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Healthcare law and policy outlook for 2020

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Introduction

A wide array of healthcare and paid leave reforms appear poised to move forward in 2020, with Congress, the Trump administration, state legislatures and the courts shaping these initiatives. Controlling costs, modernizing privacy and digital initiatives, improving competition in the healthcare marketplace, and expanding access to paid family and medical leave are key goals driving many reforms. Healthcare access and affordability also rank as top campaign issues in this presidential election year.

At the federal level, rules on drug importation, coupons and an international reference-based drug pricing model could advance this year. Other transparency rules in the works would make negotiated rates — including for prescriptions drugs — available to group health plans, participants and even the general public for the first time. Despite ongoing party divisions in Congress, bipartisan support could bring changes to rein in drug prices and curb surprise medical bills, among other healthcare issues. While paid leave proposals have bipartisan support, the parties differ significantly on their approaches, making enactment a challenge.

The employer shared-responsibility (ESR) mandate and reporting requirements under the Affordable Care Act (ACA) remain in place, but litigation could strike down the entire law — 10 years after its enactment. Other lawsuits challenge recent ACA regulations, including the final rules governing association health plans (AHPs), short-term limited duration insurance (STLDI), and accommodations for employers with religious or moral objections to contraceptive coverage. In addition, litigation will force the courts to interpret a number of other issues, such as gender discrimination, that could have implications for health plans.

At the state level, employers can expect new individual health coverage mandates, plan assessments and paid leave laws, which will increase the complexity of administering uniform benefit programs across jurisdictions. Rather than wait for federal legislation or regulation, states are also acting to curb drug costs and surprise medical bills.

While the variety of behavioral health and wellness programs in the marketplace has grown, the laws and regulations governing these offerings continue to evolve. Employers will need to track the shifting legal landscape to ensure their wellness plans and behavioral health programs comply.

This GRIST summarizes expected 2020 compliance and policy developments affecting health and leave benefits and suggests action steps for employers.

Regulatory outlook

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Prescription drug reforms

At the federal level, a key Supreme Court case will address whether state laws regulating pharmacy benefit managers (PBMs) can apply to self-insured ERISA plans that offer prescription benefits. Last year's passage of the CREATES Act as part of an appropriations package (PL 116-94) could bolster sales of generic and biologic alternatives to brand-name drugs. In addition, the Trump administration's Safe Importation Action Plan could keep drug-cost reforms on the federal agenda for 2020.

Some setbacks in 2019 to the Trump administration's aggressive drug-pricing regulatory agenda may mute agencies' efforts this year. The administration has decided not to finalize proposed rules to eliminate federal anti-kickback safe harbors that allow drug manufacturers to use rebates in Medicare Part D. Another regulation requiring drug manufacturers to disclose list prices in direct-to-consumer TV advertising is on hold, pending appeal of a court decision blocking the rule (*Merck & Co., Inc. v. HHS*, 385 F.Supp.3d 81 (D.D.C. 2019)).

Regardless of these setbacks, some 2020 agency action is likely on drug importation, coupons and transparency. As discussed later, however, most drug reforms will take place in the states, where cost-control initiatives have surged, partly in response to federal inaction.

ERISA preemption of some state drug reforms

The US Supreme Court this year will consider the interaction between ERISA and a state drug-pricing law (*Rutledge v. Pharm. Care Mgmt. Ass'n, cert. granted*, No. 18-540 (U.S. Jan. 10, 2020)). This appeal challenges an 8th Circuit decision finding ERISA preempts an Arkansas law (2015 Act 900) regulating the rates that PBMs must pay to reimburse pharmacies.

To promote uniform benefit administration nationwide, ERISA prevents state laws from regulating matters that "relate to," "refer to" or "have a connection with" self-insured ERISA plans. The 8th Circuit has twice struck down state PBM laws — the Arkansas law and a similar Iowa statute (*Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017)) — finding the laws interfere with how an ERISA plan is administered.

In an amicus brief supporting Arkansas' appeal, attorneys for the US Department of Labor (DOL) argue the state law regulates only the relationship between PBMs and pharmacies, not between an ERISA plan and its PBM. Should the justices agree with that argument, other states' similar laws might apply to all PBMs administering prescription drug benefits — whether for an insured plan or a self-insured ERISA plan. These state laws vary but generally regulate some aspect of the pricing lists setting the maximum allowable cost (MAC) that a PBM will reimburse a pharmacy for a specific generic drug.

If the Supreme Court instead upholds the 8th Circuit decision, the only avenue for PBM reforms affecting self-insured ERISA plans would involve federal action: Either Congress would have to enact federal standards, or DOL would have to exercise its regulatory authority in this area. States also may craft a narrower approach to PBM regulation.

Drug importation expected to progress

The administration's Safe Importation Action Plan will see further action year, setting up two pathways for importing certain prescription drugs:

- **Pathway 1 pilot project to allow importation from Canada.** Proposed regulations from the Food and Drug Administration (FDA) would authorize a pilot project allowing states, wholesalers or pharmacists to import certain drugs from Canada. Drugs excluded from the project include controlled substances, biological products, infused drugs and intravenously injected drugs, among others. Participants would have to submit a plan to the US Department of Health and Human Services (HHS) for approval. States could propose an arrangement with a wholesaler or pharmacist as part of the application process. The time-limited pilot will require reporting and renewal.

- **Pathway 2 to allow drug manufacturers to import their own drugs into the US.** Under this pathway, manufacturers of FDA-approved drugs could sell a foreign version of those drugs in the US as long as the FDA finds the foreign and US versions are the same. Draft guidance says manufacturers could sell the foreign drug under a different National Drug Code (NDC) than the US version. This would allow manufacturers to introduce the drug at a lower price than their current distribution contracts require for the US version. Unlike the pathway 1 pilot project, this program could allow importation of more medications (like insulin) from more countries (not just Canada).

While these pathways hold some promise, both rely on action by the states or drug manufacturers to move forward.

Drug coupons

HHS has already taken a step in 2020 to clarify last year's guidance on whether drug coupons for brand-name medications without generic equivalents should count toward ACA's out-of-pocket maximum for nongrandfathered plans. The proposed 2021 Notice of Benefit and Payment Parameters says that plans may — but are not required to — count toward the out-of-pocket maximum any form of direct cost-reduction support for specific medications that drug manufacturers offer to enrollees.

In the proposal, HHS says that other interpretations could conflict with IRS guidance (Notice 2004-50) for high-deductible health plans (HDHPs) paired with health savings accounts (HSAs). Under Q&A-9 of that notice, an HDHP must credit only amounts actually paid by an enrollee toward the deductible and "disregard drug discounts and other manufacturer and provider discounts," HHS notes. If this guidance is finalized, it will ease some compliance concerns about so-called copay accumulator programs and other PBM arrangements devised largely to address the rising costs of specialty drugs.

Drug-pricing transparency

Agencies could finalize rules to support President Trump's healthcare transparency executive order (EO 13877), shedding light on the complicated, often-hidden calculations behind drug prices. A 2019 proposed regulation would require group health plans and issuers to disclose the negotiated rate for all items and services, including prescription drug benefits. (For more details on the proposed rule, see the next section.)

In the proposed rule, regulators asked how best to provide meaningful information on consumers' cost-sharing liability for prescription drugs and account for rebates, discounts, and dispensing fees. The key question is how to provide accurate pricing information to consumers — who might pay a different amount for the same medication from one month to the next — without an explanation of benefits breaking down how the plan/PBM arrived at that price.

Action steps

Here are some steps for plan sponsors to take in tracking prescription drug reforms in 2020:

- **ERISA preemption of state reforms.** Track which way the Supreme Court rules in the ERISA preemption case, and monitor ongoing state drug reforms to assess their impact on health plans. Will state laws that add new price transparency and other protections help plan sponsors negotiate lower costs for certain medications? Or will new PBM regulations simply create costs that will be shifted to employers and consumers?

- **Drug importation.** If operating in states that join the federal drug-importation pilot, evaluate how to take advantage of these programs to control benefit costs for certain medications. If any drug manufacturers pursue the second pathway to importation, analyze whether this creates opportunities to access lower-cost medications — and whether those savings are sustainable in the long term.

  – Keep in mind that the FDA will need to issue final rules and provide the appropriate certification to Congress before even the first pathway to importation can begin. This might not happen in time for employers to make plan design changes for 2021. Another uncertainty is what, if any, roadblocks Canada might put up that could impede importation. Take these uncertainties into account if contacted by vendors seeking to help plans import medications from Canada.

- **International drug pricing.** Watch for proposed Trump administration rules on an international referenced-based pricing model for Medicare Part B drugs. While these rules would not directly affect employer plans, the reforms — like the now-withdrawn proposed changes to Medicare Part D's rebate safe harbors — could impact the entire market. Despite pushback from some congressional Republicans, the regulations are still on the latest HHS regulatory agenda.

- **Drug coupons, price transparency.** Look for final regulations on drug coupons and price transparency. If the drug coupon rule is finalized as proposed, benefit materials should clearly explain the plan's decision on whether drug coupons do or do not count toward the deductible. Make sure relevant copay

accumulator programs meet the final rule, other ERISA requirements and IRS Notice 2004-50. Employers with insured plans will also need to take relevant state laws into account.

Related resources

Mercer Law & Policy resources

- Agencies won't enforce ACA rule on drug coupons and out-of-pocket costs (Sept. 3, 2019)
- Executive order targets healthcare price and quality transparency and HSA/FSA changes (July 10, 2019)

Other Mercer resources

- Big change ahead for Medicare — and employers will feel it too (Nov. 8, 2018)
- Mercer comment letter on HHS blueprint to lower drug prices and reduce out-of-pocket costs (July 16, 2018)

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Transparency for group health plans

Proposed transparency in coverage rules should be finalized later this year but probably won't take effect for at least another year. Those rules, along with the final hospital transparency rule, should provide unprecedented insights into the rates that participants and plans pay for medical services and prescription drugs. Providers and PBMs generally have treated negotiated rates as proprietary and been unwilling to provide that information to plan sponsors. The transparency rules could infuse more competition into the healthcare marketplace, allowing plan sponsors to negotiate better rates, while giving participants upfront estimates of medical expenses to compare different providers. As discussed in the next section, a number of other transparency initiatives could have implications for employer health plans as well.

Cost information

Both sets of rules come in response to the executive order on increasing transparency in healthcare costs and quality. The proposed transparency in coverage rules would require nongrandfathered group health plans, including self-funded plans and health insurance issuers, to take two key actions:

- **Provide a self-service transparency tool.** This internet-based self-service tool would disclose personalized out-of-pocket costs for all covered healthcare items and services (with paper copies available on request). Participants could get an estimate of their cost-sharing liability for any in- or out-of-network provider, allowing them to compare costs before receiving medical care. The tool would have to enable searching by billing code, descriptive terms, provider name and other relevant factors (such as geography). The tool would also have to track a participant's accruals toward any cumulative treatment limitations (like day or visit limits).

- **Make machine-readable files publicly available.** Standardized machine-readable files, updated monthly, would contain the plan's negotiated rates for in-network providers and past allowed payments to out-of-network providers. Regulators intend this requirement to facilitate price comparison and consumer-oriented innovation in the healthcare market.

To encourage consumers to shop for better prices, the rule would offer relief from minimum loss ratio (MLR) rebates if insured plans share cost savings with enrollees who choose less-expensive providers.

Penalties for violations

Group health plans failing to meet the new transparency rules could face steep ACA penalties of $100/day per participant. However, many group health plans can't administer the proposed requirements without input from insurers. So a proposed safe harbor would spare an employer with a fully insured group health plan from having to provide the transparency disclosures to participants, as long as a written agreement

requires the insurer to do so. If the insurer fails to provide the required information, the insurer — not the group health plan — will face liability for the violation.

The proposed rules also provide relief for group health plans that act in good faith and with reasonable diligence to provide the disclosures, but make an error or omission or are unable to obtain complete or accurate information from another entity. Group health plans likewise would face no penalties if the website hosting the transparency tools and files is temporarily inaccessible.

Litigation likely

Four hospital groups have already filed a lawsuit challenging the final hospital transparency rule (*Am. Hosp. Ass'n v. Azar*, No. 19-03619 (D.D.C. Dec. 4, 2019)). The transparency rules for group health plans and insurance issuers seem likely to face a similar court challenge from providers seeking to protect what they view as proprietary information.

Action steps

Watch for the final transparency rules for group health plans, and track any litigation challenging these rules and the hospital transparency rule. If and when the final rules take effect, plan sponsors may be able to use the newly disclosed data to negotiate lower rates and provide better cost estimates to participants.

Related resources

Mercer Law & Policy resources

- Mercer comments on proposed transparency in coverage rules (Jan. 31, 2020)
- Executive order targets healthcare price and quality transparency, and HSA/FSA changes (July 10, 2019)
- Top 10 compliance issues for 2020 health and fringe benefit planning (June 25, 2019)
- Mercer shares views with senators on controlling healthcare costs (March 6, 2019)
- 2019 compliance and policy outlook for employer-sponsored health benefits (Feb. 6, 2019)

Other Mercer resources

- The new transparency regulations: Will consumers finally be able to shop for healthcare? (Nov. 21, 2019)
- Executive order on transparency, HSAs: What employers need to know (June 27, 2019)

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Other healthcare regulations

In addition to the regulatory initiatives on prescription drugs and transparency for group health plans, a number of other regulatory items could have a significant effect on group health plans. Many of these initiatives follow up on President Trump's executive order to improve price and quality transparency in healthcare (EO 13877).

IRS actions

Look for IRS rules or guidance on these issues in 2020:

- **Final rules on individual-coverage and excepted-benefit health reimbursement arrangements (HRAs).** Starting in 2020, individual-coverage and excepted-benefit HRAs meeting certain conditions can play a role in an employer's healthcare strategy. IRS may finalize proposed rules on how these new types of HRAs — particularly individual-coverage HRAs — interact with ACA's ESR requirements and the nondiscrimination rules for self-funded group health plans under Section 105(h) of the Internal Revenue Code. Until IRS issues final regulations, employers interested in offering individual-coverage HRAs may rely on the proposed rules.

- **Guidance on carryovers for health flexible spending arrangements (FSAs).** As directed by EO 13877, IRS expects to issue guidance aimed at increasing the amount of health FSA funds that individuals can carry over at the end of the year. Under current rules, health FSAs may allow carryovers up to $500.

- **Proposed rules to treat expenses for direct primary care arrangements and health sharing ministries as medical care.** Consistent with EO 13877, proposed rules would classify expenses for direct primary care arrangements and health sharing ministries as "medical care" under Section 213 of the Internal Revenue Code. As a result, account-based health plans, such as health FSAs, HRAs and HSAs, could pay for or reimburse expenses for these alternative arrangements — and possibly others. Under a direct primary care arrangement, a patient or plan typically contracts directly with a primary care provider to deliver healthcare services for a set monthly fee. (As discussed later, proposed federal legislation (HR 3708) would also allow participants in HSA-qualifying HDHPs who enter direct primary care service arrangements to remain HSA-eligible and use HSAs to reimburse associated fees.) Health sharing ministries allow individuals with common religious beliefs to pool payments to cover member medical expenses.

Other transparency initiatives

Besides the transparency regulations discussed earlier, other activity in this area could have implications for employer group health plans:

- **HHS guidance allowing increased access to de-identified claims data.** Under EO 13877, HHS, in consultation with other agencies, must increase access to de-identified claims data from "taxpayer-funded healthcare programs and group health plans." The aim is to let researchers, innovators and others use this data to develop tools that allow patients to be better informed about their healthcare options. The order appears to require HHS to look to existing datasets to de-identify this information and make it available to researchers. HHS issued a report in December 2019 that outlines its vision for data-sharing and suggests public use of de-identified data may eventually be possible.

- **Agency reports to inform transparency initiatives.** EO 13877 also directs federal agencies to issue a number of reports related to price and quality transparency, including surprise medical billing and quality measures. HHS has launched a Quality Summit to begin examining many of these issues.

- **Final rules on open application-programming interfaces (APIs).** HHS could finalize proposed interoperability rules that would provide guidance for enabling plans, providers and patients to exchange data seamlessly in a uniform format. The proposal calls for all Medicare Advantage, Medicaid managed care and public exchange plans to make data available through an open API. This would allow patients to access their data and provide it to others using third-party software applications. Employers should monitor whether this change carries over to the private sector. The rules shouldn't apply directly to employer-sponsored plans, but HHS is hoping that the private sector will voluntarily maintain APIs using the same uniform format.

Proposed HIPAA privacy rules

The HHS Office for Civil Rights (OCR) issued a request for information in December 2018, asking for input on changing the privacy and security rules under the Health Insurance Portability and Accountability Act (HIPAA). The goal is revise those rules to promote value-based and coordinated healthcare, while preserving the privacy and security of individuals' protected health information (PHI). The request specifically sought comments on several aspects of the HIPAA privacy rule, including how to:

- Promote information-sharing for treatment and care coordination and/or case management by amending the privacy rule to encourage, incentivize or require covered entities to disclose PHI to other covered entities

- Encourage covered entities to share treatment information with parents, loved ones and caregivers of adults facing health emergencies, with a focus on the opioid crisis and serious mental illnesses

- Implement the Health Information Technology for Economic and Clinical Health (HITECH) Act's requirement to include electronic health records when supplying an accounting of PHI disclosures in a

manner that is helpful to individuals, but minimizes regulatory burdens and disincentives to the use of electronic health records

- Eliminate the requirement for providers to make a good-faith effort to obtain written acknowledgement of their privacy practices from their patients.

The OCR had set a goal of issuing these proposed regulations in fall 2019, but that timeline has slipped. In the meantime, employers could use guidance on how the Public Health Service Act's confidentiality rules under 42 CFR Part 2 interact with HIPAA. Part 2 has more stringent confidentiality requirements than HIPAA for information that would identify a patient as having or having had a substance use disorder. However, those rules apply only to records generated from Part 2 providers — generally, federally assisted treatment programs. Violations of the Part 2 rules can have criminal penalties.

Employers should confirm that their self-funded group health plans are receiving only de-identified Part 2 data. Self-funded plan sponsors should also have third-party administrators (TPAs) represent that they will comply with Part 2 as part of their service contract or business associate agreement. Employers should consult with counsel if their self-funded group health plan does — or may in the future — receive Part 2 data.

Proposed electronic disclosure rules

Proposed DOL regulations would give retirement plans a new safe harbor method for electronic delivery of participant notices. Plan administrators could make disclosures required under Title I of ERISA available on a website, after providing initial notice to participants and beneficiaries about how to access the documents. Participants still could request paper copies of specific documents or completely opt out of electronic delivery. The proposal did not include welfare plans, but the regulators welcomed comments on whether it should.

Action steps

Follow each of these regulatory initiatives, and be prepared to implement them when effective.

Related resources

Mercer Law & Policy resources

- DOL proposes new electronic delivery rule for retirement plan notices (Nov. 1, 2019)
- Health savings account reforms pass key House panel (Nov. 1, 2019)
- IRS outlines how individual-coverage HRAs can meet ACA employer mandate (Oct. 29, 2019)
- Executive order targets healthcare price and quality transparency, and HSA/FSA changes (July 10, 2019)
- Final rules ease restrictions on health reimbursement arrangements (June 14, 2019)

Other Mercer resources

- Executive order on transparency, HSAs: What employers need to know (June 27, 2019)
- Administration proposes major expansion of health reimbursement accounts (Oct. 25, 2018)

Legislative outlook

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Federal health and leave legislation

Democratic presidential candidates have split over plans to expand health coverage. Progressives are touting "Medicare for all," but moderates are pushing to strengthen the ACA while adding a Medicare-like public option that would compete with private plans. Many of these proposals are embraced in pending legislation, although the measures won't advance in this Congress.

On the other hand, bipartisan support could bring action on narrower proposals to lower healthcare costs by ending surprise medical bills and controlling drug prices. Lawmakers are trying to craft a healthcare package for final passage in May that would extend several expiring Medicare provisions and might include drug-pricing reforms. The Congressional Budget Office has scored certain drug-pricing and surprise-billing proposals as producing substantial savings to the federal government, which may improve the odds for these reforms. However, other proposals to ease HSA rules or provide paid family and medical leave face an uncertain future, despite some backing from both parties.

Medicare expansion

Although Medicare-for-All does not appear to have much support beyond liberal Democrats, several bills pending in Congress would expand Medicare, create a Medicare-like public option or allow older individuals — for example, people aged 50 or older who are not yet eligible for Medicare — to buy into the program. These bills include the Medicare Buy-In and Health Care Stabilization Act (HR 1346), Medicare-X Choice Act (HR 2000), Choose Medicare Act (HR 2463), and Expanding Health Care Options for Early Retirees Act (HR 4527).

The bills have virtually no chance of passing the current Congress. Even if the next election expands the Democrats' control to the White House and Senate, Medicare expansion would not be easy to enact, given the intra-party disagreements and the healthcare industry's intense opposition to a public option. A Medicare-based public option could enjoy some big competitive advantages — such as lower premiums — over private plans, fueling concerns about potential cost-shifting to and erosion of private coverage.

ACA changes

Republicans in Congress have largely turned away from efforts to repeal and replace the ACA. However, if the courts ultimately invalidate all or significant parts of the ACA (see later discussion of *Texas v. United States*), Republicans have not reached any consensus on what a replacement plan should look like — beyond restoring protections for pre-existing conditions. In contrast, Democrats want to increase ACA subsidies to help lower-income individuals buy health coverage from the public marketplaces; boost funding for open enrollment in those marketplaces; and roll back Trump administration rules allowing ACA-noncompliant coverage, such as STLDI.

The outcome of ACA litigation and the general election will shape this debate about expanding coverage and the future of the law. Like the 2018 midterm elections, this fall's elections will serve as a referendum on President Trump's and congressional Republicans' health policy agenda.

ESR assessment repeal unlikely. Although Congress last year agreed to repeal the Cadillac tax on "high-cost" employer-sponsored health plans, any legislative changes to the ACA's ESR mandate are very unlikely this year. Since Congress zeroed out the law's individual-mandate penalty as part of the 2017 tax overhaul, employer groups have pushed to repeal the ESR mandate, arguing that it's moot with effective repeal of the individual mandate. The idea hasn't won much support in Congress, however, due to concerns about the potential to cause revenue losses and reward noncompliant employers. An earlier Republican bid to provide retroactive relief from ESR assessments failed to gain traction for the same reasons.

ESR reporting relief also unlikely. While ESR assessment relief or repeal has little support, bipartisan proposals in Congress — the Commonsense Reporting Act (HR 4070, S 2366) — would streamline related reporting requirements. The bills propose a voluntary prospective reporting system that would relieve employers from having to file IRS Form 1094-C. In addition, employers in the voluntary reporting system would create Form 1095-C individual statements for a limited number of employees: Only employees for whom the employer has received notice that they or their dependents purchased coverage through an ACA public marketplace would receive Form 1095-C. This legislation continues to languish, however, partly due to fears of harming IRS's ability to administer ACA premium tax credits for eligible individuals. In addition, several states are looking to the federal reporting system to help implement their own individual coverage mandates (see later discussion of state laws).

Surprise medical bills

Large and unexpected balance bills from out-of-network providers are a growing concern for patients and employer plan sponsors trying to explain these charges. Surprise medical bills frequently arise from emergency care or treatment provided at an out-of-network facility or by an out-of-network provider at an in-network facility. In such cases, after the patient's health plan pays benefits under its terms, the out-of-network provider bills the individual for the difference between the plan-paid amount and the billed charges.

Amid one of the fiercest and most expensive lobbying battles in years, leaders of the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee reached a bipartisan agreement on surprise medical bills last December. However, party leaders and other House committees with jurisdiction over the issue didn't back the deal. The agreement would amend existing ACA protections to cover not only out-of-network emergency and ambulance services but also nonemergency services received from out-of-network providers at in-network facilities. The legislation would set a benchmark rate for out-of-network providers based on median in-network rates but allow arbitration if the benchmark rate exceeds $750.

These beefed-up consumer protections would apply broadly to nongrandfathered group health plans — whether insured or self-funded — and to individual policies. A number of states have already enacted similar patient protections, and others are considering legislation (see later discussion of state laws).

The House-Senate deal attempts to strike a compromise between healthcare payers and providers. Employers and health insurers want to settle payment disputes with out-of-network providers by paying a median in-network rate for a given area. These payers staunchly oppose arbitration — the preferred approach of hospitals and doctor groups — as costly and problematic for designing networks attractive to participants and medical providers.

Unlike the House-Senate deal, competing legislation recently passed by the House Ways and Means Committee (HR 5826) would not use a benchmark based on median in-network rates to settle payment disputes. Instead, all surprise medical bills — without a minimal dollar threshold — would be subject to baseball-style arbitration if the payer and provider cannot reach an agreement within 30 days. The arbitrator would have to consider the median contracted rate for the service and could not take into account usual and customary charges or more provider-friendly standards, such as billed charges. The White House has criticized the bill for its strong reliance on arbitration.

Another proposal (HR 5800) recently approved by the House Education and Labor Committee largely mirrors the House-Senate deal, using a median contracted rate, with baseball-style arbitration for contested bills when that rate is more than $750.

House leaders have a difficult job ahead to reconcile these proposals into a single package that could be put to a vote in the chamber, and the Senate has not indicated whether it will take up surprise billing legislation. However, congressional leaders are feeling political urgency to address this issue and are being urged on by President Trump. In addition, Congress needs the projected savings from measures curbing surprise medical bills to help pay for "must pass" legislation in May to renew a group of Medicare and Medicaid programs.

Drug-pricing reforms

As federal agencies and states pursue prescription drug reforms (see discussions of related federal regulatory and state activity), proposals pending in Congress tackle rising drug costs from several angles. While major drug-pricing reforms will remain a key topic for Congress in 2020, passage of game-changing legislation will prove difficult.

Part D reforms

The Democrat-led House has passed a sweeping measure (HR 3) that would allow the Medicare Part D program to negotiate prices for some pharmaceuticals and offer those negotiated prices to private plans. House Democrats would use the savings from lower drug costs to add dental, hearing and vision benefits to Medicare, among other things. But the bill is a nonstarter in the Republican Senate.

Senate Finance Committee leaders have issued their own bipartisan proposal that would lower costs for seniors, while penalizing drugmakers that raise their prices faster than the rate of inflation — a reform also included in HR 3. President Trump has endorsed the package, but Senate Majority Leader Mitch McConnell, R-KY, appears disinclined to bring it to a vote, and most Finance Committee Republicans voted against the bill when the panel approved it last year. Republican lawmakers view the requirement that drugmakers pay

a "rebate" to Medicare if a drug's price rises faster than inflation as a government "price control" that will stifle innovation.

As a result, the Senate bill's prospects for passage remain unclear. Employer groups are concerned that the extensive Medicare savings envisioned in the proposal could lead to substantial cost-shifting to private group health plans.

Meanwhile, House Democrats are insisting that any major deal should authorize the government to directly negotiate drug prices — a long-time priority for progressives. Republicans will not consider this proposal, even though President Trump supported the idea during his election campaign.

Patent reforms

Relatively modest bipartisan measures to speed up the generic supply chain stand the best chance of passing Congress this year. These reforms would ban pay-for-delay settlements between generic and brand-name drugmakers and crack down on other perceived abuses of the drug approval and patent systems.

PBM reforms

Increased oversight and transparency of PBM services could also land in a drug-pricing or another healthcare package. Certain PBM and generic drug-pricing provisions could be drawn from the comprehensive Lower Health Care Costs Act (S 1895), approved last year by the Senate HELP Committee. Key provisions include a ban on spread pricing, a rebate pass-through requirement for commercial plans and several reforms targeting anti-competitive terms in provider contracts.

Modernizing HSA standards

Though a legislative priority for employers, proposals to modern HSA and HDHP standards face an uncertain future in 2020 because of costs, politics and a short election-year calendar. Proposed changes would allow innovative plan designs and more predeductible coverage of chronic conditions. The Trump administration is addressing some of the desired changes through new guidance and regulations.

An extensive package of HSA reforms that passed the Republican-led House in the prior Congress featured bipartisan provisions to promote value-based care — including predeductible coverage for telemedicine services or employer onsite medical clinics — without risking HSA-eligibility. Three related bills passed the House Ways and Means Committee last October, with strong support from both parties. One bill would allow participants in HSA-qualifying HDHPs who enter direct primary care service arrangements (DPCSAs) to remain HSA-eligible and use HSAs to reimburse DPCSA fees (HR 3708). Another measure would permit predeductible HDHP coverage of inhalers to treat *any* chronic lung disease (HR 4716). Under the third bill, HSAs — as well as health FSAs, HRAs and Archer medical savings accounts — could pay for or reimburse costs for over-the-counter menstrual care products, even without a prescription (HR 1922).

More recent Senate legislation — the Chronic Disease Management Act of 2020 (S 3200) — would allow HSA-qualifying HDHPs to cover care related to chronic disease management on a predeductible basis. The bill would codify IRS guidance (Notice 2019-45) issued in July 2019.

Numerous other bills would increase the maximum annual contribution limits for HSAs, allow Medicare beneficiaries to continue contributing to HSAs, and permit the use of HSA funds to pay health insurance premiums and gym memberships, among other reforms. However, these measure face an uphill climb to enactment.

Federal paid leave proposals

Despite bipartisan interest in Congress and White House support for paid leave, consensus has yet to emerge on federal legislation. None of the current proposals in Congress would provide federal preemption of the growing number of state and local paid leave laws (see later discussion) that create administrative challenges for multi-jurisdictional employers. However, the federal spending package enacted last December extends through 2020 the federal tax credit for certain employers providing paid family and medical leave.

Paid family and medical leave. The leading Democratic bill in Congress is the Family and Medical Insurance Leave (FAMILY) Act (HR 1185, S 463). This legislation would provide up to 12 weeks of paid family and medical leave through a new program, funded by employer and employee payroll contributions, within the Social Security Administration. Although the FAMILY Act could pass the Democrat-controlled House, the Senate would not take up the measure.

Paid parental leave. Republican proposals in the Senate focus more narrowly on paid leave for new parents, funded by a drawdown of an employee's Social Security benefits that would get repaid by delaying their checks past retirement age. Neither the New Parents Act (S 920) nor similar legislation have garnered much support. The White House and Ivanka Trump are interested in paid parental leave legislation but have not advocated for a specific proposal. President Trump's fiscal year 2021 budget proposal calls for a federal-state paid parental leave program within DOL's unemployment insurance program that would provide up to six weeks of benefits after childbirth or adoption. Congress is not expected to take up the proposal.

Recently introduced bipartisan legislation, the Advancing Support for Working Families Act (S 2976), would give new parents the option to receive up to $5,000 of the child tax credit as an advance payment, providing them flexibility to cover costs after having or adopting a child. Under a retirement plan reform enacted as part of the December 2019 spending package, employers can give defined contribution plan participants a similar option to take penalty-free withdrawals of up to $5,000 for expenses related to childbirth or adoption.

Little federal progress likely. The broader partisan stalemate on paid leave is set to continue in 2020 and fuel more state and local activity. Meanwhile, employer groups are exploring potential legislative and regulatory paths to address the resulting compliance challenges for multi-jurisdictional operations. A Republican proposal — the Workflex in the 21st Century Act (HR 4219) — in the prior Congress would have established a voluntary, national ERISA standard for paid leave and flexible work programs. However, the bill never got traction and hasn't been reintroduced.

Action steps

Employers should monitor congressional developments and consider engaging in advocacy activities through their representatives in Washington, DC, or trade groups.

Related resources

Mercer Law & Policy resources

- SECURE Act leaves questions about distributions for birth or adoption (Jan. 28, 2020)
- Cadillac, other ACA taxes repealed in spending bill (Dec. 17, 2019)
- Health savings account reforms pass key House panel (Nov. 1, 2019)
- Bipartisan bills would simplify ACA employer-reporting requirements (Aug. 12, 2019)
- IRS expands predeductible preventive care for HSA-qualifying health plans (July 23, 2019)
- Senate package targets healthcare costs, surprise medical bills (June 12, 2019)
- Senate bill would end drug rebates in employer plans (March 14, 2019)
- Mercer shares views with senators on controlling healthcare costs (March 6, 2019)

Other Mercer resources

- State paid leaves: Three things employers should do in 2020 besides comply (Jan. 30, 2020)
- Federal workers to get paid leave: What's next for employers? (Dec. 19, 2019)
- Huge financial stakes for employers as Congress looks for deal on surprise medical bills (Dec. 12, 2019)
- Heard @ HLTH: Washington insiders discuss the hottest policy topics (Nov. 14, 2019)
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- The dirty secret exposed: Balance billing is big business (Sept. 19, 2019)
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- Mercer, stakeholders brief Congress on ending surprise billing through market-based reform (July 19, 2019)
- Employers called to action as battle intensifies over curbing surprise medical bills (July 11, 2019)

- Senate panel OKs surprise medical bill reforms but plans changes (June 27, 2019)
- Congress searching for accord on 'surprise' medical bills (June 13, 2019)
- 'Medicare-for-All' gets hearing on Capitol Hill (May 2, 2019)
- Employers weigh in on drug rebates (April 11, 2019)
- PBM chiefs spar with lawmakers over drug pricing (April 11, 2019)
- Mercer comment letter to Sen. Lamar Alexander on how to reduce healthcare costs (March 1, 2019)
- Senate drug price hearing spotlights rebates (Feb. 28, 2019)
- Trump speech hits drug price concerns as Congress charts own path (Feb. 7, 2019)
- The pressure is on to modernize time-off benefits: 6 survey findings (Jan. 16, 2019)

5

State health and leave issues

States will continue efforts to expand health coverage through waivers, individual mandates and — in some states — AHPs. The AHP option (29 CFR § 2510.3-5) is one of two 2020 state issues that will hinge on court rulings (see later discussion of these cases). On the other issue, the US Supreme Court will decide whether ERISA preempts state PBM laws enacted as a way to reduce prescription drug costs (see earlier discussion).

State approaches to enhancing healthcare affordability include imposing cost-sharing caps and — due to a new push by the federal FDA (discussed earlier) — importing drugs from Canada. While Congress debates legislation on surprise medical bills (see previous discussion), states will continue to enact insurance laws to protect their own residents.

Continuing the trend seen in recent years, states will move forward with paid family and medical leave (PFML) programs and accrued paid time off (PTO) for illness and other reasons.

Increased healthcare access

State initiatives to expand health coverage likely will include more ACA Section 1332 innovation waivers. Reinsurance, the most common type of waiver so far, could support other changes to a state's health coverage structure. For example, Georgia proposes to take residents off the federal Healthcare.gov enrollment platform and establish a Georgia-specific subsidy program in place of the current federal subsidies. Two states — Colorado and Washington — have moved forward with public health insurance options. Other states may follow with their own programs.

In the wake of the Trump administration's actions to relax ACA plan standards, states are taking divergent paths. Many states have begun adding ACA consumer protections to state insurance laws, including contraceptive coverage mandates, pre-existing exclusion bans and first-dollar coverage of preventive services. After Congress zeroed out a federal penalty for going without coverage, five states and Washington, DC, now require residents to maintain health coverage. More states may consider adding similar requirements in 2020, leading to increased state-by-state reporting obligations for employers.

Conversely, several states are looking to further relax ACA protections in an attempt to reduce consumer costs and increase available coverage. Some states also are pushing ahead to allow regional small employers and sole proprietors to establish AHPs under the Trump administration rule. However, a federal court struck down portions of that rule (*New York v. US Dep't of Labor*, 363 F. Supp. 3d 109 (D.D.C. 2019)), creating potential conflicts with some of the new state laws.

Drug costs

State lawmakers will look for options to reduce prescription drug costs for state residents. Three approaches have gained traction: cost-sharing caps, PBM regulations and drug importation. Two states — Colorado and Illinois — set a cost-sharing limit of $100 for a 30-day supply of insulin. As costs for life-saving prescription drugs continue to rise, more states may impose similar limits on insured plans, although these limits generally don't apply to self-insured ERISA plans.

As discussed earlier, the US Supreme Court will soon decide whether, and to what extent, ERISA preempts an Arkansas law (2015 Act 900) regulating PBMs (*Rutledge v. Pharm. Care Mgmt. Ass'n*, *cert. granted*, No. 18-540 (U.S. Jan. 10, 2020)). Portions of the Arkansas law served as a model for similar laws enacted in 2019 by numerous states, including Louisiana, Maine, Minnesota, New Hampshire and South Carolina. These laws look to regulate PBM transparency, disclosures, certain contract terms and/or the "maximum allowable cost" lists for drugs. If the Supreme Court agrees with the DOL amicus brief and decides ERISA doesn't preempt the Arkansas law, the ruling could spur more states to increase regulation of PBMs.

A third tactic to control drug costs — importation — received a boost from an FDA proposed rule providing states a pathway to import drugs from Canada (see earlier discussion). Two states — Florida and Vermont — have already submitted concept papers outlining their proposals. Other states are certain to follow.

Surprise medical bills

Curtailing surprise medical bills remains a priority for many states. While Congress continues to debate a federal solution (see previous section), states have been moving forward with their own programs for insured plans.

Common elements of state legislation include a ban on balance-billing for out-of-network services provided in specified settings; a benchmark payment tied to Medicare, network-negotiated rates, or usual, customary and reasonable costs by location; and arbitration, often via the state or state-approved arbitrators. Any state's approach applies only to insured plans, but at least two states — New Jersey and Washington — give self-insured plans the option to participate in the state program.

If Congress passes legislation to curb surprise medical bills, whether that federal law will preempt state laws is unclear. If Congress does not pass legislation, states will continue to enact this type of legislation.

Paid leave

In 2020, PFML benefits become available in Washington state and Washington. DC, to covered employees who need time off to care for their own or a family member's serious health condition, bond with new child or, in Washington state, handle military exigencies. These jurisdictions join California, New Jersey, New York and Rhode Island, where programs are already operating.

This year, Massachusetts will continue collecting contributions to fund PFML benefits that will become available in 2021, and Connecticut will prepare for its program's employee contributions to begin in 2021. Oregon will follow a year later.

Other states have been studying PFML options. A Colorado task force has approved a proposal and presented it to lawmakers to enact a PFML program.

Besides pursuing PFML insurance programs, states are considering accrued PTO requirements for employers. These laws generally include a cap on PTO accrual and, in most jurisdictions, provide only "sick and safe time off" to tend to an employee's or a family member's health needs. Allowed uses of PTO typically include to undergo wellness checkups; resolve issues related to stalking, domestic abuse or sexual assault; or handle school, day care or work closures caused by a public health emergency. However, two states — Maine and Nevada — give employees the right to use their accrued PTO for any reason.

Enacting PTO laws may become a growing state trend this year. New York's governor has announced his goal to establish a paid sick leave mandate there. Other states, such as Illinois, may resurrect similar legislation that failed to pass last year.

Action steps

Here are some steps to stay on top of state developments in 2020:

- Track state health initiatives affecting insured plans and be ready if state health coverage policies have a broader reach.
- Watch for more states to implement individual health coverage mandates with related reporting requirements. If providing health coverage to employees in those states, work with vendors to simplify reporting.
- Monitor the outcomes of court and legislative battles over PBM regulation for possible cost changes.
- Expect more states to enact surprise medical billing laws for insured plans, and some may give self-insured plans the option to participate.
- Focus on streamlining processes to conform company leave policies with different states' paid leave programs and mandates.

Related resources

Mercer Law & Policy resources

- 2020 state paid family and medical leave contributions and benefits (Feb. 14, 2020)
- Roundup of selected state health developments, fourth-quarter 2019 (Jan. 21, 2020)

- Massachusetts readies for paid family and medical leave (Jan. 13, 2020)
- Roundup of selected state health developments — third-quarter 2019 (Oct. 28, 2019)
- More states approve Pathway 2 association health plans (Oct. 21, 2019)
- Connecticut enacts paid family and medical leave (Aug. 29, 2019)
- DC details employer reporting for individual health coverage mandate (Aug. 20, 2019)
- Roundup of selected state health developments — second-quarter 2019 (July 29, 2019)
- ME, NV accrued paid leave mandates expand state sick leave law totals — state chart included (July 1, 2019)
- Senate package targets healthcare costs, surprise medical bills (June 12, 2019)
- Employers need to prepare now for Washington, DC's universal paid leave (June 11, 2019)
- New push for ACA innovation waivers aims to rekindle states' interest (May 21, 2019)
- New Jersey posts update on health-coverage reports due in 2020 (April 16, 2019)
- US Supreme Court declines to hear Maryland drug-pricing case (March 1, 2019)

Litigation and enforcement

6

Litigation to strike down the ACA

At the end of 2019, the 5th US Circuit Court of Appeals upheld a lower court ruling that strikes down the ACA's individual mandate as unconstitutional, but the appellate court did not decide if other parts of the law must fall (*Texas v. United States*, No. 19-10011 (5th Cir. Dec. 18, 2019)). The case now goes back to the US District Court for Northern Texas for additional analysis of questions about the rest of the law's status, but an appeal is pending at the US Supreme Court.

While the Supreme Court has declined to expedite the case, the justices later this month will consider whether to take up the appeal. The high court could decide to hear the case this term and render a decision before the 2020 election in November. However, the decision not to fast-track the case suggests that the justices are not in a hurry and will let the litigation first play out in the lower courts.

Lower court strikes entire ACA

The case arose after 2017 tax legislation reduced the individual-mandate penalty for not having health coverage to $0 starting this year. Citing the 2012 Supreme Court decision upholding the constitutionality of the individual mandate under Congress' taxation powers (*Nat'l Fed'n of Indep. Bus. v. Sebelius* (567 US 519)), Texas and several other Republican-led states sued, arguing the individual mandate is no longer constitutional without any tax penalty. The states also contended that the individual mandate can't be severed from the rest of the ACA, so the entire law must fall. The district court sided with the GOP states.

Appeals court orders fresh look at severability, new arguments

The 5th Circuit upheld the lower court's ruling that the individual mandate is no longer constitutional because it is no longer a tax. However, the appellate court asked the district court to give more analysis of the severability issue, including arguments the Department of Justice (DOJ) first raised on appeal. Severability is a legal concept that allows a court to invalidate a single provision within a larger piece of legislation without striking the entire law.

The 5th Circuit said that the severability analysis in the district court opinion is incomplete in two ways. First, the lower court gave relatively little attention to the intent of Congress in 2017, which had observed the ACA's actual implementation before reducing the individual-mandate penalty without making other changes. Second, the district court did not do the necessary legwork of parsing all ACA provisions and explaining why certain segments are inextricably linked to the mandate.

Action steps

Monitor whether the courts eventually conclude that other ACA provisions — or all of the ACA — are integral to the individual mandate and must also be invalidated. Since Congress has already reduced the penalty for

those without health insurance coverage to $0, the litigation has no immediate impact on employers or employees. But the litigation could have dramatic effects on the entire healthcare system if courts strike down much or all of the ACA. The Supreme Court will likely have the final say.

Related resources

Mercer Law & Policy resources

- Latest ACA case: Appeals court rules individual mandate unconstitutional (Dec. 19, 2019)
- 2019 compliance and policy outlook for employer-sponsored health benefits (Feb. 6, 2019)

Other Mercer resources

- Employers will face difficult decisions if ACA ruling stands (Dec. 17, 2018)
- Texas judge declares ACA invalid; appeals planned (Dec. 17, 2018)
- ACA returns to court (Sept. 6, 2018)
- GOP on defense over ACA pre-existing condition protections (June 14, 2018)

7

Other noteworthy litigation

Texas v. United States isn't the only health benefit case vying for attention from the Supreme Court this term. Others include the ACA's contraceptive coverage mandate and sex discrimination protections under Title VII of the 1964 Civil Rights Act. The latter case could have implications for the ACA's Section 1557 nondiscrimination provisions as well. On the other hand, a significant ERISA case on cross-plan offsetting is no longer on the Supreme Court's docket, leaving some uncertainty in this area.

Meanwhile, lower courts will continue to hear challenges to the Trump administration's AHP and STLDI rules. Litigation involving the Mental Health Parity and Addiction Equity Act (MHPAEA) remains active too. A district court decision invalidating recent HIPAA guidance on fee limits for supplying PHI to third parties may also be of interest to employers.

ACA contraceptive mandate

The Supreme Court is poised to rule on the ACA's contraceptive coverage mandate and the appropriate accommodation for employers with religious or moral objections to contraceptives (*Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, *cert. granted*, No. 19-431 (U.S. Jan. 17, 2020). Parties have been sparring over the mandate and accommodations for objecting employers since this requirement took effect in 2012 for nongrandfathered group health plans.

Obama-era regulations. The Obama-era rules prescribed an avenue for employers with religious objections to avoid group health plan coverage of contraceptives, while still providing employees of those organizations access to no-cost contraceptives. However, religious organizations objected that the accommodation scheme didn't go far enough and sued, arguing it infringed on their freedom of religion.

In 2016, the Supreme Court avoided a decision on the merits of the case and remanded it to the lower courts for the parties — religious entities and federal regulators — to work out an accommodation process acceptable to all sides (*Zubik v. Burwell*, 578 US 3 (2016)). However, in the final days of the Obama administration, the agencies announced in an FAQ that a compromise was not feasible, effectively leaving the accommodation process unchanged.

Trump-era revised rules on hold. Shortly after taking office, President Trump issued an executive order (EO 13798) directing federal agencies to address conscience-based objections to the contraceptive mandate. In response, regulators issued a new rule significantly expanding the religious accommodation and adding an opportunity for employers with moral objections to avoid the mandate. Legal challenges have since blocked implementation of those rules (*Pennsylvania v. President US*, 930 F. 3d 543 (3rd Cir. 2019); and *California v. US Dep't of Health & Human Servs.*, 941 F. 3d 410 (9th Cir. 2019)). The consolidated cases are now before the Supreme Court, with a decision expected this summer.

Separate RFRA claims. Meanwhile, a district court in Texas has permanently enjoined enforcement of the contraceptive coverage mandate for any entities with religious objections. The Texas court found the mandate and the Obama-era accommodation violate the Religious Freedom Restoration Act (RFRA) (*Deotte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019)).

Stay tuned. If the Supreme Court strikes the Trump-era contraceptive coverage rules, appeals in the Texas case blocking enforcement of the ACA mandate and Obama-era religious accommodation rules presumably will continue. On the other hand, if the Supreme Court upholds the Trump rules or issues an expansive ruling broadly interpreting the RFRA, the Texas matter may become moot.

Gender discrimination and group health plans

Legal challenges over denied benefits for gender reassignment surgery aren't slowing down. At least 21 states and Washington, DC, now provide protections for transgender individuals with insured coverage, according to the Movement Advancement Project. At the federal level, benefit denials for gender dysphoria have triggered MHPAEA cases, and employer-sponsored health plans limiting transgender benefits have faced Title VII discrimination claims. Under Title VII, an employer-sponsored group health plan must extend equally comprehensive coverage to both sexes and cannot discriminate on sex-based characteristics (*Newport News Shipbuilding Co. v. EEOC*, 462 U.S. 669 (1983)).

This term, the Supreme Court is hearing cases challenging the scope of Title VII's ban on sex discrimination in compensation and other terms, conditions, and privileges of employment, including benefits. The outcome of this litigation could have a significant impact on coverage under employer-sponsored group health plans. The decisions also could influence how courts and HHS interpret ACA's Section 1557 nondiscrimination provision, which bans discrimination based on sex (as well as race, age and disability) in health programs and activities receiving federal funds.

Title VII

Whether Title VII's protection against sex discrimination extends to transgender employees is the issue before the Supreme Court this term in *R.G. & G.R. Harris Funeral Homes v. EEOC* (*cert. granted*, No. 18-107 (U.S. April 22, 2019)). The court will also decide if Title VII protects against employment discrimination based on sexual orientation (*Bostock v. Clayton Cty., Ga.*, *cert. granted*, No. 17-1618 (U.S. April 22, 2019)).

ACA Section 1557

ACA Section 1557 incorporates the definition of sex discrimination in Title IX of the Education Amendments of 1972, which governs schools receiving federal funds. Neither statute identifies discrimination based on gender identity as a type of sex discrimination, but until recently, agency guidance and lower courts consistently concluded that Title IX (and Title VII) protections extend to gender identity. Obama-era regulations likewise interpreted ACA Section 1557 to prohibit discrimination based on gender identity, gender expression and transgender status in health plans and programs receiving federal funds.

The Trump administration changed course, withdrawing prior guidance that banned bias based on gender identity or transgender status in federally funded schools. The administration also declined to defend the challenged portions of the Section 1557 regulations explicitly prohibiting discrimination based on gender identity. A Texas district court vacated those parts of the 1557 regulations, finding they went well beyond the law's ban on sex discrimination (*Franciscan Alliance v. Azar*, No. 16-cv-0108 (N.D. Tex. Oct. 15, 2019)). That ruling is now on appeal before the 5th Circuit (No. 20-10093).

Other lower courts have come to the opposite conclusion, finding Section 1557 does prohibit gender-based discrimination (see, for example, *Tovar v. Essentia Health*, No. 16-100 (D. Minn. Sept. 20, 2018); *Boyden v. Conlin*, 341 F.Supp.3d 979 (W.D. Wis. 2018); and *Flack v. Wis. Dep't of Health Servs.*, 328 F.Supp.3d 931 (W.D. Wis. 2018)). Entities covered by Section 1557 — such as hospitals, clinics and state Medicaid programs — that fail to comply with Section 1557 still face the risk of lawsuits for sex discrimination.

Meanwhile, proposed new Section 1557 regulations would remove protections for transgender individuals and make other significant changes to the remaining provisions of the Obama-era rules. Although comment period for the proposed rules closed on Aug. 13, 2019, HHS has yet to publish final regulations.

AHP and STLDI regulations

In response to a 2017 executive order (EO 13813) on promoting healthcare choice and competition, final 2018 regulations expanded access to AHPs and STLDI. Opponents of these rules argue, in part, that the changes will destabilize the individual and small-group markets and drive up the cost of coverage. Both rules have spawned legal challenges, but so far, court action has invalidated only parts of the AHP regulation.

AHP controversy

Longstanding DOL guidance has distinguished between "bona fide" AHPs, which have a single plan at the association level, and other AHPs, under which each participating employer separately sponsors its own ERISA plan. Employers participating in a bona fide AHP share a common business interest and an organizational purpose beyond providing benefits, and bona fide AHPs enjoy certain advantages under the ACA and ERISA.

The 2018 final AHP rules gave small employers, working owners, franchises and certain large employers a new pathway to form bona fide AHPs. The new pathway allowed unrelated employers in the same geography — not just employers in the same trade, industry, line of business or profession — to form an AHP. However, a federal district court last year invalidated the portion of the DOL rules establishing the new pathway, finding it unreasonably expanded ERISA's definition of employer (*New York v. US Dep't of Labor*, 363 F. Supp. 3d 109 (D.D.C. 2019)).

That decision is now on appeal at the DC Circuit (No. 19-5125), which heard arguments last November and could issue a ruling anytime. Even as the litigation continues, some states have used their legislative and regulatory authority to limit bona fide AHPs, fearing destabilization of the individual and small-group markets, but other states have issued AHP-friendly guidance.

STLDI challenge

The 2018 final STLDI regulations allow individuals to have those policies for up to three years, significantly expanding the three-month limit under prior rules. STLDI is not subject to many of the ACA's consumer protections and can only be purchased off the public exchanges. A coalition of consumer advocates challenged the final rule, arguing in part that it is inconsistent with the ACA and could undermine enrollment in ACA-compliant plans. The court disagreed, finding the Trump administration did not exceed its authority when expanding the duration and availability of STLDI (*Ass'n for Cmty. Affiliated Plans v. Treasury*, 392 F. Supp. 3d 22 (D.D.C. 2019)).

The matter is now on appeal at the DC Circuit (No. 19-5212), with arguments slated in March. In the meantime, some states have limited the availability of STLDI within their borders, while others require these policies to comply with ACA's mandated coverage of pre-existing conditions and essential health benefits.

HIPAA fee limit for producing PHI

A recent district court decision invalidated HIPAA guidance that imposes a fee limit for supplying PHI to third parties (other than the patient). With the limit removed, HIPAA covered entities (including group health plans) and the business associates can charge higher fees for fulfilling such PHI requests.

Under HIPAA, individuals have the right to access their own PHI without paying more than the reasonable cost of the labor, supplies and postage for producing the information. (Some state laws go further and require providing one copy of PHI at no cost.) The 2009 HITECH Act authorizes third-party directives — that is, requests by individuals to have their electronic PHI sent directly to a third party without a HIPAA authorization.

In 2013, the HIPAA omnibus rule broadened the HITECH Act's third-party directive to include requests for PHI in any format, not just electronic records. In 2016, HHS guidance expanded the reasonable-cost limit on PHI fees to include third-party directives (see Q&As about HIPAA's access rights). Prior to this guidance, covered entities and business associates fulfilling third-party directives and requests initiated by third-parties could charge higher fees.

A medical records provider challenged the 2016 guidance (and related HIPAA rules). The federal district court found HHS violated federal administrative law by extending the fee restrictions through Q&As rather than a formal rule-making process open to public comment (*Ciox Health, LLC v. Azar*, No. 18-00040 (D.D.C. Jan. 23, 2020)). While the court vacated the fee portion of the 2016 guidance, HHS could adopt a similar limit through the formal regulatory process. The court also vacated parts of the 2013 HIPAA omnibus rule compelling delivery of PHI to third parties regardless of the records' format, noting the HITECH's requirement applies only to certain electronic health records. HHS has not indicated whether it will appeal the ruling.

Mental health parity litigation

Mental health parity cases are substantial in number and scope, and this trend shows no sign of slowing in 2020. Large plans in particular are targets of high-profile parity litigation over coverage exclusions or

reimbursement rates for mental health or substance use disorders (MH/SUDs). Examples of these disputes involve:

- Plans excluding residential treatment facilities for MH/SUD treatment but covering skilled nursing facilities for medical conditions (see, for example, *Craft v. Health Care Serv. Corp.,* 84 F.Supp.3d 748 (N.D. Ill. 2015); and *Danny P. v. Catholic Health Initiatives*, 891 F.3d 1155 (9th Cir. 2018))

- Plans excluding wilderness therapy (see, for example, *Vorpahl v. Harvard Pilgrim Health Ins. Co.,* No. 17-1084 (D. Mass. July 20, 2018); *A.Z. v. Regence Blueshield*, 333 F. Supp. 3d 1069 (W.D. Wash. 2018); and *Alice F. v. Health Care Serv. Corp.,* 367 F.Supp.3d 817 (N.D. Ill. 2019))

- Plans excluding ABA therapy for autism (see, for example, *Wilson v. Anthem Health Plans of Ky., Inc.,* No. 14-00743 (W.D. Ky. Dec. 18, 2019); *J.R. v. Blue Cross & Blue Shield of Ill.,* No. 18-01191 (W.D. Wash. 2019)); and *Doe v. United Behavioral Health*, No. 19-07316 (N.D. Cal. filed Nov. 7, 2019))

- Plans setting lower out-of-network reimbursement rates for MH/SUD services provided by psychologists and counselors than for out-of-network services from other providers (*Smith v. United Healthcare Ins. Co.,* No. 18-6336 (N.D. Cal. July 18, 2019))

In addition, recent litigation has increasingly focused on the guidelines that plans use to make medical-necessity decisions on mental health claims. For examples, see *Ariana M. v. Humana Health Plan of Tex.*, 854 F.3d 753 (5th Cir. 2017); *Doe v. Oxford Health Plan Ins., Inc.,* No. 17-1485 (D. Conn. Nov. 5, 2019); *Wit v. United Behavioral Health*, No. 14-2346 (N.D. Cal. Feb. 28, 2019); *Peter F. v. United HealthCare Servs., Inc.,* No. 17-00435 (D. Utah Nov. 18, 2019); and *S.B. v. Oxford Health Insurance Inc.,* No. 17-1485 (D. Conn. Nov. 5, 2019).

ERISA and cross-plan offsetting

Employers sponsoring self-funded ERISA plans have a fiduciary duty to monitor service providers, including their claims payment practices, and to ensure the accuracy of summary plan descriptions (SPDs) and related plan documents. Cross-plan offsetting — the practice of offsetting one employer plan's overpayments to out-of-network providers by reducing claim payments to those providers under another of the employer's plans — is likely to remain a risk for ERISA fiduciary breach claims in 2020.

Employers had hoped to see the cross-plan offsetting issue resolved when UnitedHealth Group appealed an adverse 8th Circuit decision to the Supreme Court (*Peterson v. UnitedHealth Group Inc.,* 913 F. 3d 769 (8th Cir. 2019)). The appellate court decision focused almost exclusively on plan documents, finding none explicitly or implicitly authorized cross-plan offsetting, although some did permit same-plan offsetting. In that case, DOL filed an amicus brief, arguing that United's practice of cross-plan offsetting violates ERISA. Although the 8th Circuit ultimately did not rule on that issue, the judges noted cross-plan offsetting "at the very least … approaches the line of what is permissible." UnitedHealth initially appealed to the Supreme Court, but later dropped its appeal in favor of settlement discussions.

A Supreme Court ruling on the ERISA question would have had implications across the industry. Bulk recovery is a common billing practice among insurers and TPAs but is not always reflected appropriately in plan documents. With UnitedHealth dropping its appeal, the 8th Circuit opinion remains controlling law in seven states: Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota and South Dakota. On the other hand, DOL's amicus brief presumably represents a legal position the agency is willing to enforce nationwide.

Action steps for employers

With so much active litigation with implications for employer-sponsored health plans, here are a few steps employers may want to take to keep on top of developments:

- **Contraceptive coverage mandate.** Health plan sponsors with religious or moral objections to contraceptive coverage should consult with legal counsel on the best way to assert those objections and avoid the mandate. Keep in mind that the current legal status of the mandate and implementing regulations will remain in flux until — and possibly even after — the Supreme Court issues its decision on the Trump-era accommodation rules.

- **Sex discrimination in employment and benefits.** Watch for the Supreme Court's decision on the reach of Title VII's sex discrimination ban. The ruling will have broad consequences for employment policies and could have direct implications for self-insured plans' coverage of gender transition services. For employers and plans receiving federal funds, consider the ruling's impact on ongoing litigation over the scope of ACA's Section 1557 nondiscrimination provisions (and the latest proposed regulations). Employers with health benefit plans that contain blanket, categorical coverage exclusions for transgender- or transition-related healthcare services and procedures should consult with counsel to ensure compliance with Section 1557 and Title VII.

- **Market stability and access to AHPs.** Monitor the impact of the STLDI and AHP changes on the individual and small-group markets. Destabilization could not only make those markets less attractive to early retirees and other workers ineligible for employer coverage, but also cause cost-shifting to employer plans. If deciding whether to participate in an AHP, stay abreast of judicial developments and state restrictions.

- **Fees for supplying PHI to third parties.** HIPAA covered entities (including self-insured group health plans) and business associates looking to charge a fee for providing PHI to third parties should discuss the HIPAA requirements and the implications of the recent district court opinion with legal counsel. Plans may also begin to see proposed amendments to business associate agreements to allow charging a fee higher than the reasonable cost when responding to third-party directives.

- **Mental health parity.** Review health plans' MH/SUD coverage restrictions and claim-processing procedures for compliance with the mental health parity rules to reduce risk of litigation.

- **ERISA fiduciary rules and claims processing.** Evaluate plan documents, administrative-service agreements and actual TPA/issuer practices for recouping overpayments to healthcare providers. If

cross-plan offsetting or a bulk recovery process is used, consult with legal counsel about ERISA fiduciary obligations and decide how to address this practice.

Related resources

Mercer Law & Policy resources

- Mental health parity FAQs address nonquantitative limits, disclosures (Dec. 17, 2019)
- Top 10 compliance issues for 2020 health and fringe benefit planning (June 25, 2019)
- Litigation, legislation leave AHP guidance in flux (May 2, 2019)
- Cross-plan offsetting raises questions for ERISA health plans (March 12, 2019)
- Final association health plan rule offers new opportunities for employers (Nov. 8, 2018)

Other Mercer resources

- Contraceptive coverage: good for women, good for business (July 12, 2018)
- New association health plan rules present opportunity for small businesses (June 19, 2018)
- Trump administration rolls back ACA contraceptive mandate (Oct. 9, 2017)

8

ESR reporting and enforcement

Applicable large employers (ALEs) remain subject to potential ESR assessments for failing to offer affordable, minimum-value coverage to ACA full-time employees. IRS continues to issue proposed ESR assessments (Letter 226-J) and letters about missing Forms 1094/1095-C (Letter 5699). Some employers may succeed in getting proposed ESR assessments reduced because of reporting errors or IRS system issues. However, letters about missing returns underscore the need for each aggregated ALE group member to complete and submit Forms 1094/1095-C information returns for its own ACA full-time employees.

The agency has given no indication that ESR enforcement efforts will slow down in 2020. This means large employers must continue to gather data on coverage offers and enrollment for the 2020 reports due in 2021.

Deadline extended again, penalty relief renewed for 2020

Now in the fifth year of ESR reporting, IRS has again extended the deadline for furnishing health insurance coverage statements to individuals (Forms 1095-B/C) — this time, to March 2 (Notice 2019-63). But ALEs, small self-funded employers and carriers still must meet the original deadline of Feb. 28 (for paper filings) or March 31 (for electronic filings) to submit information returns (Form 1094-B or C, with accompanying 1095s) to IRS.

Notice 2019-63 also extends prior penalty relief for incorrect or incomplete 2019 reports due in 2020. To qualify for this good-faith relief, employers must make reasonable efforts to comply with the reporting requirements and meet applicable deadlines.

Despite repeated extensions of this relief, employers have no guarantee that IRS will grant relief again for the 2020 filings due in 2021.

First-time limited relief for failure to furnish individual statements

For insurance carriers and small self-funded employers (fewer than 50 ACA full-time employees), Notice 2019-63 also provides relief from the penalty for failing to furnish health coverage statements to individuals (Form 1095-B). To qualify for this relief, the employer's or carrier's website must prominently display a notice meeting certain requirements (e.g., contact email and physical address with telephone number for questions), and individuals requesting a statement must receive one within 30 days. However, as noted above, carriers and small self-funded employers still must submit information returns (Forms 1094/1095-B) to IRS by the applicable deadlines.

This penalty relief has no effect on the requirement that ALEs — whether insured or self-funded — furnish individual statements (Form 1095-C) to ACA full-time employees and submit those statements to IRS using the 1094-C transmittal form.

Future changes possible

Without any federal penalty for failing to have health insurance, individuals no longer need a statement demonstrating coverage from a carrier or small self-funded employer (Form 1095-B) or a large self-funded employer (Form 1095-C). But the forms still give IRS information to administer ESR assessments and premium tax credits. In addition, five states and Washington, DC, have enacted individual health coverage mandates that currently — or likely will — require some form of reporting by individuals, carriers and employers (see earlier discussion). As the federal reporting requirements change, state reporting requirements that rely on the federal forms and rules may change as well.

Action steps

Complete 2019 ACA reporting by the 2020 deadline, plan for 2020 reporting due in 2021 and continue to monitor ESR strategies. Since IRS continues to issue Letters 226-J, have a plan for responding to proposed assessments. Monitor federal and state legislative and regulatory activity that may modify current data collection and reporting processes. As discussed earlier, however, Congress appears unlikely to enact any ESR relief.

Related resources

Mercer Law & Policy resources

- Latest ACA case: Appeals court rules individual mandate unconstitutional (Dec. 19, 2019)
- ACA individual statement deadline and good-faith relief extended again (Dec. 4, 2019)

Other Mercer resources

- ACA assessment letters are coming (Nov. 16, 2017)

Behavioral health and wellness

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Behavioral health trends

Innovations in behavioral health have picked up steam in recent years. Digital platforms for MH/SUD treatment are attracting more investors, and employers are looking for more cost-effective ways to address behavioral health through workplace initiatives and group health plans. While these emerging technologies hold promise, they also present evolving compliance challenges for plan sponsors. Along with increased state and federal enforcement of mental health parity laws, legal issues for behavioral health products include the still-developing federal regulation of digital tools and the varying state telemedicine, privacy and security rules. Resolving these compliance concerns will require employers to review new behavioral health products with legal professionals.

Telemedicine and mental health parity

In recent years, telemedicine options for behavioral health have increased in the marketplace. This trend coincides with changes in federal and state laws to encourage telemedicine, especially as a way to address the shortage of behavioral health professionals in some areas. The mental health parity regulations and enforcement guidance do not address telemedicine, so questions about various designs will continue to arise.

Fee differences. Some telemedicine vendors charge a higher fee for MH/SUD services than for medical/surgical (M/S) services. The parity rules generally require comparable cost-sharing for both types of services, regardless of any cost differences to the plan or sponsor. This means a plan imposing a higher copay or coinsurance for MH/SUD telemedicine than M/S telemedicine is likely out of compliance. Plans should conduct the financial testing described in the parity rules to make that determination.

Coverage differences. Even a telemedicine benefit that offers only M/S services needs close review. The parity rules require an analysis of all benefit offerings in each classification, comparing MH/SUD to M/S coverage. Regulators and courts might view a telemedicine program that covers certain M/S services but excludes all MH/SUD services as providing less comprehensive care for MH/SUD conditions relative to the coverage in other parts of the group health plan. This is a parity red flag, similar to the compliance concerns raised when plans exclude residential treatment for MH/SUD conditions but cover inpatient care for M/S conditions. At a minimum, health plan sponsors should evaluate any exclusion of MH/SUD conditions from telemedicine benefits as a nonquantitative treatment limit and make sure comparable factors went into the decision to cover M/S visits but not MH/SUD visits.

Predeductible HDHP costs. For employers sponsoring HSA-compatible HDHPs, participants who have yet to meet their deductible generally must pay the full market rate for telemedicine services. This can result in higher out-of-pocket costs for MH/SUD services than for M/S services if the vendor is charging different rates. In this case, the disparity in cost to the participant should not raise any parity concerns, since the plan

is not imposing differing financial requirements but simply passing on the entire predeductible cost for both M/S and MH/SUD services.

Novel EAP offerings warrant revisiting basic ERISA rules

Many plans sponsors have sought to modernize their employee assistance programs (EAPs) with new offerings, such as counseling to address anxiety, depression, substance use and other disorders. Agencies will likely welcome these developments as the federal government looks for ways to address the opiate crisis and shortages in counseling professionals who can provide short- or long-term behavioral health treatment.

Most employers are familiar with federal parity rules that caution against using EAPs as the gatekeeper for a group health plan's behavioral health benefits. EAPs are also ERISA welfare benefit plans, so basic rules regarding benefit descriptions, plan documents and continuation of coverage apply as well. In addition, many — if not most — stand-alone EAPs that provide medical care (rather than just coaching or referrals) must comply with group health plan regulations, including many ACA consumer protections. The line between coaching and medical care, however, is not always clear, so employers need to review what services the EAP is providing and evaluate whether those services are a type of medical care.

Some EAPs that provide limited medical benefits might qualify as an "excepted benefit," reducing — but not eliminating — federal compliance obligations. EAPs that qualify as an excepted benefit won't, for example, have to comply with the MHPAEA. Under the 2013 final parity regulations setting out the criteria for this exception, an excepted-benefit EAP cannot provide "significant benefits in the nature of medical care." No bright line determines what benefits are considered significant, and the EAP marketplace likely has great variation on this issue. EAPs qualifying as excepted benefits must still comply with basic ERISA rules, such as the requirements on plan documents and continuation of coverage.

Digital tools will become more common, but will get increased scrutiny

The use of behavioral health apps to provide coaching or treatment for health plan participants will continue to grow. The administration generally supports telemedicine and digital health tools, seeing the value and cost-saving benefits of delivering healthcare in the most convenient manner to patients. For example, proposed interoperability rules for certain public programs would encourage plans to use an applied programming interface (API) to share clinical and claims information directly with the consumer. (For more details on these rules, see Other transparency initiatives.)

The proliferation of digital health tools, however, has brought a growing consensus that HIPAA's privacy and security rules inadequately address these technologies, leaving wide gaps in consumer protections. At the federal level, efforts to update HIPAA and regulate digital health products are just beginning. For instance, draft FDA guidance on clinical decision support software attempts to provide more clarity to medical device and healthcare companies marketing software and mobile apps. At the state level, California's beefed-up law to protect consumer data and privacy could spark similar initiatives in other states, with implications for behavioral health innovations.

Increased state activity trending

States are the primary enforcers of federal mental health parity standards for insured plans. States are likely to ratchet up their enforcement of those standards, consistent with their own interpretations of the federal parity law. Through insurance market examinations, for example, states can obtain information on how carriers use nonquantitative treatment limits and what criteria form the basis for denying mental health claims. The Pennsylvania Department of Insurance recently completed market conduct exams, imposing significant fines on carriers. Similar exams in New Hampshire resulted in two insurers agreeing to implement compliance assurance plans.

States also are passing insurance laws and developing regulations to address perceived problems — beyond parity compliance — in the behavioral health system. For instance, New York's Department of Financial Services recently issued guidance for carriers and other utilization-review entities to implement state-law changes in how plans choose the criteria used to make coverage decisions for mental health claims.

Action steps

Here are some steps employers interested in promoting behavioral health or telemedicine may want to take:

- Make sure telemedicine and EAP vendors have reviewed relevant federal law and demonstrate compliance with these standards.
- Consider obtaining written assurances that vendors are meeting state licensing rules and other state laws that regulate telemedicine or EAP providers. These standards vary from state to state, but examples include laws regulating the corporate practice of medicine or restricting online prescribing of medication.
- Stay informed about the developing legal standards for mobile apps. Before offering telemedicine through an employer-provided mobile app, review a standard set of threshold questions with compliance professionals: Is the app providing medical care? Is the benefit offered to all employees, or just those in the group health plan? Do HIPAA's privacy and security protections apply? If HIPAA does not apply, what other federal or state laws are implicated?
- Monitor both federal and state enforcement activity. State enforcement of mental health parity won't directly affect self-insured ERISA plans, but federal regulators like DOL do review state examinations of insurers, since these entities often provide TPA services to self-insured plans subject to DOL audits. According to DOL, it can enforce parity against insurance companies that provide TPA services to self-funded ERISA plans and is pursuing global parity corrections by TPAs.

Related resources

Mercer Law & Policy resources

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

- Top 10 compliance issues for 2020 health and fringe benefit planning (June 25, 2019)

Other Mercer resources

- Mercer participates in White House roundtable on mental health, addiction treatment (Sept. 19, 2019)
- If you don't cover MAT for opioid use disorder, here's why you should (Sept. 26, 2018)
- Mental health and opioids in health policy spotlight (April 26, 2018)
- Proof that focus is needed on mental health benefits (Oct. 12, 2017)
- How does your benefits plan stack up against mental health parity regulations? (Sept. 22, 2017)

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Wellness strategies

Wellness programs warrant a fresh look, given the ongoing uncertainty about permissible financial incentives for some programs and ongoing DOL scrutiny for compliance with HIPAA's rules for reasonable alternative standards to earn health-contingent rewards.

Financial incentives under ADA and GINA

Under the Americans with Disabilities Act (ADA) and Genetic Information Nondiscrimination Act (GINA), wellness programs with health screenings (such as employee or spousal health risk assessments or biometric screenings) must ensure participation is strictly voluntary and not coerced in any way. Under Equal Employment Opportunity Commission (EEOC) rules first effective in 2017, a program met this voluntary standard as long as any financial incentives for participation didn't exceed 30% of the cost of self-only coverage. However, court action vacated the financial incentive sections of both the ADA and GINA rules (29 CFR 1630 and 29 CFR 1635), effective Jan. 1, 2019 (*AARP v. EEOC*, 292 F.Supp.3d 238 (D.D.C. 2017)).

EEOC has not indicated when or if it will issue new financial incentive guidelines. All other EEOC standards for employer-sponsored wellness programs — such as the notice and consent requirements — remain in place. As a result, employers offering wellness programs with health screenings face continuing uncertainty as to how much of a financial incentive is too much and causes program participation to be involuntary and impermissible under the ADA and GINA.

In the meantime, EEOC field offices can take enforcement action against employers, and private parties can bring suit. In one class action (*Kwesell v. Yale University*, No. 19-1098 (D. Conn. filed July 16, 2019)), current and former employees allege that the $25/week higher health insurance premium for failing to complete certain health screenings (e.g., mammogram, colonoscopy or diabetes screening) makes the program involuntary under the ADA wellness rules. The complaint also argues that completing the program would result in impermissible sharing of information protected by GINA.

Health-contingent rewards under HIPAA

Wellness programs linked to a group health plan must also comply with HIPAA rules, which have financial incentive limits and other requirements (e.g., reasonable design, disclosures and confidentiality) for programs with rewards contingent on health-related factors or outcomes.

DOL has been enforcing these rules — particularly the reasonable-alternative standard and notice requirements that are meant to protect participants from discrimination based on a health factor. The agency has brought complaints against employers for failure to offer a reasonable alternative to a premium

surcharge for participants who use tobacco or don't meet certain biometric targets. Careful compliance with HIPAA's wellness program requirements is essential for employers looking to avoid DOL scrutiny.

Action steps

Work to comply with all existing legal requirements for wellness programs. Revisit financial incentives for health screenings in light of uncertainty about permissible financial incentives under the ADA and GINA rules. Verify that wellness programs tied to a health plan are meeting HIPAA requirements — especially the reasonable-alternative standards for health-contingent programs.

Related resources

Mercer Law & Policy resources

- 2019 outlook for wellness strategies (Feb. 6, 2019)

Other Mercer resources

- What do the EEOC and well-being have in common? (Jan. 16, 2019)
- Are you investing in the right well-being initiatives? Find out now (Jan. 11, 2019)
- Taking the pulse of employee wellness programs (July 12, 2018)