

Law & Policy Group | GRIST

2022 health law and policy outlook

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Section 1 Introduction

A wide array of healthcare policy changes and compliance issues for employers will continue to evolve in 2022, shaped by the Biden administration, Congress, state legislatures and the courts. Controlling costs, increasing transparency and healthcare access, protecting consumers, and improving competition in the marketplace are key goals driving many of the changes.

Despite partisan gridlock on numerous healthcare issues in Congress, bipartisan support could bring measures to expand telehealth access, broaden access to behavioral health services and further expand transparency, among other things. Democrats may also revive their efforts to extend expanded Affordable Care Act (ACA) subsidies, broaden coverage and control drug prices on a party-line basis under special budget rules. While both parties support paid leave, the partisan divide in approach make enactment of a federal mandate unlikely.

At the state level, the pandemic continues to influence legislative priorities. Employers can expect new or enhanced paid leave benefits, continued focus on mental health parity, and efforts to expand access to telehealth. Rather than wait for federal legislation or regulation, states are also acting to curb drug costs and regulate pharmacy benefit managers (PBMs).

Federal agencies are expected to adjust COVID-19 requirements for employers and group health plans as the pandemic wanes. Implementation and enforcement efforts will concentrate on transparency, surprise billing and mental health parity. The agencies are expected to sharpen their focus on privacy and cybersecurity, as well as on federal nondiscrimination laws, including requirements for employer-sponsored wellness programs. The ACA's employer shared-responsibility (ESR) mandate and reporting requirements remain in place, but changes may be coming for Form 5500 reporting.

A wide variety of litigation has implications for employer-sponsored health plans. These cases include challenges to COVID-19 testing payments, pharmacy benefit designs, behavioral health coverage terms, surprise billing and association health plan (AHP) rules, the ACA's preventive care mandate, and accommodations for employers with religious or moral objections to contraceptive coverage. In addition, ERISA preemption lawsuits are contesting state laws regulating PBMs and local laws mandating certain employer health coverage. Employers continue to face litigation risks related to COBRA notice requirements.

This GRIST summarizes expected 2022 policy, regulatory, and enforcement developments affecting health and leave benefits.

Section 2

Federal legislative outlook

After the president's climate and social spending package — the Build Back Better Act (BBBA) (HR 5376) — died in the Senate last December, Democrats are reevaluating what healthcare, drug pricing and paid leave proposals can pass this year. To accommodate moderate Senate Democrats, the party hopes to enact early this year a scaled-down version of the filibuster-proof budget bill. That measure could include some of the original bill's healthcare and drug pricing reforms, although next steps are unclear. The BBBA's ambitious plan to create a new federal paid leave entitlement almost certainly will not be revived.

At the same time, lawmakers from both parties are considering potential bipartisan action to support telehealth, lower healthcare costs and expand access to mental healthcare. In addition, House Republicans are preparing their 2023 healthcare reform agenda as polls show a growing likelihood that the party could win control of one or both chambers in November.

As midterm elections draw closer and the political season heats up, legislative action is set to slow. Congress will head home early to campaign, but lawmakers will return for a post-election lame-duck session.

Proposals affecting employer health plans that may survive

With slim majorities on the line in the midterm elections, Democrats are under tremendous pressure to pass some form of the BBBA this year. The healthcare and drug pricing reforms in the expansive bill passed by the House in November generally have support across the party. As a result, those reforms may land in a smaller budget reconciliation bill that could pass with a simple majority instead of the usual 60 votes needed to end Senate debate. The House-passed bill contains a number of provisions that would affect employer health plans, including the following:

- The ACA's play-or-pay affordability percentage for employer coverage would decrease from the current 9.61% (indexed) to 8.5% of employee household income (or an applicable affordability safe harbor) for 2022 through 2025. The percentage would not be indexed for inflation until 2027.
- The two-year (2021–2022) expansion and increase of ACA marketplace subsidies under the American Rescue Plan (ARPA) (<u>Pub. L. No. 117-2</u>) would extend through 2025. ACA marketplace coverage would continue to be fully subsidized for individuals earning up to 150% of the federal poverty level (FPL), and subsidies would continue to be available to individuals earning more than 400% of the FPL.
- ACA marketplace subsidies would be available from 2022 through 2025 to individuals
 with household incomes below 138% of the FPL in states that have not expanded their
 Medicaid programs. These individuals could receive subsidies even if they have access
 to employer-sponsored affordable, minimum-value coverage. Employers would not face
 play-or-pay assessments for this new group of subsidy-eligible individuals.

- Drug companies that raise prices for certain drugs faster than general inflation for Medicare and employer plans would face penalties. In addition, Medicare (but not employer plans) could negotiate prices for a limited number of drugs.
- To increase drug pricing transparency, PBMs would have to provide employer plan sponsors semiannual reports on costs, fees and rebates associated with the PBM contract.
- Cost-sharing limits would apply to insulin for individuals in employer plans, private insurance and Medicare.
- The Labor Department would gain authority to impose civil monetary penalties on employers and insurers violating the mental health parity rules.

While these provisions appear to be Democratic priorities to include in a revised bill, the outlook is uncertain, and the proposed effective dates are almost certain to change. In addition, everything in a revised bill must comply with the Senate's budget reconciliation rules, which require that the legislation directly affect the federal budget, among other things. Any provisions found in violation would need to be modified or dropped; otherwise, the entire measure would lose its privileged status under the budget reconciliation rules. The House-passed bill's proposals to limit insulin costs for employer plan members and to calculate inflation caps for drug prices based partly on what employers pay for drugs might not survive the budget reconciliation process.

Paid leave

The BBBA would guarantee up to four weeks of paid family and medical leave (reduced from 12 weeks in prior drafts) from either the federal government, state paid leave programs or employers. However, any revised bill will almost certainly omit that proposal due to opposition from Sen. Joe Manchin, D-WV. The House plan would leave the current patchwork of state and local laws in place and raise a host of operational issues for employers, who will continue to push for a nationally uniform compliance option.

Manchin believes paid leave legislation could draw bipartisan support and should be addressed outside of the budget reconciliation process. Nonetheless, the partisan divide remains wide, with Republicans generally favoring proposals focusing more narrowly on paid leave for new parents. As a result, the paid leave stalemate in Congress is set to continue this year, fueling more state and local activity.

Extending telehealth flexibilities

A bipartisan push is underway to renew a telehealth provision in the Coronavirus Aid, Relief and Economic Security (CARES) Act (<u>Pub. L. No. 116-136</u>) for high-deductible health plans (HDHPs). That provision allowed HDHPs to cover telehealth and other remote care services on a predeductible basis, without jeopardizing an individual's eligibility to make or receive health savings account (HSA) contributions. In addition, an HSA-eligible individual could receive coverage for telehealth and other remote care services from a stand-alone vendor outside of the HDHP before satisfying the HDHP's statutory minimum annual deductible. This flexibility expired at the end of 2021 for calendar-year plans (later for noncalendar-year plans).

Bipartisan legislation in both chambers would make these CARES Act provisions permanent, but lawmakers appear more inclined to pass a temporary extension, possibly for two years. Action on an extension may come as part of government spending legislation that must pass by March 11. In the meantime, lawmakers and a broad range of stakeholders are urging the IRS not to enforce the pre-CARES Act restrictive HDHP/HSA rules as Congress eyes renewing the relief.

Employer groups are also asking Congress to make permanent the <u>temporary telehealth</u> <u>policy</u> provided by regulators during the ongoing public health emergency. The temporary relief treats telehealth and remote care services like an excepted benefit, eliminating the need for the coverage to comply with many ERISA and ACA group health plan mandates (e.g., first-dollar coverage of ACA-mandated preventive care). Under the proposed legislation (like the temporary relief), employers could offer telehealth arrangements not just to benefits-ineligible employees like part-time or seasonal workers, but also to employees who opt out of the employer-sponsored major medical plan.

Mental health

The Senate Finance Committee aims to introduce bipartisan legislation this year that addresses behavioral healthcare issues, and both chambers will continue to work on proposals to expand access and services. In response to a recent <u>request for information</u> from the Finance Committee, plan sponsor lobbying organizations submitted lengthy comments that outline policies to support and supplement employers' efforts. Recommendations include:

- Expanding the use of telehealth
- Supporting employers' ability to offer mental health services in employee assistance programs (EAPs)
- Encouraging the Department of Labor (DOL) to provide clearer guidance on how to comply with mental health parity rules
- Exploring policies to increase network participation by mental health providers

Prospects for action on related legislation this year are uncertain, but bipartisan work on these issues will continue into the next Congress.

Modernizing HSA standards

Most proposals to modernize HSA and HDHP standards — a long-standing legislative priority for employers — are unlikely to advance in 2022 because of costs, politics and a short election-year calendar. While chances are good that Congress will at least temporarily extend the CARES Act's telehealth/HDHP provisions, action on additional reforms will likely have to wait until the next Congress. Such reforms include:

- Allowing predeductible coverage at employers' on-site medical clinics or for chronic disease management, without jeopardizing an individual's eligibility to make or receive HSA contributions
- Permitting participants in HSA-qualifying HDHPs who enter direct primary care arrangements (DPCAs) to remain HSA-eligible and use HSAs to reimburse DPCA fees

- Increasing the maximum annual contribution limits for HSAs
- Allowing Medicare beneficiaries to continue making or receiving HSA contributions
- Permitting the use of HSA funds to pay health insurance premiums and gym memberships

These measures are not likely to move this year but may get a boost in 2023 if Republicans win control of Congress.

Employer ACA reporting

Lawmakers will likely reintroduce bipartisan legislation this year to streamline ESR reporting duties under the ACA's mandate for employers to offer "affordable" minimum essential coverage to ACA full-time employees or pay a tax assessment. The new version of the Commonsense Reporting Act (<u>HR 5318</u>) is expected to again propose a voluntary prospective reporting system that would relieve employers from having to file IRS <u>Form 1094-C</u>. In addition, employers in this system would create <u>Form 1095-C</u> individual statements for only employees for whom the employer has received notice that they or their dependents purchased coverage through an ACA public marketplace.

The legislation faces a steep climb, however, due to a crowded election-year congressional calendar and fears of harming IRS's ability to administer ACA premium tax credits for eligible individuals. In addition, several states use the federal reporting system to help implement their own individual coverage mandates.

Healthcare costs

As a part of ongoing efforts to address rising healthcare costs and promote higher-quality care, lawmakers are expected to push for bipartisan legislation that would prohibit anti-competitive contracting terms between providers and health plans.

House Republicans' Healthy Future Task Force. Controlling healthcare costs while improving the quality of care are also goals of the <u>Healthy Future Task Force</u> that House Republicans have formed to prepare their 2023 reform agenda. Targets for the task force and several subcommittees include promoting employer innovations to lower costs and improve care, enhancing transparency, and increasing competition among healthcare providers. The task force has issued several requests for information, and employer groups are preparing to submit extensive comments over the coming weeks.

Section 3

State legislative outlook

State and local governments will concentrate on paid leave, COVID-19, prescription drugs, mental health parity and telemedicine. All but four states — Montana, Nevada, North Dakota and Texas — are holding regular legislative sessions this year.

State coverage mandates for fully insured health plans will continue to see action. More local jurisdictions may consider implementing health coverage requirements similar to those in <u>San Francisco</u> and <u>Seattle</u>, despite ongoing legal challenges to those mandates (see the ERISA preemption discussion in the *Litigation outlook* section).

The Supreme Court's 2020 decision allowing a state to regulate prescription drug managers' pharmacy reimbursements (*Rutledge v. Pharm. Care Mgmt. Ass'n*, 140 S. Ct. 812 (2020)) appears to have triggered an increase in state PBM legislation. A more recent case from the 8th US Circuit Court of Appeals may accelerate this trend (*Pharm. Care Mgmt. Ass'n v. Wehbi*, No. 18-2926 (8th Cir. Nov. 17, 2021)). Employers may also see their insured plans subject to state laws requiring pharmacy coupons to accumulate against a participant's cost sharing.

COVID-19

COVID-19 has implications beyond paid leave. For example, a pending New York bill (<u>A 227</u>) would require insured health plans to use a specific formula for reimbursing any necessary (including COVID-19) vaccination costs. California law (<u>2021 Ch. 729</u>, SB 510) already requires insured health plans to cover COVID-19 diagnostic and screening tests with no patient cost sharing. This mandate includes employment-related screening, which is broader than the federal requirement under the Families First Coronavirus Relief Act (FFCRA) (<u>Pub.</u> L. No. 116-127) and CARES Act.

Employers may have to pay for COVID-19 tests under certain state wage and hour laws. For example, several states have long required employers to cover the costs of tests that are a condition of employment. As the need for testing increases, more states may mandate employers to pay for COVID-19 testing.

Although the federal Occupational Safety and Health Administration (OSHA) has withdrawn its COVID-19 vaccination and testing emergency temporary standard (ETS) for private-sector employers with 100 or more employees, some states may impose a similar standard. Twenty-one states and Puerto Rico have OSHA-approved plans applicable to all employers (private and public), while five more states and the US Virgin Islands have OSHA-approved plans covering only governmental employers, according to a Congressional Research Service summary. These jurisdictions can impose workplace requirements on major COVID-19 issues, like vaccines, testing, face coverings and reporting. For example, Cal/OSHA's FAQs require California employers to cover periodic testing at no cost to employees. Governmental employers in states without an OSHA-approved state plan are not subject to OSHA standards.

Vaccination status continues to be a polarizing topic. Some states have imposed mandates for certain workforce segments (e.g., healthcare, long-term care, school or state government

employees), while other prohibit such mandates, as illustrated in this <u>Kaiser Family</u> Foundation summary.

Prescription drugs

The US Supreme Court's *Rutledge* decision has had a lasting ripple effect. That decision upheld an Arkansas PBM law against an ERISA preemption challenge. Late last year, an appellate decision upheld part of North Dakota's PBM law (ND Laws §§ 19-02.1-16.1 to 16.2), again rejecting an ERISA preemption challenge in the *Wehbi* case. Many states appear ready to restrict PBM activities, which could affect employers' plan design.

Legislative action is likely in these areas:

Provision	Description	Example of a pending bill
Any willing pharmacy	Often prohibits preferential treatment for affiliated pharmacies	Ohio, <u>HB 336</u>
Mail-order and steerage limitations	Commonly allow participants to have the same pricing at in-person pharmacies	Arizona, <u>SB 1161</u>
Maximum allowable cost (MAC)	Typically limits how a PBM can define MAC, often used to set reimbursement rates	Florida, <u>SB 742</u>
Drug affordability board	Typically empowers a nonelected board to set rates for high-cost drugs; already in place in a few states	Washington, <u>HB 1671</u>
Licensing	Can be a prelude to additional regulation	Vermont, <u>SB 238</u> , <u>HB 353</u>
Audit restrictions	Usually limit a PBM's ability to audit a pharmacy	Nebraska, <u>LB 767</u>
Specialty drugs	May limit the definition of specialty drugs, which are offered at higher cost sharing	Kentucky, <u>HB 457</u>

States have begun requiring that drug manufacturer assistance — often in the form of coupons — must accumulate toward the plan deductible and out-of-pocket maximum, with a deductible exception for HSA-eligible HDHPs. This trend should continue for insured plans. PBM laws often fail to specify whether the scope is limited to PBM activities for fully insured plans or also extends to self-funded plans; consult PBMs for clarity. In addition, employers may want to discuss potential impact of PBM-focused legislation with their PBM and medical third-party administrator (TPA) or insurance carrier.

Mental health parity

Federal restrictions on nonquantitative treatment limitations (NQTLs) for coverage of mental health and substance use disorders have prompted states to focus on mental health parity. Bills typically center on a specific behavioral health benefit. For example, a Colorado law (2021 Ch. 439, HB 1068) now requires fully insured coverage of an annual mental health wellness examination at no cost to the patient. Expect additional state legislative and regulatory action, particularly in the areas of autism and gender-affirming treatments.

Telemedicine

Lawmakers are prioritizing improved access to telemedicine this year, especially as the availability of virtual primary care grows. States have several levers to enhance telemedicine:

Provision	Example of a pending bill
Allows providers licensed in another state to provide services	Massachusetts, HB 2367
Expands permitted telemedicine technology to include audio-only services	Florida, <u>SB 312</u>
Removes in-person visit requirements before allowing a telemedicine visit with a physician	Vermont, <u>SB 205</u>
Requires reimbursement parity between in-person and virtual visits	Pennsylvania, SB 705
Mandates telemedicine coverage of services related to mental health and substance use disorders	California, <u>AB 935</u>

Last year, several states joined the <u>Psychology Interjurisdictional Compact</u> (PSYPACT), an interstate compact between states that facilitates telepsychology across state boundaries. To date, <u>28 states</u> have joined PSYPACT, with Wisconsin (<u>AB 537</u>) the most recent to do so. Another nine states have introduced legislation to enter PSYPACT: Connecticut, Florida, Idaho, Indiana, Massachusetts, Michigan, Rhode Island, South Carolina and Washington.

Coverage mandates

Among the coverage mandates likely to emerge for fully insured plans, a few types stand out:

- Financial caps on insulin coverage, including pumps, often on a first-dollar basis (with an exception for HSA-eligible HDHPs); see Delaware's recently enacted law (2021 Ch. 33, SB 107)
- Increased contraceptive coverage, particularly related to male contraception and duration of coverage; see New Jersey's recently passed law (2021 Ch. 376, SB 413)
- Expanded availability of fertility treatment for same-sex couples and singles

Single-payer initiatives are under consideration in California and New York. In California, <u>AB</u> <u>1400</u> ("CalCare") has reignited the debate over healthcare for all. Even though the bill died in February before reaching a floor vote, this issue may be revisited in the near future. In New York, some version of the New York Health Act (<u>SB 5474</u>) has been introduced in every legislative session since the early 1990s, but support is growing.

Paid leave

As states head into the third year of the COVID-19 health crisis, legislators are apt to continue expanding paid leave laws. As the COVID-19 emergency subsides, lawmakers may enact long-range measures for future emergencies rather than rely on the stop-gap approach of the past two years. Multistate employers grappling with the tangle of state paid leave laws will want to watch for new proposals, as well as updates to or expansion of existing laws. These employers will need to work toward a streamlined implementation process for a new or revised leave mandates.

Paid sick, COVID-19 and other paid leave accruals

Laws requiring employers to provide paid sick leave or other accrued paid leave may spread to more states during this year's legislative sessions. Additional provisions addressing paid leave for widespread contagions and other public health emergencies may become embedded in new or existing paid sick leave mandates. At least two states — <u>Colorado</u> and <u>New Jersey</u> — have already enacted such measures to prepare for future outbreaks.

PFML expansion

Paid family and medical leave (PFML) regulations in <u>Colorado</u> and <u>Oregon</u> will advance in 2022, as both states prepare to start collecting plan contributions in 2023. With federal paid leave proposals stalled, efforts to establish state PFML programs may gain more traction. States with existing programs may look to expand them, as <u>Rhode Island</u> recently did by increasing the maximum leave duration. California sought to increase benefit amounts in 2021 legislation (<u>AB 123</u>) and may make a similar attempt in 2022. In addition, programs may add the option of using PFML for public health emergencies and expand the list of family members, as <u>New York</u> has done.

Section 4

Federal regulatory outlook

The high level of federal enforcement activity in 2021 will likely continue into 2022. The 2021 Consolidated Appropriations Act (CAA) (Pub. L. No. 116-260) injected new life into mental health parity oversight, and IRS no longer provides good-faith relief for ESR reporting errors. DOL and the Office for Civil Rights (OCR) within the Department of Health and Human Services (HHS) have been increasingly vigilant about the privacy and security of health information. Additional guidance on wellness programs and Form 5500 could come out this year. Three high-profile regulatory developments for 2022 involve COVID-19-related group health plan requirements, transparency and surprise billing.

COVID-19 temporary coverage mandates and relief

Since the COVID-19 outbreak began, temporary coverage mandates and relief measures have impacted group health plans. Examples range from no-cost coverage for COVID-19 diagnostic testing to extended deadlines for COBRA elections and payments and special enrollment under the Health Insurance Portability and Accountability Act (HIPAA). Some changes apply only during the COVID-19 "public health emergency" (PHE). Others apply only during the COVID-19 "national emergency." And some have durations explicitly set by statute.

COVID-19 considerations for group health plans will continue throughout 2022, with the PHE, national emergency and related agency guidance still in place for now. Plan sponsors should watch for future agency guidance extending, modifying, or creating new COVID-19 relief for plans and/or participants. Employers should review the continuing coverage mandates, agencies' various forms of COVID-19 relief and related communications to plan participants. Some employers may want to continue certain benefit enhancements beyond the required coverage period, while others may want to revert to prepandemic terms. In any event, participant communications and plan documentation are essential.

Public health emergency

The HHS secretary has authority to determine when a PHE exists and may extend a PHE indefinitely in 90-day intervals. The COVID-19 PHE was first declared on <u>Jan. 31, 2020</u>, and has been <u>renewed repeatedly</u>, most recently on <u>Jan. 14, 2022</u>. The current PHE runs through April 15, 2022; however, PHE renewals could continue well into 2022, although recent reports contemplate an earlier expiration. HHS has <u>indicated</u> that it will provide 60 days' advance notice before terminating the PHE (or letting it expire).

During the COVID-19 PHE, the following changes apply:

• Free COVID-19 test coverage. Group health plans must cover COVID-19 diagnostic testing and related services without any participant cost sharing (including deductibles, copayments and coinsurance), prior-authorization requirements, or other medical-management standards, as long as a licensed healthcare or otherwise authorized provider deems the testing medically appropriate. As of Jan. 15, 2022, group health plans also must cover at least eight at-home over-the-counter (OTC) COVID-19 diagnostic tests per participant, beneficiary or enrollee in a 30-day period (or a calendar month)

without any participant cost sharing, prior-authorization requirements or other medical-management standards. In stark contrast to other COVID-19 tests, the OTC COVID-19 test coverage mandate does not require a participant to obtain an attending healthcare provider's order or undergo an individualized clinical assessment. The departments of Labor, Treasury and HHS issued several FAQs over the past two years to help employers comply with these requirements (see FAQs parts 42, 43, 44, 51 and 52). As discussed later in the *Litigation outlook* section, payment disputes over the COVID-19 test coverage mandate have landed in court.

- EAP COVID-19 testing services. An EAP may remain an excepted benefit even if the program adds coverage for COVID-19 diagnostic testing (FAQs Part 42, Q&A-11). This relief also applies during the COVID-19 national emergency period described below. To preserve an EAP's excepted-benefit status once the PHE and national emergency end, plan sponsors should amend plan terms to discontinue these COVID-19 services. Otherwise, the EAP might be deemed to provide "significant benefits in the nature of medical care," triggering certain group health plan requirements under HIPAA, ERISA, ACA and other laws.
- Stand-alone telehealth services. An employer may offer stand-alone telehealth to
 employees such as part-time or seasonal workers who are not eligible for other
 health coverage from that employer. During the PHE, the telehealth benefit is not subject
 to many group health plan mandates under ERISA, the ACA and other laws (e.g., firstdollar coverage of ACA-mandated preventive care) (FAQs Part 43, Q&A-14). As
 discussed earlier, employer groups are asking Congress to make this relief permanent.
- Advance notice of SBC changes not needed. The 60-day advance notice requirement for certain changes to a summary of benefits and coverage (SBC) is waived (FAQs Part 42, Q&A-9 and Q&A 14, and FAQs Part 43, Q&A-13).
- **Flexibility for grandfathered plans.** Grandfathered group health plans may maintain that status even if they later revoke benefits added during the PHE (FAQs Part 43, <u>Q&A-15</u>).
- Eased HIPAA privacy rules. Some HIPAA privacy rules particularly related to telehealth communications — are relaxed. HHS has confirmed that most inquiries about vaccination status do not trigger HIPAA privacy protections.

This <u>GRIST</u> discusses these federal health coverage requirements and flexibilities, implementation issues, and open questions.

National emergency and outbreak period relief

A national emergency differs from the PHE described above. Former President Donald Trump <u>declared</u> that the COVID-19 outbreak constituted a national emergency beginning March 1, 2020. President Joseph Biden <u>renewed</u> the national emergency declaration on Feb. 24, 2021, and <u>again</u> on Feb. 18, 2022.

While the COVID-19 national emergency continues, various federal agencies have authority to waive or modify certain requirements. During the COVID-19 national emergency, group health plans must extend certain participant deadlines that would have expired during the "outbreak period." The outbreak period began March 1, 2020, and will end 60 days after the end of the COVID-19 national emergency or other date announced by the enforcing

agencies. For example, if the national emergency expires on March 1, 2023, the outbreak period will end 60 days later on April 30, 2023.

IRS and DOL have issued relief easing other deadlines for health and other benefit plans and participants. (See this <u>GRIST</u> for more information about the outbreak period relief.) The national emergency and outbreak period relief extends:

- The 30-day period (or 60-day period in certain circumstances) to request special enrollment under HIPAA
- The 60-day period to elect COBRA continuation coverage, the time frame for making initial and ongoing COBRA premium payments, and the date for individuals to notify the plan about a COBRA qualifying event or a disability determination
- Deadlines for participants to file a benefit claim, appeal a denied claim, and request or perfect an external review of a denied claim (starting with 2022 plan years, external review includes many surprise medical bills)
 - The claim-filing deadline extension also extends the run-out periods for health flexible spending arrangements (general and limited-purpose).

In light of the ongoing national emergency, the applicable periods will be disregarded until the earlier of (i) one year from the date a particular individual or plan was first eligible for relief, or (ii) 60 days from the end of the COVID-19 national emergency (i.e., the end of the outbreak period). Once the relief expires, the paused periods for individuals and plans will resume.

First-dollar or predeductible telehealth coverage under HDHPs

As discussed <u>earlier</u>, temporary relief permitted HSA-qualifying HDHPs to cover telehealth and other remote care services on a predeductible basis, without jeopardizing an individual's eligibility to make or receive HSA contributions. The relief also allowed an otherwise HSA-eligible individual to receive coverage for telehealth and other remote care services from a stand-alone vendor outside of the HDHP before satisfying the HDHP statutory minimum annual deductible, without affecting eligibility for HSA contributions.

This relief was not tied to either the PHE or national emergency and expired — or will expire for some noncalendar-year plans — at the end of the plan year that started in 2021 (Dec. 31, 2021, for calendar-year plans). Unless Congress enacts new relief or IRS temporarily extends nonenforcement relief, HDHPs that took advantage of this relief should resume charging participants for any predeductible telehealth services that are not HSA-compatible.

OSHA's infectious disease rule

OSHA has been working since 2010 on a <u>proposed infectious disease rule</u>. This rule, which remains on the agency's latest regulatory agenda, could replace OSHA's COVID-19 vaccination and testing <u>ETS</u>, which was <u>withdrawn</u> after an unfavorable US Supreme Court ruling (<u>Nat'l Fed'n of Bus. v. OSHA</u>, Nos. 21A244 and 21A247 (US Jan. 13, 2022). The goal of the proposed rule is to protect employees in healthcare and other high-risk workplaces from infectious disease hazards. The rule would cover both long-standing diseases like tuberculosis, varicella (chickenpox and shingles), and measles, as well as new and emerging threats like COVID-19.

Rather than propose a regulation, OSHA is examining alternative control measures to protect employees from exposure to pathogens that can cause significant disease. Workplaces that might need such measures include healthcare, emergency response, correctional facilities, homeless shelters, drug treatment programs and other settings where employees face increased risk of exposure to potentially infectious people. A standard could also apply to laboratories handling materials that may contain pathogens, as well as pathologists, coroners' offices, medical examiners and mortuaries.

A proposed permanent regulation or standard could come out as early as April 2022.

Transparency

In 2022, plan sponsors need to focus on implementing of a number of new transparency requirements under the 2021 CAA and the <u>final transparency-in-coverage rules</u>. Some of the new requirements apply for 2022, while others are <u>on hold</u> or won't take effect until 2023. Plan sponsors that have not already done so should ensure compliance with each of these requirements — a job usually handled by the plan's carriers or TPAs.

Beyond imposing immediate compliance burdens, the transparency requirements should provide insights into the cost of coverage under group health plans and foster a more transparent healthcare marketplace. Greater transparency should help stakeholders — including employers — address wide price variations, reduce waste in the healthcare system and help individuals make informed choices about healthcare spending.

Machine-readable files

The most daunting new requirement for employers involves posting machine-readable files (MRFs) with a group health plan's in-network rates and out-of-network allowed amounts and billed charges. The files should provide unprecedented transparency, which could improve competition and flatten increases in healthcare costs.

The MRF requirement applies for plan years beginning on or after Jan. 1, 2022, but regulators are deferring enforcement until July 1, 2022. Plans with plan years beginning after July 1, 2022, must post files by the first day of the 2022 plan year. Plan sponsors should already be coordinating with vendors to ensure timely posting of the files, with monthly updates.

The MRFs are likely to contain massive amounts of raw data that most employees won't understand. However, experts are expected to aggregate and analyze data, allowing stakeholders — including employer plan sponsors — to be better informed when negotiating for benefits and services. Additional insight into anticompetitive behaviors in healthcare is also possible. Regulators haven't provided a clear set of recordkeeping rules for the files, which is a critical issue, given the storage space needed to archive them.

Compliance with the transparency-in-coverage rules presents challenges because group health plan sponsors typically don't have access to all negotiated prices and can't provide the transparency disclosures without input from the plan's insurer or TPA. Nonetheless, group health plans failing to meet the new transparency rules could face steep penalties of \$100/day per participant.

Limited compliance relief. The transparency-in-coverage rules offer some limited relief to sponsors in two situations:

- A safe harbor spares an employer with a fully insured group health plan from having to
 post the MRFs, 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. Carriers, however, may not be inclined to sign such an
 agreement.
- The 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 won't face penalties if the website hosting the files is temporarily inaccessible. In both cases, the plan must correct the problem as soon as practicable.

Prescription price reporting on hold. Although the rules call for the MRFs to include prescription drug prices, that requirement is on hold, pending further rule-making. Agencies are reviewing whether this requirement remains appropriate in light of the CAA's required reporting on pharmacy benefits and drug costs (described below).

Prescription drug reporting

Employers will need to coordinate with vendors to comply with extensive new prescription drug reporting required by the CAA. Plans should prepare to report 2020 and 2021 data by Dec. 27, 2022. An <u>interim final rule</u> and <u>technical guidance</u> explain how a plan's multiple vendors, such as TPAs and PBMs, will separately report data for the plan.

Regulators will aggregate the data for all plans and publish the information on the internet. The report should provide valuable information about competition and market concentration in the pharmaceutical and healthcare industries. Key data to report are:

- Number of participants and beneficiaries
- States in which the plan is offered
- 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the plan, including total paid claims for each drug
- 50 most costly prescription drugs for the plan by total annual spending, including the annual spending for each drug
- 50 prescription drugs with the greatest increase in plan expenditures year over year, including the change in amounts spent
- Total spending on healthcare services by plan, broken down by type of costs, including:
 - Medical costs
 - Hospital costs
 - Provider costs (primary care and specialty)
 - Rx drug costs (pharmacy and hospital)
 - Other medical (such as wellness)

- Average monthly premium paid by employers, participants and beneficiaries
- Prescription drug rebates by therapeutic class
- Prescription drug rebates for the top 25 drugs

Disclosures on health plan ID cards

Group health plan identification (ID) cards now must include new consumer-friendly information to help patients understand their coverage and reduce out-of-network bills. Employers should work with vendors to make sure that physical or electronic health plan ID cards include any applicable deductible or out-of-pocket maximum, along with a telephone number and website address for obtaining consumer assistance, such as information on hospitals and urgent care facilities that have a contractual relationship with the plan. Until regulations come out, agencies expect good-faith compliance beginning with the 2022 plan year.

Up-to-date provider directories

Beginning in 2022, group health plans must take specific steps to ensure that provider directories are easily accessible and up-to-date. In response to perceived widespread directory errors, new patient protections are available to participants who rely on faulty provider directories.

Employers will need to confirm that their group health plan vendor's public website provides an accurate, verified database containing directory information on each healthcare provider and healthcare facility with a direct or indirect contractual relationship with the plan. Group health plans also must prepare to respond to participant questions about a provider's network status. If the database incorrectly lists an out-of-network provider as in-network and a participant or beneficiary obtains items or services from that provider, the plan must limit cost sharing to the in-network amount and credit those amounts toward the in-network deductible or out-of-pocket maximum.

Regulators expect good-faith compliance beginning with the 2022 plan year until regulations come out. Nonetheless, employers should now review potential liabilities and indemnifications for directory errors.

Continuity-of-care requirements

When a patient's provider moves out of network, the 2021 CAA requires continuity of care so the patient can avoid paying out-of-network rates or switching providers in the middle of a course of treatment without adequate notice. While many plans already provided continuity of care, the CAA provision appears to be broader in scope.

If a provider contract is terminated or a plan terminates the network, a "continuing care patient" can continue plan benefits under the same terms and conditions for the earlier of 90 days or the date when the participant is no longer considered a continuing patient. This provision does not apply to for-cause terminations (for example, when a provider fails to meet quality standards or commits fraud). Plans terminating a provider contract must also provide notices to affected participants.

Regulators expect good-faith compliance beginning with the 2022 plan year until they issue regulations. Employers should review their plan's continuity-of-care provisions (if any) and determine whether to make changes to comply with the law.

Broker and consultant disclosures

Brokers and consultants expecting to receive at least \$1,000 for their services must disclose to group health plans all direct and indirect compensation in service contracts or arrangements entered into, extended, or renewed on or after Dec. 27, 2021. Plan fiduciaries will need to review those disclosures to ensure the compensation is reasonable.

Recent <u>guidance</u> says that covered service providers and plan fiduciaries should implement the <u>new disclosure requirements</u> using a good-faith, reasonable interpretation of the law, pending future guidance or rule-making. Regulators also said that they view similar disclosure requirements for pension plans as a good faith and reasonable step toward compliance for group health plans.

No gag clauses that prohibit sharing price and quality information

Group health plan sponsors will need to attest that none of their plan-related contracts with providers, provider networks or associations, TPAs, or other service providers offering access to a provider network has a prohibited type of gag clause. The ban applies to gag clauses that would directly or indirectly restrict the plan or insurer from doing any of the following:

- Providing provider-specific cost or quality-of-care information or data
- Electronically accessing deidentified claims and encounter data
- Sharing such information consistent with applicable privacy regulations

Regulators intend to issue additional guidance on how to submit these attestations. Plan sponsors should have legal counsel review any applicable contracts for gag clauses, particularly because attestations may need to be submitted — or at least preserved — in 2022.

Self-service cost transparency tool

Plans must prepare to offer a self-service cost transparency tool for 500 covered services and items for the 2023 plan year (and for all covered services and items by the 2024 plan year). Under the final transparency-in-coverage rules, this internet-based self-service tool must:

- Disclose personalized out-of-pocket costs for all covered healthcare items and services (with paper copies available on request)
- Give participants an estimate of their cost-sharing liability for any in- or out of-network provider, allowing them to compare costs before receiving medical care
- Enable searching by billing code, descriptive terms, in-network provider name and other relevant factors (such as geography)
- Track a participant's accruals toward any cumulative treatment limitations (like day or visit limits), deductibles and out-of-pocket maximums

Insured plan sponsors may also want to review with their carriers the impact on potential medical loss ratio (MLR) rebates. To encourage consumers to shop for better prices, the rule allows insurers to reduce MLR rebates if insured plans share cost savings with enrollees who choose less-expensive providers.

A similar CAA provision applies to plan years beginning on or after Jan. 1, 2022, although enforcement is delayed until the 2023 plan year. Regulators intend to propose rules aligning the CAA's price comparison tool with the existing self-service cost transparency tool, but adding the requirement to make the tool available by telephone.

Air ambulance reporting

Plans and insurers will have to submit air ambulance data for calendar-year 2022 by March 31, 2023, and data for calendar-year 2023 by March 30, 2024. Regulators have issued <u>proposed regulations</u> on air ambulance reporting and asked for comments on a number of issues; final regulations may come later this year. With this reporting, regulators hope to better understand the extent of claims filed for air ambulance providers.

Advance explanation of benefits (EOB)

Healthcare providers and facilities will have to provide group health plans a good-faith estimate of expected charges when an enrollee schedules a specific item or service. A group health plan that receives an estimate or an enrollee's request for such an estimate has to meet tight time frames to provide an advance EOB with detailed information about the plan's coverage of the scheduled item or service. The agencies are delaying enforcement of this provision pending publication of regulatory guidance.

Surprise billing

The No Surprises Act (NSA) (Title I of Pub. L. No. 116-260) took effect for providers and facilities on Jan. 1, 2022, and applies for group health plans years beginning on or after that date. The law protects patients from surprise out-of-network bills for emergency care and certain other medical services. Besides ensuring compliance for the 2022 plan year, employer plan sponsors should watch for the rollout of key NSA processes. For example, plan enrollees can use a new federal website and hotline to complain about surprise bills. These complaints could trigger agency enforcement action against health plans. Employer plan sponsors should also monitor the 2022 launch of the independent dispute resolution (IDR) process. The IDR process will resolve payment disputes between health plans and out-of-network providers for services protected from surprise billing. The outcome of these disputes will significantly impact the NSA's cost to health plans.

IDR begins

A key provision in the interim final regulations (IFRs) requires the IDR arbitrator to presume that the qualified payment amount (QPA) is the appropriate payment for an out-of-network provider. Complicated rules specify how to calculate the QPA, but it is generally derived from a health plan's contracted rates. The arbitrator can deviate from the offer closest to the QPA only after a clear demonstration that the value of the item or service is materially different from the QPA. If, as regulators envision, arbitrators routinely select the offer closest to the QPA, a group health plan's costs should be lower than if it routinely had to pay an amount closer to the billed charges. However, whether an arbitrator must give the QPA more weight than any other factor may change as regulators issue final rules and litigation unfolds.

Employers should ensure that their insurer or plan administrator develops an IDR strategy informed by the IDR results as they come into focus. Out-of-network providers will be monitoring IDR outcomes as well. If out-of-network providers find ways to convince arbitrators to deviate from the QPA, that strategy will likely proliferate.

NSA guidance beyond IDR

Regulators could issue additional surprise billing guidance to resolve operational issues or respond to stakeholder comments. Regulators sought comments on a wide range of surprise billing topics, such as whether surprise-billing protections should apply to care at urgent care centers and when a participant can consent to balance bills for services otherwise protected.

Litigation

Provider groups have filed multiple lawsuits asking the federal courts to invalidate the QPA presumption. As plan sponsors proceed with their NSA compliance efforts, they should simultaneously track this litigation and its impact on the IDR process and—potentially—IDR outcomes. For details, see the Surprise billing discussion in the *Litigation outlook* section.

Mental health parity

The CAA injected new life into mental health parity oversight, and health plan sponsors should expect more enforcement in 2022. A much-anticipated <u>report</u> on group health plan and insurer compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) detailed regulators' findings from 2021. The report focused on the newly required comparative analysis of nonquantitative treatment limitations (NQTLs). Notably, DOL is increasing staffing and resources to support these reviews.

Issues with NQTL comparative analyses

Flaws found in comparative analyses. The <u>2021 CAA</u> required agencies to deliver this annual report to Congress, with the first due by Dec. 27, 2021. During 2021, DOL requested comparative analyses from more than 150 plans and insurers. The Centers for Medicare and Medicaid Services (CMS) made similar requests to four nonfederal governmental plans and nine insurers. Interestingly, regulators found that all of the comparative analyses failed to pass muster when first received. The five main flaws were:

- 1. Failing to identify the benefits, classifications or plan terms to which the NQTL applies
- 2. Failing to describe how the NQTL is designed or applied in practice to mental health or substance use disorder benefits and medical/surgical benefits
- 3. Providing insufficient detail on the factors, sources and evidentiary standards used for the NQTL
- 4. Omitting any stringency analysis of how the factors, sources and evidentiary standards are applied
- 5. Generally failing to show parity in NQTLs in written plan terms and plan operations

When regulators make a final determination of noncompliance, the report must publicly identify the offending parties. While 45 plans and insurers have received preliminary determinations of noncompliance, the report did not list any offending parties since the

review process is ongoing. How the regulators will treat corrective actions in making final determinations is unclear. Final determinations of noncompliance likely will appear in the next report to Congress.

Areas of focus. The report provided valuable insights into current areas of MHPAEA focus for the agencies, which:

- Selected most organizations for review based on open investigations
- Found deficiencies in most reviews and a general lack of preparedness
- Are increasing staffing and resources to support these reviews
- Found many employers "erroneously assumed" that service providers had prepared or could prepare a compliant comparative analysis for the employer-sponsored plan

Common NQTLs raising parity issues. The regulators identified the 14 most common NQTLs causing problems:

- 1. Preauthorization/precertification
- 2. Network provider admission standards
- Concurrent care review
- 4. Limitations on <u>applied behavior analysis</u> and other treatments for autism spectrum disorders
- 5. Out-of-network reimbursement rates
- 6. Treatment plan requirements
- 7. Limitations on medication-assisted treatment for opioid use disorder
- 8. Provider qualification or billing restrictions
- 9. Limitations on residential care or partial hospitalization programs
- 10. Nutritional counseling limitations
- 11. Speech therapy restrictions
- 12. Exclusions based on chronicity or treatability of condition, likelihood of improvement, or functional progress
- 13. Virtual or telephonic visit restrictions
- 14. Fail-first or step therapy requirements

Enforcement ongoing. Tellingly, the report did not mention good-faith efforts or other types of relief, despite otherwise providing a large amount of practical information. Finally, the report signaled two additional areas of future focus related to mental health parity: network adequacy and provider directory accuracy.

More parity developments coming

The CAA requires DOL, Treasury and HHS to finalize all NQTL guidance and regulations by June 2022. The departments have indicated that they intend to update the <u>self-compliance</u> tool (last updated before the CAA was enacted), continue <u>outreach</u> and <u>education</u> efforts, and increase enforcement activity through the CAA review process as well as litigation.

Starting this year, the annual report will be due on Oct. 1, and how these reviews develop will be interesting to see. As noted <u>earlier</u>, if some version of the BBBA is enacted this year, the legislation could include a provision permitting DOL to impose civil penalties for MHPAEA violations.

Plan sponsors need to have the NQTL comparative analysis ready to provide to DOL during an audit or investigation or to participants on request. Employers should review the current version with legal counsel for problems identified in the MHPAEA report and address any plan design or administrative changes needed.

Litigation

As employers continue to grapple with MHPAEA compliance and agency enforcement actions, lawsuits from plan participants and beneficiaries alleging wrongful denial of mental health and substance use disorder claims continues to be a real risk. For details, see the behavioral health benefits discussion in the *Litigation outlook* section.

ESR reporting

Deadline to send statements to individuals extended. IRS no longer provides good-faith relief for ESR reporting errors, but <u>proposed IRS regulations</u> provide mixed news for employers in 2022. The good news is that the deadline for providing Forms 1095-B and 1095-C to employees and participants will be March 2 instead of Jan. 31. (Reporters still must meet the Feb. 28 IRS deadline for paper filings — March 31 for electronic submissions — accompanied by the appropriate 1094 transmittal form.)

No more good-faith relief for flawed filings. The bad news is that the good-faith relief for inaccurate or incomplete filings — which first applied for the initial 2015 reporting year — is no longer available for reports filed in 2022 and later years. The proposed regulations did not extend transitional penalty relief for filings that have "missing and inaccurate taxpayer identification numbers and dates of birth, as well as other information required on the return or statement," despite good-faith efforts to complete correctly. IRS signaled this change in Notice 2020-76, saying 2020 would be the last year of transitional relief for reporting mistakes.

Reasonable-cause penalty waiver still available. Nevertheless, employers and insurers that fail to meet the reporting requirements may still be eligible for penalty relief if IRS determines the failure satisfies the standards for a reasonable-cause waiver under Internal Revenue Code (IRC) Section 6724. As a result, employers need to be extra careful in complying with the applicable rules and promptly correcting mistakes when discovered.

Alternative for furnishing some MEC statements. IRS also has proposed an alternative method for furnishing MEC individual statements, similar to the method first allowed in Notice 2020-76. Employers could use the alternative method for part-time staff, COBRA enrollees, retirees or other nonfull-time employees who participate in a plan. Under that alternative, instead of sending out statements to those individuals, a MEC reporter can post a website

notice informing those individuals that they can obtain a copy of the statement by sending a request to a physical or email address. Reporters must provide statements within 30 days of receiving a request, but electronic delivery is an option if certain conditions are met.

ESR penalties remain a risk. As always, the specter of an ESR penalty hangs over the reporting process. Systemic mistakes or incorrect reporting can result in large penalties through the Letter 226J process. In addition, late reporting to IRS can result in penalties of up to \$280 per return through the Notice 972CG process. Applicable large employers should have one or more employees who are very familiar with the reporting instructions and work with outside experts to ensure compliance.

Privacy and cybersecurity

DOL and HHS's OCR have been increasingly vigilant about enforcing HIPAA rules related to the privacy and security of protected health information (PHI). Recent OCR enforcement activity has focused on individuals' right to access records containing PHI. OCR has stepped up enforcement and provided additional guidance on cybersecurity — seen as one of the top threats to PHI. OCR's recent <u>cybersecurity newsletter</u> concentrates on issues with legacy computer systems and the use of patches.

Given that most systems are maintained by third-party HIPAA business associates, employers sponsoring group health plans must actively monitor cybersecurity compliance. This concern is heightened by the general trend toward cloud-based solutions.

On a related front, the National Institute of Standards and Technology (NIST) last year requested public comments in an effort to update its 2008 HIPAA security rule guidance. If this update occurs in 2022, group health plans will likely need to review and update their security policies and procedures and consider conducting a new risk assessment.

Employers should also focus on internal controls. With the potential for an OCR audit or investigation always looming, a critical HIPAA task is to perform a comprehensive risk assessment of all systems containing electronic PHI.

In 2021, DOL issued <u>informal cybersecurity guidance</u> on the overall fiduciary duty to prudently operate all ERISA plans, including the duty to prudently select and monitor service providers. While the guidance was directed primarily at retirement plans, DOL left open the possibility of future guidance targeting group health plans.

Wellness

Since the December 2017 decision that partially vacated the Equal Employment Opportunity Commission (EEOC)'s wellness program rules (*AARP v. EEOC*, No. 16-2113 (D.DC Dec. 20, 2017)), employers have lacked complete guidance on the financial limits for wellness incentives. The Americans with Disabilities Act (ADA) requires that workplace wellness programs must be "reasonably designed" and "voluntary," and a similar set of rules applies under the Genetic Information Nondiscrimination Act (GINA). EEOC's concern is that wellness incentives should "reasonably" promote health without being so significant that they make program participation coercive.

Last year, EEOC proposed and then withdrew regulations that would have aligned the ADA and GINA wellness rules with the <u>HIPAA wellness rules</u>. EEOC may issue revised wellness rules this year, but the timing is far from certain.

Form 5500 reporting

<u>Form 5500</u> and its <u>instructions</u> underwent <u>changes</u> for the 2021 plan year. These changes relate to defined contribution multiple-employer plans, as required by the Setting Every Community Up for Retirement Enhancement (SECURE) Act of 2019 (<u>Div. O of Pub. L. No. 116–94</u>). Notably, DOL affirmed that multiple employer welfare arrangements (MEWAs) must continue to report participating employer information for the 2021 plan year, despite stakeholder requests to eliminate that reporting.

All of these changes are part of a larger effort to revise Form 5500 for the 2022 plan year. In the fall 2021 <u>regulatory agenda</u>, DOL said it intends to issue more changes — including some affecting group health plans — with the goal of "modernizing" requirements to make the data more mineable. However, these changes appear unlikely to be finalized before 2022 plan-year reporting begins.

Nondiscrimination issues

In 2021, HHS <u>indicated</u> that it plans to replace a <u>2020 final ACA Section 1557 rule</u>, so the ban on sex discrimination would again encompass sexual orientation and gender identity bias. Section 1557, which applies to entities — including group health plans — that receive HHS funds, prohibits discrimination in healthcare activities and programs on the basis of race, color, national origin, sex, age and disability. The 2020 final rule is subject to ongoing litigation.

The 2021 announcement aligns with the Obama administration's interpretation of federal laws banning sex discrimination — a position adopted even before the Supreme Court ruled that Title VII of the 1964 Civil Rights Act bars discrimination on the basis of sexual orientation and gender identity (*Bostock v. Clayton Ctv., GA*, 590 US 140 (2020)). Accordingly, the 2016 final Section 1557 rule prohibited those forms of bias and required nondiscrimination notices and taglines in significant communications. The rule also required covered entities to provide coverage of transgender services.

The Biden administration last year <u>announced</u> a return to the 2016 rule's interpretation of sex discrimination. HHS this year <u>plans</u> to reissue a Section 1557 rule, which may include other provisions similar to the 2016 version and will likely have a broad reach. For example, retiree medical plans that receive Medicare Part D <u>retiree drug subsidy</u> could be considered Section 1557 covered entities.

In addition, the <u>proposed 2023 Notice of Benefit and Payment Parameters</u> (NBPP) would prohibit public exchanges, as well as certain insurers, agents and brokers from discriminating against consumers on the basis of sexual orientation and gender identity.

When the proposed Section 1557 regulations and the final NBPP are issued later this year, plan modifications may be necessary. Employers should ensure their health plans cannot be construed as discriminating on the basis of sexual orientation or gender identity. Particular focus should center on these areas (identified in the proposed NBPP) that may present future ligation and/or regulatory risks:

- Transgender benefit exclusions or limitations, for example, on gender-affirming surgery and hormone therapy
- Age-based limitations for hearing aids, autism spectrum disorder and fertility treatment

- Adverse tiering of prescription drugs (majority of drugs for certain medical conditions placed in high cost tier, discriminates against those with high-cost condition)
- Diagnosis-based coverage limits on foot care (particularly related to diabetes)
- Discriminatory marketing practices

Earlier this year, DOL, HHS and IRS also held a <u>listening session</u> on the ACA's provider nondiscrimination provisions under <u>Section 2706(a)</u> of the Public Health Service Act. This is likely a prelude to a proposed rule, perhaps later this year.

Litigation

Each version of the Section 1557 implementing regulations and HHS's enforcement policy are the subject of ongoing litigation. Meanwhile, plan participants and beneficiaries continue to bring lawsuits alleging Section 1557 discrimination by employer group health plans. For details, see the <u>Section 1557 nondiscrimination</u> discussion in the *Litigation outlook* section.

Section 5

Litigation outlook

This year will bring new legal disputes between payers and providers over payments for COVID-19 testing. In addition, challenges to federal COVID-19 vaccination requirements for various workforces will continue. Other ongoing litigation of interest to employer group health plans involves the surprise billing rules, behavioral health coverage, prescription drug benefits, dialysis coverage and state restrictions on abortion access.

ACA-related challenges also will continue, even though the US Supreme Court last year ruled against a constitutional challenge to the individual health coverage mandate in a case that could have invalidated the entire ACA (*California v. Texas*, No. 19-840 (US June 17, 2021)). Plan participants continue to bring discrimination claims under Section 1557, while lawsuits challenging HHS's authority to enforce the law and implementing regulations carry into 2022. Legal challenges to the contraceptive coverage requirement have expanded to include the broader preventive care coverage mandate. Actions involving the provider conscience and AHP rules may restart this year unless the Biden administration decides not to support either rule. However, litigation over the group health plan price transparency rules fizzled after the administration delayed enforcement of the requirements related to prescription drug costs.

COVID-19 testing payment disputes

Last year, payers and providers sued over payments for COVID-19 testing of health plan participants. This year, payers have to answer to providers alleging wrongful denial of claims (see, e.g., *Diagnostic Affiliates of Northeast Houston v. United Healthcare Servs.*, No. 21-cv-0131 (N.D. TX Jan. 18, 2022)). On the other side, providers have to defend against claims of price gouging (see, e.g., *Premera Blue Cross v. GS Labs*, No. 2:21-cv-01399 (W.D. WA filed Oct. 14, 2021)).

More cases like these are likely since the FFCRA requires group health plans to cover the cost of COVID-19 diagnostic testing and related services, but the CARES Act doesn't specify a reimbursement amount for out-of-network providers. Instead, the law requires covered plans to pay those providers' publicly listed cash price or negotiate a lesser payment.

Payer groups continue to lobby Congress to protect against COVID-19 test overcharges. In the meantime, employer sponsors may want to review TPA processes and payments for out-of-network COVID-19 test claims and watch for developments in these cases.

COVID-19 vaccination workforce requirements

After weeks of legal ping-pong, OSHA this year <u>withdrew</u> its COVID-19 <u>ETS</u> for private-sector employers with 100 or more employees. The ETS had required employers to develop, implement and enforce a policy requiring either COVID-19 vaccinations for all workers or weekly testing of any unvaccinated worker.

The rule's withdrawal came after a US Supreme Court order barred enforcement of the ETS while legal challenges to it continue (*Nat'l Fed'n of Bus. v. OSHA*, Nos. 21A244 and 21A247

(US Jan. 13, 2022)). The decision significantly dimmed any chance of the ETS ultimately surviving a Supreme Court review of the agency's authority to impose the standard.

Nevertheless, the ETS serves as a proposed OSHA rule for a permanent (nonemergency) standard. If OSHA publishes a final rule requiring employers in general to adopt vaccine or testing policies — for COVID-19 or any other infectious disease — the rule will likely face court challenges.

Healthcare workers

A CMS <u>interim final rule</u> (IFR) requiring COVID-19 vaccinations for employees in healthcare settings that receive federal funds fared better before the Supreme Court. The court ruled that CMS could enforce the IFR while legal challenges continue (<u>Biden v. Missouri</u>, Nos. 21A240 and 21A241 (US Jan. 13, 2022)).

If the IFR again appears before the Supreme Court, whether CMS will prevail is unclear since the January order was narrowly decided. Timing is also unclear. Although challengers to the rule may want to expedite the cases in the lower courts, the Supreme Court may not be in a rush to hear any final appeals.

OHSA also is finalizing a permanent COVID-19 healthcare standard, based on the healthcare ETS that expired in late December 2021. That ETS required many safety measures but stopped short of mandating vaccines for healthcare workers. Several labor unions have sued OSHA seeking to revive the ETS until the agency finalizes the permanent rule later this summer or fall (*Nat'l Nurses United v. OSHA*, No. 22-1002 (D.C. Cir. filed Jan. 5, 2022)).

The healthcare ETS did not face employer opposition when issued in June 2021, but Arizona, South Carolina and Utah (three of the 21 states with OSHA-approved state plans) failed to adopt it or more protective regulations, as required by law. A permanent standard — even one without a vaccine mandate — could face opposition from some states with OSHA-approved plans.

Federal contractors and subcontractors

The federal contractor vaccine mandate is currently enjoined nationwide because of legal challenges brought in multiple federal district courts. The federal government is in the process of appealing these decisions in the 5th, 6th, 8th and 11th circuits. Decisions in these courts may not come before summer.

In the meantime, federal contractors do not have to comply with the vaccine mandate, but employers that have already entered into agreements on COVID-19 workplace safety measures may need to consider whether those agreements are still enforceable. As a reminder, President Biden's September 2021 Executive Order 14042 directs executive departments and agencies to ensure that covered contracts and "contract-like instruments" require contractors and subcontractors to comply with the Safer Federal Workforce Task Force guidance. That guidance requires all covered contract employees to be fully vaccinated against COVID-19.

Surprise billing

Healthcare provider groups have filed multiple cases challenging certain provisions in the surprise billing rules (see, e.g., *Texas Med. Ass'n v. HHS*, No. 6:21-cv-00425 (E.D. TX filed

Oct. 28, 2021); <u>Ass'n of Air Med. Servs. v. HHS</u>, No. 1:12-cv-03031 (D. DC filed Nov. 16, 2021); <u>Am. Med. Ass'n v. HHS</u>, No. 1:21-cv-03231 (D. DC filed Dec. 9, 2021); <u>Am. Soc'y of Anesthesiologists v. HHS</u>, No. 1:21-cv-06823 (N.D. IL filed Dec. 22, 2021); and <u>Georgia College of Emergency Physicians v. HHS</u>, No. 1:21-cv-5267 (N.D. GA filed Dec. 23, 2021)). If these challenges succeed, employer plans could see increased costs. As the litigation continues, surprise billing compliance obligations remain in place for employer-sponsored group health plans.

Medical providers and facilities take issue with the presumption in the <u>IDR interim final rule</u> (IFR) that the qualifying payment amount (QPA) is the correct reimbursement amount for out-of-network services. Provider groups argue that the law lists many factors that an arbitrator may consider, such as the out-of-network provider's experience and training, and does not give presumptive weight to the QPA. Amicus briefs on behalf of <u>employer-sponsored plans</u> and <u>insurers</u> support deference to the QPA in IDR determinations. The court in *Texas Medical Association v. HHS* agreed with providers and <u>vacated</u> select provisions of the IFR, in effect removing the presumption in favor of the QPA. An appeal is expected. One of the provider lawsuits also argues that entire sections of the No Surprises Act are unconstitutional, including the provisions establishing the IDR process and banning balance billing for emergency and nonemergency services (<u>Haller v. HHS</u>, No. 2:21-cv-7208 (E.D. NY filed Dec. 31, 2022).

If the provider lawsuits succeed in giving arbitrators more flexibility to deviate from the QPA, the amount health plans must pay out-of-network providers for protected services could increase. The IDR system also could become more expensive if providers increasingly use the process to get higher out-of-network payments.

Behavioral health benefits

As federal MHPAEA enforcement for employer group health plans increases, private actions brought by plan beneficiaries show no sign of lessening. Individuals continue to file MHPAEA lawsuits, challenging coverage denials for wilderness therapy, residential treatment, outpatient psychotherapy and applied behavioral analysis (ABA) therapy, among others. The most common behavioral health conditions in these cases include major depression, eating disorders, autism spectrum disorders and attention-deficit/hyperactivity disorder (ADHD). Private actions account for the majority of MHPAEA cases, which challenge not only coverage terms but also the way plan terms are applied.

Class actions and remedies

This year may bring an increase in proposed class actions seeking to have denied behavioral health claims reprocessed. These actions involving mental health and substance use disorder benefits often allege ERISA fiduciary duty violations by claim administrators. Specifically, the plaintiff class (or proposed class) alleges the claim administrator uses overly restrictive plan coverage guidelines — out of line with generally accepted standards of care — to avoid paying for mental health and substance use disorder treatments (see, e.g., Berceanu v. UMR Inc., No. 3:19-cv-00568 (W.D. WI Dec. 15, 2021); and Beach v. United Behavioral Health, No. 3:21-cv-08612 (N.D. CA filed Nov. 4, 2021)).

One case also alleges the plan impermissibly required accreditation standards for residential treatment facilities — without a comparable requirement for rehabilitation facilities — in violation of MHPAEA (*Deighton v. Aetna Life Ins. Co.*, No. 2:21-cv-07558 (C.D. CA filed Sept. 21, 2021)). In another case, an appellate court allowed a MHPAEA challenge to the

exclusion of speech therapy for autism to proceed, but affirmed the dismissal of the fiduciary breach claim (*N.R. v. Raytheon Co.*, No. 20-1639 (1st Cir. Jan. 31, 2022)).

These cases challenging plan coverage terms all seek to have denied claims reprocessed, much like the watershed case <u>Wit v. United Behavioral Health</u> (No. 14-cv-02346 (N.D. CA, Nov. 3, 2020)). In that case, a federal district court ordered the reprocessing of more than 67,000 behavioral health claims. The order is currently on appeal, and DOL has filed an <u>amicus brief</u> supporting plan participants' and beneficiaries' right to challenge the claim denials under ERISA (*Wit v. United Behavioral Health*, No. 20-17363 (9th Cir.)).

Prescription drug benefits

Group health plans and participants have asked the US Supreme Court to find that TPAs and PBMs act as ERISA plan fiduciaries when setting prescription drug prices (<u>John Doe 1 v. Express Scripts</u>, No. 21-471 (US filed June 25, 2021)). The case is about a 10-year deal between Anthem and Express Scripts, which gave Express Scripts discretion to set prescription drugs prices for Anthem's customers. Five years into the deal, Anthem alleged that Express Scripts grossly inflated those prices.

The federal district court declined to hold either company liable as an ERISA fiduciary, and the 2nd US Circuit Court of Appeals affirmed. The Supreme Court hasn't decided whether to hear the appeal. This case is part of a continuing push to hold TPAs and PBMs accountable as ERISA fiduciaries.

Mail-order pharmacy benefits

Certain mail-order pharmacy benefit designs could trigger discrimination claims this year. Last December, a case involving an allegedly discriminatory mail-order drug policy was settled just prior to arguments before the US Supreme Court. In <u>CVS Pharmacy, Inc. v. John Doe</u> (No. 20-1374 (US filed March 26, 2021)), the petitioners asked the court to decide whether a disparate-impact claim of disability discrimination could be brought under Section 504 of the Rehabilitation Act and, by extension, Section 1557 of the ACA.

In this case, an employer-sponsored group health plan applied in-network rates for specialty drugs only if delivered by mail or drop-shipped to a local CVS store for pickup. Plaintiffs alleged this policy had a discriminatory impact on people with disabilities — specifically, people with HIV/AIDS — by requiring participants who prefer other pharmacies to pay higher out-of-network rates.

The US Justice Department filed an <u>amicus brief</u> arguing that these laws prohibit both unintentional (aka disparate impact) and intentional disability discrimination, and liability attaches if meaningful access to a benefit is denied. Employers may want to review mailorder requirements in their pharmacy benefit plans to identify potential access issues for plan participants.

Dialysis benefits

The US Supreme Court will hear a case alleging a plan's dialysis benefit violates the Medicare Secondary Payer Act (MSPA) and rules addressing end-stage renal disease (ESRD). In *Marietta Mem'l Hosp. Emp. Health Benefit Plan v. DaVita, Inc.* (No. 20-1641 (US filed May 21, 2021)), the plan covers all dialysis providers as out-of-network, limits reimbursement to 87.5% of Medicare and subjects dialysis charges to heightened scrutiny.

The court will consider whether these provisions violate the MSPA by differentiating ESRDenrollees, causing them to switch from the employer plan to Medicare for better dialysis coverage.

The court is scheduled to hear the case on March 1 and will likely issue an opinion before the end of June. The outcome could have a significant impact on dialysis benefits for ESRD participants in employer group health plans.

Restrictions on abortion access

State laws restricting access to abortion are on the national stage this year in more ways than one. Texas's law (2021 SB 8) banning abortions after six weeks of pregnancy remains in effect, with procedural obstacles thus far preventing a legal review under the US Constitution and US Supreme Court precedents (*Whole Women's Health v. Jackson*, No. 21-463 (US Dec. 10, 2021).

The US Supreme Court may ultimately address Texas's restrictions on a woman's access to abortion later this year and will likely be influenced by the court's decision on the continued viability of the precedent set in *Roe v. Wade* (410 US 113 (1973)). The justices are currently considering whether to uphold that precedent or let Mississippi's more restrictive abortion law (2018 HB 1510) stand (*Dobbs v. Jackson Women's Health Org.*, No. 19-1392 (US filed June 15, 2020)).

If these restrictive abortion laws survive legal challenges, abortion services may become essentially unavailable in some states. Employer group health plans concerned about ensuring equal access to abortion services for plan participants wherever they live should consider (in consultation with tax counsel) travel and lodging benefits for participants required to travel to access an abortion.

Federal right to abortion

On Dec. 1, 2021, the US Supreme Court heard arguments in *Dobbs v. Jackson Women's Health*, which could overturn the nearly 50-year-old standard set by *Roe*. In *Roe* and later affirmed in *Planned Parenthood of Southeastern PA v. Casey* (505 US 833 (1992)), the court held that states could not ban abortion before a fetus is viable outside the womb — approximately 24 weeks of pregnancy. *Dobbs* involves Mississippi's law banning abortions after 15 weeks of pregnancy.

During arguments, a majority of the court appeared willing to undo the standard announced in *Roe* in favor of allowing states to ban abortion prior to viability. A decision in *Dobbs* is expected before the end of June.

State laws restricting abortion access

Access to abortion services is most limited in Southern and Midwestern states. If the Supreme Court overturns *Roe*, at least 12 states have "trigger laws" banning all or nearly all abortions that will take effect automatically. At least 13 states have laws banning abortion at six or eight weeks of pregnancy that courts have blocked from taking effect, citing Supreme Court precedent. Those laws could take effect with a court order lifting the earlier block.

In addition, a number of states have already taken steps to limit access to medications that induce abortion. Late in 2021, the Food and Drug Administration (FDA) <u>removed</u> the inperson dispensing requirement for abortion medications, which are available through the first

10 weeks of pregnancy from a certified healthcare provider, including a pharmacist. At least 19 states have made it illegal to send or receive abortion medications via mail, restricted access to the drugs after seven weeks of pregnancy and/or prohibited access via telehealth. Thirty-three states allow only physicians to provide abortion pills.

ERISA preemption

State efforts to enact legislation regulating some aspect of employee benefits likely will spur additional ERISA preemption challenges in the coming year. Besides further challenges to state restrictions on PBM contracts, two additional cases could impact plan sponsors in other jurisdictions if the laws are upheld:

- The US Supreme Court may take up a Seattle health coverage mandate for hotel workers (Mun. Code ch. 14.28) that the 9th Circuit upheld (<u>ERISA Indus. Comm. v. Seattle</u>, No. 2:18-cv-01188 (9th Cir. March 17, 2021); <u>No. 21:1019</u> (US filed Jan. 19, 2021). A denial by the high court or a win for Seattle could spark multiple state and municipal laws targeting specific industries or sectors.
- If Washington's long-term care plan (WA Rev. Code <u>ch. 50B.04</u>) withstands the current preemption challenge (<u>Pacific Bells, LLC v. Inslee</u>, No 2:21-cv-01515 (W.D. WA filed Nov. 9, 2021)), other states may consider similar programs.

COBRA class actions

Lawsuits challenging the sufficiency of COBRA notices will continue in 2022. For at least the last five years, COBRA election notices have triggered lawsuits claiming the employer failed to follow <u>DOL requirements</u>. A common complaint is that the notice failed to name the health plan administrator, as required by law (see, e.g., <u>Crockett v. Gen. Motors</u>, No. 2:22-cv-10240 (E.D. Mich. filed Feb. 7, 2022); and <u>Stubbs v. Wells Fargo</u>, No. 8:22-cv-00104 (M.D. Fla. filed Jan. 12, 2022)).

Recent lawsuits allege the COBRA notice fails to include information about the <u>federally subsidized COBRA premiums</u> temporarily available under ARPA or the <u>extension of election and payment deadlines</u> during the COVID outbreak period (see, e.g., <u>Johnson v. McDonald's Corp.</u>, No. 1:21-cv-24339 (S.D. FL filed Dec. 15, 2021); and <u>Vasquez v. Wal-Mart Stores</u>, No. 2:21-cv-00848 (M.D. FL filed Nov. 10, 2021)). (For more details on the outbreak period relief, see the earlier <u>discussion</u>)

With class certification, daily statutory penalties and attorney's fees sought in these cases, the potential financial liability should motivate employers to review their COBRA notices.

Section 1557 nondiscrimination

Expect HHS to issue a revised ACA Section 1557 rule this year banning healthcare providers and programs that receive federal funding from discriminating against people because of their sexual orientation or gender identity. This will be the third version of this rule. The two previous iterations are both subject to ongoing legal challenges. In addition, a decision from the US Supreme Court is expected this spring in a case asking the court whether damages for emotional distress can be awarded under Title VI of the 1964 Civil Rights Act — and by extension, the Rehabilitation Act and Section 1557 (*Cummings v. Premier Rehab Keller*, No. 20-219 (US filed Aug. 21, 2021). The court's ruling may have bearing on discrimination claims brought under Section 1557 by individuals, which show no signs of slowing down.

Legal challenges to the Section 1557 rules

The <u>2016 Section 1557 rule</u> generated several legal challenges to its definition of "sex," which included gender identity, sex stereotypes and termination of a pregnancy. The Trump administration's <u>2020 revised rule</u> narrowed the regulation's scope and eliminated the expanded protections against sex discrimination detailed in the 2016 rule.

Two federal district courts issued preliminary injunctions blocking parts of the 2020 rule that limited the ban on sex discrimination (*Whitman Walker Clinic, Inc. v HHS*, No. 1:20-cv-01630 (D. DC Sept. 2, 2020); and *Walker v. Azar*, No. 1:20-cv-02834 (E.D. NY Aug. 17, 2020)). Those cases are currently on hold at the request of the Biden administration. A number of other federal district court cases challenging the slimmed-down protections in the 2020 rule are also on hold (*New York v. HHS*, No. 1:20-cv-05583 (S.D. NY filed July 20, 2020); *Boston Alliance of Gay, Lesbian, Bisexual and Transgender Youth v. HHS*, No. 1:20-cv-11297 (D. MA filed July 9, 2020); *Chinatown Service Center v. HHS*, No. 1:20-cv-00331 (D. DC filed Feb. 5, 2021)). Many of these cases may be rendered moot if the revised rule expected this spring reinstates or goes beyond the 2016 rule's protections against sex discrimination.

Legal challenges to agency authority

In May 2021, HHS <u>announced</u> it would interpret and enforce Section 1557 to prohibit discrimination based on sexual orientation and gender identity. Three lawsuits challenging this reading of the statute are underway (<u>Am. College of Pediatricians v. Becerra</u>, No. 21-cv-0195 (E.D. TN filed Aug. 26, 2021); <u>Christian Emp'rs Alliance v. EEOC</u>, No. 21-cv-00195 (D. ND filed Oct. 18, 2021); and <u>Neese v. Becerra</u>, No. 21-cv-0163 (N.D. Tex filed Aug. 25, 2021)).

In addition, orders from two federal courts blocking HHS from enforcing this interpretation against thousands of religiously affiliated providers and members of certain medical and employer groups are on appeal, with decisions expected this year (*Franciscan Alliance v. Becerra*, No. 21-11174 (5th Cir.); and *Religious Sisters of Mercy v. Becerra*, No. 21-1890 (8th Cir.)). The district court orders will stay in place unless overturned, regardless of changes to the implementing regulations the Biden administration may make this spring.

Individual actions

As various iterations of regulations implementing Section 1557 and HHS's enforcement authority face ongoing legal challenges, individual actions continue to allege discrimination in violation of the law. A common complaint against state health plans and private employer plans is wrongful denial of transgender care.

Contraceptive coverage

Look for ongoing litigation over the scope of religious and moral exemptions to the ACA's contraceptive coverage mandate. In 2020, the US Supreme Court held that agencies had the authority to create the exemption, but the court stopped short of ruling on whether the Trump-era rules were arbitrary and capricious (*Little Sisters of the Poor v. PA*, 140 S. Ct. 2367).

Cases challenging the rules continued in lower courts until they were put on hold in early 2021 when the administration changed (*Massachusetts v. HHS*, No. 21-1076 (1st Cir.); *California v. HHS*, No. 4:17-cv-5783 (N.D. CA); *Pennsylvania v. Biden*, No. 2:17-cv-04540

(E.D. PA); and *Irish 4 Reproductive Health v. HHS*, No. 3:18-cv-491 (N.D. IN)). On Aug. 16, 2021, regulators announced their intention to tackle amending the Trump-era rules within six months (ACA implementation FAQs, Part 48).

Once the rule-making process begins, the courts may review whether to continue the stays, dismiss the cases or allow the litigation to continue. In any case, the Biden administration's revisions to the contraceptive coverage rules are likely to generate new litigation.

Preventive care mandate

Expect a federal district court decision on a constitutional challenge to the ACA preventive care mandate (*Kelley v. Becerra*, No. 20-cv-00283 (N.D. TX filed July 20, 2020)). The preventive care mandate requires health plan coverage without cost sharing for preventive services identified by the US Preventive Services Task Force, the Health Resources and Services Administration, and the Advisory Committee on Immunization Practices. Plaintiffs assert this mandate — ACA Section 2713 — violates the US Constitution's appointments and vesting clauses and the nondelegation doctrine and ask the court to declare this section of the ACA unenforceable.

If the court agrees with the challengers, which is expected, employer group health plans would no longer have to cover without cost sharing any of the preventive services mandated by Section 2713. The Biden administration would undoubtedly appeal such a decision, but whether the ruling would remain in effect while on appeal is unclear. In addition to the constitutional challenge, plaintiffs argue that some specific coverage requirements related to contraceptives and HIV preventative medications violate the Religious Freedom Restoration Act.

Provider conscience rule

HHS likely will complete its review of the <u>provider conscience rule</u> this year and discontinue its appeal of federal district court orders striking down the rule. The rule expands and consolidates enforcement authority over a variety of healthcare conscience laws focusing on abortion, sterilization, assisted suicide, advanced directives and other types of medical care. The rule also allows healthcare workers to refuse to provide a service that goes against their personal religious or moral beliefs.

Three different federal district courts vacated the rule before it took effect. The Trump administration's HHS appealed, but the Biden administration sought to put the cases on hold before arguments were heard (*New York v. HHS*, No. 19-4254 (2d Cir. filed April 27, 2020); and *City and County of San Francisco v. Azar*, No. 20-15398 (9th Cir. filed Oct. 20, 2020)). To forestall the continuation of these lawsuits by private entities seeking to defend the rule in place of HHS, the agency could propose to rescind the rule. HHS took that approach with the most-favored nation model interim final rule regarding Medicare Part B payments.

AHP litigation

DOL may complete its review of the <u>AHP rule</u> this year and seek to discontinue the appeal of a lower court decision invalidating much of the rule. The rule expanded ERISA's definition of "employer" and made it easier for small businesses and the self-employed to form AHPs.

A federal district court set aside much of the rule (*New York v. DOL*, No. 18-1747 (D. DC March 28, 2019)). The court found the regulation was intended and designed as an end run

around the ACA, allowing groups without any real common interest and working owners without employees to band together as employers.

The Trump administration's DOL appealed, and the appellate court heard oral arguments in late 2019. However, the matter was put on hold before a decision was issued (*New York v. DOL*, No. 19-5125 (DC Cir. filed May 31, 2019)).

Section 6

Related resources

Federal legislative outlook

Mercer Law & Policy resources

- Mercer projects 2023 figures for ACA affordable employer coverage (Feb. 15, 2022)
- Tracking federal COVID-19 laws affecting employee benefits, jobs (March 30, 2021)
- Congress extends tax credit for paid family and medical leave (Feb. 12, 2021)
- CARES Act boosts telehealth, makes other health, paid leave changes (March 27, 2020)

Other Mercer resources

- Regulators' first report on mental health parity analysis finds issues (Feb. 3, 2022)
- Build Back Better Act's healthcare and paid leave reforms face uncertain future (Jan. 13, 2022)
- Mercer, stakeholder groups urge Congress to extend predeductible telehealth coverage (Dec. 9, 2021)
- Build Back Better Act heads to Senate with significant health and paid leave provisions (Dec. 2, 2021)
- House edges closer to vote on paid leave, drug pricing reforms (Nov. 11, 2021)
- Democrats' healthcare, paid leave ambitions hit fiscal reality (Oct. 14, 2021)
- Public employers: Does the president's vaccine mandate apply? (Sept. 23, 2021)
- House bill lowers employer 'play-or-pay' affordability percentage (Sept. 16, 2021)
- House Democrats reveal health, paid leave policies in budget package (Sept. 9, 2021)
- Employers step up lobbying as Congress eyes federal paid leave program (July 22, 2021)
- Senators urged to support national paid leave standard (May 20, 2021)
- Employers ask for changes as Congress mulls future of telehealth (March 11, 2021)

State legislative outlook

Mercer Law & Policy resources

- States, cities tackle COVID-19 paid leave (regularly updated)
- Illinois mandates health plan disclosure with EHB comparison (Feb. 10, 2022)

- New York to regulate pharmacy benefit managers (Feb. 9, 2022)
- Roundup of selected state health developments, fourth-quarter 2021 (Jan. 21, 2022)
- States update group health plan sponsor reporting obligations (Jan. 21, 2022)
- 2022 state paid family and medical leave contributions and benefits (Jan. 19, 2022)
- Colorado moves forward on paid family and medical leave (Jan. 4, 2022)
- States seek to rein in Rx costs and pharmacy benefit managers (Oct. 26, 2021)
- Changes to California's paid leave programs coming in 2023 (Oct. 8, 2021)
- Seattle posts 2022 health expenditure rate for hotel employers (Aug. 17, 2021)
- Oregon's paid family and medical leave contributions delayed to 2023 (Aug. 5, 2021)
- Washington adds tight exemption timeline to long-term care law (May 3, 2021)

Other Mercer resources

• State PBM legislation is a growing concern for plan sponsors (Feb. 17, 2022)

Federal regulatory outlook

Mercer Law & Policy resources

- Mercer, ERIC provide more input on CAA prescription drug reporting (Jan. 28, 2022)
- Form 5500 updates address MEPs and more (Jan. 10, 2022)
- Health plans face new liabilities for inaccurate provider directories (Jan. 4, 2022)
- Proposed regulations extend ACA individual statement due dates (Dec. 1, 2021)
- HHS adjusts 2021 HIPAA, certain ACA and MSP monetary penalties (Nov. 30, 2021)
- Deadline relief continues for health plans and participants (Nov. 12, 2021)
- Agencies issue new FAQs on COVID-19 testing, vaccines (Oct. 6, 2021)
- Top 10 compliance issues for health, fringe and leave benefits in 2022 (Sept. 7, 2021)
- DOL issues cybersecurity guidance for retirement plans (April 26, 2021)
- DOL urged to give retirement plans cybersecurity guidance (April 7, 2021)
- Tracking federal COVID-19 laws affecting employee benefits, jobs (March 30, 2021)
- Healthcare cost transparency rules and MLR changes finalized (Dec. 2, 2020)
- Justices' Title VII ruling on LGBTQ bias has health benefit impacts (June 15, 2020)
- Employer health plans have to meet new COVID-19 coverage mandate (April 21, 2020)
- COVID-19 raises HIPAA privacy, security issues (April 6, 2020)

Other Mercer resources

- New FAQs clarify issues with at-home OTC COVID-19 tests (Feb. 10, 2022)
- Regulators' first report on mental health parity analysis finds issues (Feb. 3, 2022)
- Covering at-home COVID-19 tests: Your top guestions answered (Jan. 20, 2022)
- EEOC wellness incentive rules Where are we today? (Jan. 13, 2022)
- Plans must cover at-home OTC COVID-19 tests for free (Jan. 12, 2022)
- Prepare to comply with No Surprises Act notice requirements (Dec. 16, 2021)
- We've got you covered; free at-home COVID tests coming soon (Dec. 9, 2021)
- Mercer, stakeholder groups urge Congress to extend predeductible telehealth coverage (Dec. 9, 2021)
- Regulators clarify implementation timeline of transparency provisions (Aug. 25, 2021)
- New outbreak period guidance requires plan action (March 2, 2021)
- What should employers do about outbreak period relief? (Feb. 24, 2021)
- EEOC withdraws proposed wellness regulations (Feb. 18, 2021)

Litigation outlook

Mercer Law & Policy resources

- Top 10 compliance issues for health, fringe and leave benefits in 2022 (Sept. 7, 2021)
- Supreme Court rejects ACA challenge (June 17, 2021)
- Litigation, legislation leave AHP guidance in flux (May 2, 2019)

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- <u>Employer vaccine-or-test rule on hold, healthcare worker mandate expands</u> (Jan. 13, 2022)
- Don't neglect end-of-year COBRA duties (Oct. 14, 2021)
- ABA therapy coverage exclusions raise a red flag (Oct. 7, 2021)
- It's open enrollment season: That COBRA notice could cost you (Sept. 12, 2018)



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