Compliance Monthly Update: April 2025

A brief update on what happened the prior month in group health plan compliance at the federal level–organized chronologically. If you would like additional information, please reach out to the GBS Compliance Team.

Updated model CHIP Notice released. The DOL has released a new model employer CHIP Notice (available HERE) with information current as of March 17, 2025. As a reminder, group health plans that maintain a plan with participants who reside in a state that provides premium assistance under Medicaid or CHIP have an annual notice requirement to notify employees of the potential opportunities for premium assistance. The model CHIP notice is updated periodically to reflect changes in the states that offer premium assistance and changes to the relevant state contact information.

CMS releases 2026 Medicare Part D benefit parameters and program instructions with new standard for determining creditable coverage status. On April 7, CMS announced the 2026 parameters for the defined standard Medicare Part D prescription drug benefit and released the final Calendar Year 2026 Part D Redesign Program Instructions (as well as an associated fact sheet). This guidance addresses the 2026 Medicare Part D program redesign enacted as part of the Inflation Reduction Act of 2022 (IRA) that impacts employers that offer health coverage to Medicare-eligible individuals.

- For 2026, the standard Medicare Part D plan annual out-of-pocket threshold will be $2,100 (up from $2,000 in 2025) with an annual deductible of $615 (up from $590 in 2025).
- The Medicare Part D benefit parameters are important for group health plan sponsors because they are used to determine if the prescription drug coverage offered to Part D eligible individuals is creditable or non-creditable. To be creditable, the actuarial value of the prescription drug coverage must meet or exceed the actuarial value of standard Medicare Part D coverage. Essentially, this means that creditable coverage must be at least as good as standard Medicare prescription drug coverage.
- Plan sponsors are required to notify Medicare-eligible plan participants as to whether their plan constitutes creditable coverage or not. If an individual has creditable coverage, they avoid the penalty for joining Part D late (i.e., after they are first eligible).
- The final instructions also provides a revised version of the simplified determination methodology where coverage will be considered creditable if it:
    - Provides reasonable coverage for brand name and generic prescription drugs and biological products.
    - Provides reasonable access to retail pharmacies.
    - And is designed to pay on average at least 72% of participants' prescription drug expenses.
- The final instructions do not explain the criteria CMS will use to determine whether a plan provides "reasonable coverage" or "reasonable access." The requirement to cover at least 72% of participants' prescription drug expenses is an increase from the current simplified methodology's 60% requirement.
- Importantly, CMS announced that it will allow plans to use either the old simplified methodology or the newly finalized simplified methodology for calendar year 2026 "to minimize potential risks to the employer group market and to Part D eligible individuals." However, plans

will be required to use the new simplified methodology beginning in calendar year 2027. If not using the simplified methodology, then a plan would use an actuarial evaluation.

President Memoranda directs agencies to repeal regulations. On April 9, President Trump issued a memorandum entitled Directing the Repeal of Unlawful Regulations that directs agencies to take additional steps related to a previously issued February 19 Executive Order (EO). That EO directed the heads of all executive departments and agencies to identify certain categories of regulations and provide a list of those that may be "unlawful." The new April 9 memorandum directs the agencies to now take steps to effectuate the repeal of the identified regulations, or the relevant portion of the identified regulations, and to prioritize regulations that conflict with the *Loper Bright* Supreme Court decision. We may see various regulations repealed in short order, and we will be monitoring for any changes to regulations that may impact group health plans.

Federal court holds current regulatory framework assessing employer mandate penalties is unenforceable. As a reminder, an applicable large employer (ALE) can be subject to penalties under the ACA if it fails to offer coverage to substantially all its full-time employees or if coverage is not affordable. To date, employers usually learn of possible employer mandate penalties when they receive a Letter 226-J from the IRS. In this case, an employer sued HHS after the IRS issued it a Letter 226-J proposing penalties under the employer mandate. The employer argued that HHS and the IRS improperly categorizing the Letter 226-J as a certification before the assessment of a penalty. Arguing that HHS, rather than the IRS, was required to provide the certification. Under the statutory language of the ACA, HHS is required to certify to the employer that one or more full-time employees was enrolled in a qualified health plan before the IRS can propose penalties. HHS regulations delegated the responsibility to certify employee enrollment in a qualified health plan to the IRS. Here, the Letter 226-J claimed that it served as a "certification" to the employer before assessment of the employer shared responsibility penalty. The employer responded to the IRS that it disagreed with the proposed assessment and was paying the penalty under protest. The employer then filed a refund claim with the IRS. When it did not receive a response, the employer sued HHS, and on April 10, a federal court has now ruled in favor of the employer. The court held that the ACA gives the authority to make the certification exclusively to HHS, not the IRS. For the IRS to assess the penalty, at least one full-time employee of the employer had to be certified as having enrolled in a qualified health plan. The court held that the employer was entitled to a refund, and it set aside the HHS regulation delegating IRS the authority to certify an employer before assessing an employer shared responsibility penalty as void and unenforceable. Because HHS currently has no certification process in place, the IRS is arguably unable to impose penalties. But this decision is binding only in the Northern District of Texas. The IRS and HHS could decide to change their procedures to conform to this ruling, or they also could decide to maintain their longstanding position internally and in every other district court until those courts rule against them. An employer who previously paid an employer mandate penalty may want to explore the possibility of reclaiming the penalty from the IRS in light of this decision. But ACA penalty challenges must follow specific procedures and time frames. For example, employers should not expect ACA penalties imposed and paid a decade ago to be refunded based on this new case (generally, there is a three-year statute of limitations for making a refund claim).

CMS final rule declines to include proposed rule's coverage of GLP-1s for weight loss under Medicare or Medicaid. On April 15, CMS published the final rule titled "Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" and an associated Fact Sheet. Most of this final rule is not directly applicable to group

health plans but instead implement changes related to Medicaid and Medicare coverage. Of note, however, is that the final rule did not include a proposed rule change related to weight-loss drugs (e.g., GLP-1s). The Biden administration, when they published the proposed rule, attempted to have Medicare Part D and Medicaid cover anti-obesity drugs for the 2026 contract year – which would have substantially increased access to GLP-1 drugs for weight loss. But under the final rule, anti-obesity medications, when used for weight loss or chronic weight management for the treatment of obesity, will continue to be excluded from Part D and Medicaid coverage.

Litigation allowed to proceed challenging the use of AI in claim decisions. A federal court recently issued a preliminary ruling to partially allow a case to proceed against Cigna's alleged wrongful denials of benefits by using AI to process claims. Because the participants had presented arguments sufficient to support their assertion that entrusting medical necessity decisions to the automated algorithm violated plan terms (when the claims administrator's policies indicated the determination would be made by a "medical director"), the court allowed the claim to proceed. Plan sponsors and claim administrators should monitor this case for guidance on the future use of AI in benefit plan decision making.

Trump executive order on lowering drug prices includes PBM fee transparency (no immediate impact on group health plans). On April 15, President Trump issued an executive order (and an associated fact sheet) directing federal officials to take measures to lower prescription drug prices in a variety of ways, building on initiatives addressing prescription drug prices in the first Trump administration. As a reminder, executive orders serve as directives from the President to federal agencies. They do not change existing laws but introduce administrative action through proposed regulations and instruct agencies to develop and issue regulations or guidance consistent with current statutory authority. Therefore, while the order does not immediately change any legal obligations, it does signal future regulatory actions that could impact how employers manage their group health plans. Highlights of the order that are of interest to plan sponsors include the following:

- PBM transparency. The order directs the DOL to propose new regulations aimed at improving fiduciary transparency for employer-sponsored health plans. Although the exact direction of this EO has been interpreted a few ways, forthcoming proposed regulations are expected to clarify. It is generally understood however that the EO focuses on PBMs and aims for enhanced reporting of indirect and direct compensation similar to, or within, existing 408(b)(2)(B) direct and indirect compensation reporting that is currently associated with other service providers like brokers/consultants.
    - As context, PBMs have in past taken the position that they were not a "covered service provider" that would be required to provide direct and indirect compensation disclosure. It appears this could change by adding additional fee disclosure requirements on (or about) PBMs through ERISA's prohibited transactions rules.
    - The order gives the DOL 180 days to issue proposed regulations to enhance PBM transparency, which would then need to go through the routine notice and comment period before any final regulations are issued.
- Drug importation. The executive order requires the FDA to take steps within 90 days to streamline and improve the Section 804 Importation Program created under the first Trump administration, which permits states to import drugs from Canada. Several states have filed Section 804 program requests, and Florida's program was approved on January 5, 2024. Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Vermont and Wisconsin have laws allowing for a state drug importation program – six of these states have submitted

Section 804 Importation Program proposals and are awaiting FDA approval. This executive order directs the FDA to streamline the process for these states.

Supreme Court ruling adopts simplified pleading requirements for ERISA prohibited transaction claims, which may lead to more fiduciary lawsuits. On April 17, the U.S. Supreme Court ruled in *Cunningham v. Cornell University* that employees may challenge their employer's fee arrangement with a plan service provider under loosened pleading standards for alleging a violation of ERISA's prohibited transaction rules. As a result, it will be easier for plaintiffs to claim that the plan fiduciaries acted improperly. Although the case relates to retirement plans, the same rules apply for group health plans.

- As background, ERISA establishes strict standards of conduct for plan fiduciaries. One such responsibility is the duty of loyalty, which requires plan fiduciaries to act solely in the interest of the plan's participants and beneficiaries. ERISA's prohibited transaction rules supplement the duty of loyalty by categorically barring certain transactions between the plan and a "party in interest," which includes plan service providers. Significantly, ERISA includes numerous exemptions to its prohibited transaction rules, one of which exempts contracts with service providers if no more than reasonable compensation is paid for the services.
- Previously, several courts held that plaintiffs claiming a plan engaged in a prohibited transaction needed to allege facts disproving the applicability of an exemption to the prohibited transaction rules (e.g., the reasonable compensation exemption) to move forward with their lawsuit. However, based on their statutory interpretation of ERISA, the Supreme Court has now ruled that plaintiffs only need to show that the fiduciary engaged in a prohibited transaction to pursue their claims (e.g., that the plan used plan assets to pay service providers—which nearly all plans do). Then the defendant fiduciary has the burden of proving that an exemption applies, rather than requiring the plaintiff to disprove the exemption when bringing a claim.
- This decision simplifies the standard for filing prohibited transaction claims, which may lead to more employee lawsuits. In its opinion, the Supreme Court acknowledged Cornell's concerns that the ruling would encourage meritless litigation and increase costs for plan sponsors. The Court noted that while these are serious concerns, lower courts have other ways to screen out meritless claims before cases proceed to the more costly discovery phase.
- To help minimize risk, plan sponsors should periodically review and document their compliance with ERISA's fiduciary duty requirements, including the prohibited transaction rules. This process should include reviewing service provider compensation to confirm its reasonableness. Because of the *Cunningham* ruling, more claims may get through to formal discovery, which means that documentation of decisions made by fiduciaries will be scrutinized. So again, this is a reminder for plan sponsors to revisit their fiduciary governance of the plan.

Oral arguments before the Supreme Court on the ACA preventive services mandate. On April 21, the U.S. Supreme Court heard oral arguments in a lawsuit (the *Braidwood* case) challenging the ACA requirement that non-grandfathered health plans must cover certain preventive services without cost-sharing. A final decision from the Supreme Court could be issued in June, but from the oral arguments it appears the Supreme Court is leaning towards saving the task force recommendations at issue and the constitutionality of the preventive services mandate.

- As a reminder, the ACA requires health plans to cover preventive services with no cost-sharing for participants, and the ACA empowers three agencies—the U.S Preventive Services Task Force (PSTF), the Health Resources and Services Administration (HRSA), and the Advisory Committee on Immunization Practices (ACIP)—to determine what kinds of preventive care fall within each category of mandatory coverage by issuing guidelines or recommendations.

- In March of 2023, a district court ruled in the *Braidwood* case that the ACA requirement to provide preventive services as recommended by the PSTF is unconstitutional and issued a nationwide injunction that prohibited the federal government from enforcing the ACA preventive services mandate. However, that district court ruling was stayed pending the outcome of the appeal.
- In June of 2024, the Fifth Circuit affirmed that the PSTF's members had not been validly appointed under the Constitution because they were not nominated by the President and confirmed by the Senate. The court explained that this appointment process is necessary due to the level of power exercised by the PSTF in making recommendations on preventive services required to be covered under the ACA. Under this ruling, HHS was enjoined from enforcing PSTF recommendations, but only as to the *Braidwood* plaintiffs. The court reversed the trial court's decision to vacate all agency actions taken to enforce the preventive services mandates and to universally block the agencies from enforcing the mandates with a nationwide injunction. The court withheld judgment and remanded the case back to the trial court to determine if the members of HRSA and ACIP were also unconstitutionally appointed. So, although the Fifth Circuit ruled that some aspects of the ACA preventive service requirements are unconstitutional, those requirements still apply to group health plans nationwide (except for the plaintiffs who brought this lawsuit). Therefore, the preventive services requirement remained intact for the time being.
- Then the DOJ, under the Biden administration, asked the Supreme Court to review the Fifth Circuit holding that the appointment of the PSTF is unconstitutional. On January 10, 2025, the Supreme Court agreed to hear the case, and on April 21 oral arguments were held.
- Four days after hearing oral arguments, the Supreme Court asked both the federal government and the challengers to file new briefs discussing the HHS secretary's power to appoint members to the task force.
- We will continue keeping an eye on this case and will give updates on any developments and the impact on the ACA preventive services mandate.