Protection and Affordable Care Act; HHS notice of benefit and payment parameters for 2023 (Federal Register, May 6, 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

- 2024 affordability percentage for employer health coverage drops (Aug. 23, 2023)
- Agencies propose overhaul of fixed-indemnity plan rules (July 18, 2023)
- 2024 HSA, HDHP and excepted-benefit HRA figures set (May 16, 2023)
- Summary of 2023 benefit-related cost-of-living adjustments (Jan. 25, 2023)
- 2023 federal poverty levels can impact ESR affordability (Jan. 23, 2023)
- 2023 quick benefit facts (Jan. 20, 2023)
- DOL sets 2023 penalties for health and welfare benefit plan violations (Jan. 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)
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Other Mercer resources

- House panels back bills on telehealth coverage, new plan flexibilities (June 8, 2023)
- COVID-19 national emergency may end earlier than previously announced (March 31, 2023)
- Medicaid redeterminations and the projected cost to employer health plans (Feb. 23, 2023)
- How plan sponsors can prepare for end of COVID emergency declarations (Feb. 2, 2023)

10. HSA, HRA and FSA developments

Non-Mercer resources

- Publication 15-B, *Employer's tax guide to fringe benefits* (IRS, annually updated)
- Publication 502, *Medical and dental expenses* (IRS, annually updated)
- Publication 969, *HSAs and other tax-favored health plans* (IRS, annually updated)
- HR 5688, the Bipartisan HSA Improvement Act of 2023 (Congress, Sept. 28, 2023)
- FDA approves first nonprescription daily oral contraceptive (FDA, July 13, 2023)
- Notice 2023-37, Expenses related to COVID-19 and preventive care for purposes of HDHPs (IRS, June 23, 2023)
- Agency rule list for spring 2023: Treasury Department (Office of Information and Regulatory Affairs, June 13, 2023)
- HR 1843, Telehealth Expansion Act of 2023 (Congress, June 13, 2023)
- Rev. Proc. 2023-23, 2024 inflation-adjusted HSA, HDHP and excepted-benefit HRA amounts (IRS, May 16, 2023)
- HR 3029, Primary Care Enhancement Act of 2023 (Congress, April 28, 2023)
- S 1158, Health Savings Act of 2023 (Congress, March 30, 2023)
- FFCRA, CARES Act and HIPAA implementation FAQs, part 58 (DOL, HHS and Treasury, March 29, 2023)
- S 1001, Telehealth Expansion Act of 2023 (Congress, March 28, 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)
- Health savings accounts (Congressional Research Service, Aug. 8, 2022)
- Pub. L. No. 117-103, the Consolidated Appropriations Act, 2022 (Congress, March 15, 2022)

- Health reimbursement arrangements (HRAs): Overview and related history (Congressional Research Service, March 7, 2022)
- A comparison of tax-advantaged accounts for healthcare expenses (Congressional Research Service, May 3, 2021)
- Proposed rule, Certain medical care arrangements (Federal Register, June 10, 2020)
- Pub. L. No. 116-136, the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Congress, March 27, 2020)
- Notice 2020-15, HDHPs and expenses related to COVID-19 (IRS, March 11, 2020)
- Proposed rule, Application of the ESR provisions and certain nondiscrimination rules to HRAs and other account-based group health plans integrated with individual health insurance coverage or Medicare (Federal Register, Sept. 30, 2019)
- Proposed rule, Definition of dependent under the Working Families Tax Relief Act of 2004 (Federal Register, Jan. 19, 2017)

Mercer Law & Policy resources

- 2024 transportation and health FSA limits projected (Aug. 15, 2023)
- 2024 HSA, HDHP and excepted-benefit HRA figures set (May 16, 2023)
- Summary of 2023 benefit-related cost-of-living adjustments (Jan. 25, 2023)
- 2023 quick benefit facts (Jan. 20, 2023)
- Two-year renewal of predeductible HDHP telehealth coverage now law (Jan. 11, 2023)
- CARES Act boosts telehealth, makes other health, paid leave changes (March 27, 2020)
- COVID-19 spurs IRS relief for HDHPs, state insurance guidance (March 18, 2020)
- IRS outlines how individual-coverage HRAs can meet ACA employer mandate (Oct. 29, 2019)

Other Mercer resources

- Employers to decide if OTC birth control will be covered at no cost (July 20, 2023)
- House panels back bills on telehealth coverage, new plan flexibilities (June 8, 2023)
- How to maximize HDHPs and HSAs to save costs, promote health and retain talent (March 17, 2022)
- Direct primary care gains ground as employer strategy (July 9, 2020)

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