

Compliance Directions

Looking Ahead in 2025 Gallagher

The major focus of 2024 was, of course, the presidential election. As a result of the election, we will now see a policy shift in Washington D.C. after inauguration day. As we prepare for 2025 and the new presidential administration, we review what we expect to happen in 2025 and other issues that may arise.

What Happened Last Minute

Employer Mandate Reporting

In late December, President Biden signed legislation that reduced the reporting burden on large employers subject to the Patient Protection and Affordable Care Act (ACA) Employer Mandate. As discussed in our article, [Last Minute Legislation Eases Employer Mandate Reporting](#) in this Direction issue, the legislation permits employers to use dates of birth for individuals for whom their tax identification number is unavailable without requiring multiple requests before the relief was available, provides for eases disclosure of the Form 1095-C to individuals, unless specifically requested, extends the timeframe to respond to the IRS upon the request of a Letter 226-J, and places a six-year statute of limitations on collecting such assessments.

Rescission of Proposed Moral Exemption Elimination

As discussed in our 2023 Directions article, [Proposed Preventive Care Regulations Eliminate Exemption](#), the Biden administration issued proposed regulations that would eliminate the moral exemption to the contraception portion of the ACA preventive care mandate. The regulations also proposed individual contraceptive arrangements for participants in group health plans sponsored by employers with religious objections. On December 23, the proposed regulations were rescinded.

What's Expected in 2025

The main themes for group health plans in 2025 will be telemedicine, legal challenges, prescription drugs, litigation, preventive care, and mental health parity.

Telemedicine and HDHPs

During the pandemic, telemedicine benefits expanded significantly, and Congress took steps to ensure that participants in high deductible health plans (HDHPs) could receive free access to non-preventive telemedicine services before meeting the HDHP statutory minimum deductible without impacting their ability to contribute to health savings

Compliance Directions

accounts (HSAs). The last remaining extension expires at the end of a plan's 2024 plan year (December 31, 2024, for calendar year plans). The initial spending bill provided an additional two-year extension, permitting free telemedicine interactions until the end of 2026 plan years. However, the version passed by Congress eliminated this provision. But given the popularity of this flexibility, we expect that an extension will likely be included in the next funding bill around March 2025.

Legal Challenges to Regulations

The *Loper Bright Enterprises v. Raimondo* and *Relentless, Inc. v. Dep't of Commerce* (*Loper Bright*) decision in 2024 has already begun to impact benefit regulations. *Loper Bright* overturned the long-standing *Chevron* doctrine, which required courts to defer to agency interpretations upon finding that regulatory language was ambiguous. As a result, plan sponsors should expect that most new rules and regulations issued by any federal agency, including the Departments of Labor, Treasury, and Health and Human Services (the Departments), that have enforcement authority over employers and their benefit plans will be challenged under *Loper Bright*. Ultimately, such a challenge will delay compliance while stakeholders wait for appeals to play out and a final decision to be rendered.

Prescription Drugs

State Pharmacy Benefit Manager (PBM) Regulation

We continue to see states regulating PBM business practices within their states; however, at times, those regulations can impact the design of ERISA health and welfare plans. For example, some state PBM laws prohibit discounts for network pharmacies to protect independent brick and mortar pharmacies within those states. The Pharmaceutical Care Management Association (PCMA), a PBM trade association, has taken on these state laws by arguing that those types of state laws are preempted under ERISA. If that argument is successful, a state law's applicability would generally be limited to fully insured plans written in the state, as well as public entity plans in those states. Currently, the case to watch on this topic is *Mulready vs. PCMA*, which is likely to be heard by the U.S. Supreme Court this year. Although the Supreme Court sided with Arkansas in *Rutledge vs. PCMA*, the Oklahoma law requires more of PBMs and would potentially have a greater impact on ERISA plans.

Over the Counter Preventive Care without a Prescription

The Biden administration released proposed regulations that would have required plans to cover OTC items without a prescription, including contraception, without cost sharing

Compliance Directions

under the ACA preventive care mandate. However, we do not expect these proposed regulations to be finalized under the Trump administration.

Preventive Care Mandate

The *Braidwood v. Becerra* case is likely to find its way to the Supreme Court in 2025. In 2022, a Texas federal court determined that a portion of the ACA preventive care mandate was unconstitutional. Upon appeal to the Fifth Circuit, the court agreed and argued that all three entities that make the preventive care recommendations that become part of the ACA preventive care mandate were not properly appointed. In September 2024, HHS Secretary Becerra petitioned for certiorari; however, the Supreme Court has yet to grant a review. If the Court grants review, it is unlikely that the new Secretary of HHS will defend the suit. The ultimate result, if the Supreme Court hears the case and agrees with the Fifth Circuit, could be that the ACA preventive care mandate will continue to exist but all recommendations, or at least those made by the United States Preventive Services Task Force (USPSTF) after March 23, 2010, would be unconstitutional. Plan sponsors could then choose which preventive care to cover, likely with the input from their carriers.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act (MHPAEA) final rules were issued in 2024 and became effective at the beginning of 2025 plan years. As described in our article, [Mental Health Parity Regulations Require Significant Undertaking but Provide Some Relief](#), the final rules expand on the requirement to prepare a comparative analysis on the plan's non-quantitative treatment limitations (NQTLs) on mental health and substance use disorder benefits to determine parity with the plan's NQTLs on medical and surgical benefits. The rules also outlined the new parity test for NQTLs, which requires plans to review the design and application of all the plan's NQTLs on mental health and substance use disorders, and then perform an outcomes data analysis to determine if the NQTL caused a material difference in access to care.

Beginning in 2026 plan years, the final rules also require plans to provide meaningful benefits (i.e., at least a core treatment) for a mental health or substance use disorder in each classification of benefits that medical or surgical benefits are offered. This is the portion of the regulations that is at greatest risk of litigation, as opponents are likely to challenge the meaningful benefits requirement using *Loper Bright*.

Former President Trump signed the Consolidated Appropriations Act 2021 into law, which initiated the requirement for plans to prepare an NQTL comparative analysis.

Compliance Directions

However, the Departments issued the implementing regulations under President Biden. The NQTL comparative analysis requirement will remain, but we may see new rules that ease the requirements, and likely eliminate the meaningful benefits requirement if it survives legal challenges.

What Else Could Happen

Below we focus on a few topics plan sponsors are awaiting guidance on and other topics that may arise in 2025.

Drug Coupons

We hope to get additional clarification on the interaction of the ACA out-of-pocket maximum rules and the Internal Revenue Code (IRC) HDHP rules as they pertain to drug manufacturer coupons. Many plan sponsors have implemented coupon accumulation programs that do not credit participant out-of-pocket spending for the value of any coupon. IRS guidance relating to HDHPs requires plans to count only the amount spent after the discount toward the participant's deductible for the participant to remain eligible to contribute to an HSA. The most recent guidance gave plan sponsors the choice of whether to count the value of the coupon. However, a 2023 district court decision vacated that rule, and required plans to count the value of the coupon. The Departments have indicated they will not enforce the rule until further guidance is issued. That guidance has yet to be issued. It is unclear what action HHS might take in this regard, but the nonenforcement policy will likely be in effect under the new administration until further guidance is issued.

HIPAA Privacy and Security

Reproductive Attestation

The Texas Attorney General, under the *Loper Bright* decision, challenged HHS' issuance of the HIPAA reproductive disclosure attestation rule, which prohibited the disclosure of reproductive protected health information (PHI) without an attestation providing that the PHI was not being used to enforce a law against an individual who obtained legal reproductive care. The Attorney General is also arguing that the 2000 HIPAA rule should also be vacated under *Loper Bright*. The HIPAA reproductive disclosure became required in late December 2024, so plans should already have that process in place and adopted into their HIPAA policies. However, plans must also keep abreast of the Texas litigation and the Trump administration's response to it.

Compliance Directions

Security Regulations

HHS was set to issue proposed regulations implementing modifications to the HIPAA Security Rule. The Office of Management and Budget (OMB) completed its review on December 18, but soon after, the Biden administration announced its winddown on issuing further regulations, noting that they are likely to be pulled back or reversed by the upcoming administration. The security of an individual's PHI is a bipartisan issue, so we are likely to see some movement from HHS on this issue, but it's not clear how quickly or how in depth those regulations may be.

Transparency

The Transparency requirements are a combination of rules issued under the Transparency in Coverage provisions of the ACA and new requirements under the Consolidated Appropriations Act of 2021. These requirements include the prescription drug data collection (RxDC) reports, gag clause prohibition attestations, plan identification card cost sharing information, up-to-date provider directories, the continuity of care provisions, and more. Currently, plan sponsors are relying, for a portion of the requirements, on good faith compliance guidance provided by the Departments that extends until further guidance is issued.

Additionally, the Departments alerted plan sponsors that the machine-readable file requirement must include prescription drug data, in addition to the network negotiated rates and the out-of-network allowed amounts. However, HHS has never issued the technical requirements of those files. Another requirement under the transparency umbrella is the requirement of group health plans to provide advanced explanations of benefits (AEOBs) after receipt of a provider's good faith estimate of the cost of care.

We hope to see finalized guidance on a number of these provisions, but with the goal of reducing the regulatory burden on stakeholders, it's unclear whether the Trump administration will issue any regulations on this topic.

Surprise Billing Adjustments

In 2022, the No Surprises Act (NSA) prohibited balance billing consumers for out-of-network emergency care, care provided at a network facility by an out-of-network provider, and air ambulance services. The NSA has been subject to ongoing litigation from the Texas Medical Association on behalf of out-of-network providers and from air ambulance providers. The Departments under the Biden administration have reissued regulations, but those were subject to litigation that led to those regulations being vacated. The Departments are reviewing the recent court decisions and have noted an intent to publish future guidance.

Compliance Directions

Despite all the legal wrangling, the Independent Dispute Resolution (IDR) process is ongoing. It will be difficult for the Trump administration to avoid this regulatory need, as IDR entities will not be able to make decisions without implementing regulations, making it impossible for providers to obtain final payment from plans through this process.

Pharmacy Benefit Manager Transparency

One of the major provisions eliminated from the initial spending bill was the Lowering Prescription Drug Costs Act, which would have taken a significant step to gain oversight of PBM operations. The law would have required PBMs to disclose machine-readable files to large employers that detail the PBM's spread pricing practices and the amounts of rebates, discounts, and other remuneration the PBM and plan received during the year. The PBMs would have also been required to provide summary information to all plans that plans would have had to make available to participants upon request. Another provision of that law would have required PBMs to pass through all drug manufacturer rebates and discounts to the plan for new contracts, extensions, or renewals for plan years after July 2027. We expect the next Congress to pass some version of this bill under the Trump administration, which has also expressed interest in controlling the cost of prescription drugs.

Employer Action Steps

Plan sponsors can prepare for 2025 by:

- Watching out for the possibility of a telemedicine extension for HSA contributors in early 2025.
- Keeping up to date on guidance related to prescription drugs and preventive care.
- Discussing the MHPAEA NQTL comparative analysis with the plan's insurer, third party administrator, and PBM and coordinate responsibilities for completion and disclosure.
- Preparing for potential guidance on transparency, surprise billing, PBM transparency, and more.
- Staying tuned to benefit litigation in 2025. We will likely have two cases at the Supreme Court this term as well as increased activity from *Loper Bright* challenges in an effort to dismantle past and future Departmental guidance.

The intent of this article is to provide general information on employee benefit issues. It should not be construed as legal advice and, as with any interpretation of law, plan sponsors should seek proper legal advice for application of these rules to their plans.