Compliance Monthly Update: December 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.

Final regulations issued on hospital price transparency requirements. HHS published a final rule (and associated fact sheet) intended to strengthen current hospital price transparency requirements and ensure that hospitals "provide meaningful, accurate information about the amount they charge for healthcare items and services." While compliance with the new rule is technically mandatory on January 1, 2026, HHS will delay enforcing the changes until April 1, 2026. The final rule replaces previously allowed estimated amounts when payer-specific negotiated charges are expressed as a percentage or an algorithm. Instead, the hospital must convey the median allowed amount and the 10th and 90th percentile allowed amounts.

Proposed rule would eliminate Medicare Part D creditable coverage disclosure requirements for HRAs. As a reminder, plan sponsors that provide prescription drug coverage through a group health plan must disclose to covered Part D eligible individuals and to CMS whether the value of the provided drug coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Medicare Part D. Under current guidance, HRAs are subject to this Part D reporting. But HHS and CMS issued proposed regulations on November 28 that (if finalized) would relieve HRAs (including ICHRAs) and all account-based plans of the obligation to provide notice of creditable coverage status to Medicare Part D eligible individuals and to CMS. The regulatory agencies explain that account-based plans are designed to provide cost savings through pre-tax contributions and reimbursements, and often supplement other coverage, rather than actually offering prescription drug coverage. So, the benefit design of account-based plans makes concepts such as the disclosure of creditable coverage inapplicable and unduly burdensome because comparing a reimbursement arrangement, such as an HRA, with the intricacies of Medicare Part D prescription drug coverage is not an apples-to-apples comparison. In addition, HRA participants may be confused by receiving seemingly inconsistent notices of non-creditable coverage from the HRA (because it does not directly provide prescription drug coverage) and notices of creditable coverage from their major medical plan, which does. This proposed rule would not change the notice requirements regarding Part D creditable coverage for group health plans that directly offer prescription drug benefit coverage. But the proposed exclusion of account-based plans from these notice requirements would ease the administrative burden for employers that offer HRAs.

Reminder about 2026 DCAP statutory limit increase. As a reminder, the OBBB that was signed into law on July 4, 2025, increased the amount parents can contribute to a DCAP (also known as a dependent care FSA). The limits of $5,000 ($2,500 for married but filing separately) increase to $7,500 and $3,750 respectively, effective beginning January 1, 2026. As with the prior limits, this new limit is not indexed for inflation and will remain at $7,500/$3,750 unless Congress again changes it. Employers who sponsor a DCAP and wish to allow employees to contribute up to these increased limits should review, and amended as necessary, their cafeteria (Section 125) plan document. The Section 125 regulations generally say plan amendments can only be effective after the later of the adoption date or the effective date—i.e., they must be adopted before implementing the change that is the subject of the amendment.

Guidance will allow contributions on Children's Savings Accounts through a IRC Section 125 Cafeteria Plan. On December 2, the IRS issued Notice 2025-68 (and a news release) with an initial general overview of the new tax-preferred children's savings accounts, referred to as Trump Accounts (TAs) that were part of the OBBB. As a reminder, for children born between 2025 and 2028, the federal government will seed the accounts with a one-time $1,000 contribution. The guidance confirms that, beginning July 4, 2026, employees may exclude from income employer contributions to a TA of up to $2,500 (subject to cost-of-living adjustments after 2027) per calendar year. The employer contribution limit applies per employee, not per dependent, so employees with multiple dependents may only receive a total annual employer contribution of $2,500 for all dependents' TAs. The guidance also clarifies that TA contributions may be made through cafeteria plan salary reductions, so long as the contributions are made to the TA of an employee's dependent. (Salary reduction contributions to an employee's own TA are prohibited, as this would be an impermissible deferral of compensation.) The IRS also announced that they intend to issue future proposed regulations regarding TAs which will address (in part) the coordination of cafeteria plans and TA contributions.

Governmental report released on ACA advance premium tax credits. On December 3, the Government Accountability Office (GAO) released preliminary results from an ongoing review checking for fraud risks relating to the Affordable Care Act (ACA) Advance Premium Tax Credit (APTC). As a reminder, the APTC is a subsidy that the government pays to insurance companies to make individual Exchange coverage premiums more affordable. GAO's preliminary work indicates that certain vulnerabilities remain in the administration of advance premium tax credits (APTC), based on illustrative covert testing and analyses of federal Marketplace data. The testing showed that fictitious applicants were able to obtain subsidized coverage, and GAO identified data patterns—such as unreconciled tax credits, repeated use of SSNs, and unauthorized enrollment changes—that may increase program risk, though these findings cannot be generalized to the full enrollee population and do not necessarily indicate improper payments. GAO also noted that CMS's fraud risk management processes have not been updated to reflect recent program changes, which may limit its ability to proactively address identified risks.

Johnson & Johnson fiduciary lawsuit dismissed (again). A district court in *Lewandowski v. Johnson & Johnson* has again dismissed (on standing grounds) a putative class action lawsuit against Johnson & Johnson that alleged the plan fiduciaries had mismanaged its self-funded health plan's prescription drug benefits in its selection of the PBM and by overpaying for specialty generic drugs offered on the plan's formulary. Previously (in January 2025) this court dismissed the plaintiff's amended complaint also on standing grounds but allowed a second amended complaint to be filed. The court has now again held that the amended allegations in the second complaint were not enough to cure the plaintiffs' failure to allege injuries that were sufficiently concrete and non-speculative and that could be redressed though the litigation. But the court's dismissal is without prejudice, giving the plaintiffs another opportunity to amend their complaint to attempt to cure their pleading deficiencies on standing. Regardless of the outcome of this case (and other pending group health plan fiduciary lawsuits), plan sponsors should make sure to continue engaging in prudent fiduciary decision-making processes for designing their benefit plans and in their selection of PBMs and other vendors. ERISA does not require plan fiduciaries to select the lowest cost vendors, rather they should make a prudent decision taking in the various factors in the vendor selection process to ensure the plans are designed and administered in participants best interests. Having good documentation and a process in place for making prudent group health plan decisions will generally be the most effective shield against potential lawsuits.

IRS guidance on HSA changes in the OBBB. On December 9, the IRS issued Notice 2026-05 with guidance addressing HSA-related changes made by the OBBB that was passed last July. As a reminder,

the OBBB includes several HSA-related provisions including making permanent the safe harbor allowing HDHPs to cover telehealth and other remote care services before the statutory minimum deductible is met – and without losing HSA eligibility. Also, Direct Primary Care Service Arrangements (DPCSAs) will not negatively impact HSA eligibility if certain requirements are met regarding fees charged and services provided (fees for DPCSAs are also qualified medical expenses for reimbursement from an HSA). Here are the highlights of Notice 2026-05:

- Telehealth / remote care services. The OBBB did not define "telehealth and other remote care services." The Notice also does not provide an explicit definition, but the IRS will treat benefits as telehealth and other remote care services (for the purpose of when an individual can contribute to an HSA) if they appear on HHS's annually published list of telehealth services payable by Medicare. Instructions are provided for analyzing services not on the list. In-person services, medical equipment, or drugs furnished in connection with telehealth and other remote care services may not be provided pre-deductible unless they would otherwise be treated as telehealth services under the guidance.
- DPCSAs and HSA eligibility. The OBBB narrowly defined DPCSAs as an arrangement under which the individual is provided Code Section 213(d) medical care consisting solely of *primary care services* provided by primary care practitioners, where the sole compensation for such care is a fixed periodic fee. The OBBB limits this fee to $150/month for a DPCSA covering only one individual and $300/month for a DPCSA covering more than one individual. The Notice provides that the sole compensation for care provided under a DPCSA must be the fixed periodic fee and DPCSAs may not provide items and services to individuals who are members in the arrangement and have paid a fixed periodic fee while billing separately for those items and services (through insurance or otherwise). However, DPCSAs may offer certain items and services outside of the arrangement regardless of membership and separately bill members and non-members for those items and services. DPCSA fees may be billed for periods of more than a month (but no more than a year) if the aggregate fees are fixed, periodic, and do not exceed the monthly limit (on an annualized basis). If an arrangement provides services other than permitted *primary care services*, members in the arrangement may not decline to use those services and treat the arrangement as a DPCSA. *Primary care services* is generally understood to include routine office visits, preventive care, evaluation and management of common conditions and care coordination and referral (but not specialty treatment itself).
- DPCSAs under a HDHP. A HDHP may not pay the fees for, or provide membership in, a DPCSA before the minimum deductible has been satisfied. So, to be provided pre-deductible, the DPCSA must be provided outside the HDHP. Also, if an individual is enrolled in both a DPCSA and an HDHP, the HDHP may not count the fees the individual pays for the DPSCA membership toward the HDHP's minimum annual deductible or out-of-pocket maximum. This is because an HDHP can only count amounts paid out-of-pocket for services covered by the HDHP toward the deductible and out-of-pocket maximum.
- Paying DPCSA fees from an HSA. HSAs can now reimburse DPCSA fees as qualified medical expenses, though employer-paid fees (including cafeteria plan salary reductions) are not reimbursable.
- While this guidance provides some helpful clarifications, there are still unanswered questions. The IRS requested comments on all aspects of this Notice with a comment deadline of March 6, 2026. So, hopefully additional guidance will be provided.

2025 Form 5500 series advanced copies released. On December 15, the IRS released informational copies of the 2025 Form 5500 series (with minimal changes), including Form 5500, Form 5500-SF, Form 5500-EZ, and instructions. The associated news release provides a reminder that these advanced copies

are not to be used for filing. Filers should monitor the DOL's EFAST site to learn when official electronic versions are available and able to be filed using software from EFAST2-approved vendors or directly through the EFAST2 site.

Federal government issues proposed rules to limit gender-affirming care for minors. Following a January 2025 executive order from the Trump administration directing the regulatory agencies to begin reviewing and promulgating specific actions to restrict "gender-affirming care" (GAC) for individuals under the age of 19—on December 18, HHS issued several proposed rules in furtherance of the executive order. Two proposed rules (HERE and HERE) would eliminate federal Medicaid funding for GAC services for minors and condition hospital participation in Medicaid and Medicare on compliance with these requirements. Another proposed rule would clarify that individuals with certain gender identity disorders are not protected under the disability discrimination rules issued pursuant to Section 504 of the Rehabilitation Act. HHS also issued a declaration stating that in its view, GAC services for children and adolescents are neither safe nor effective as treatment for gender dysphoria, gender incongruence, or other related disorders and, therefore, fail to meet professionally recognized standards of healthcare. Also, the FDA issued warning letters to 12 companies for marketing chest binders as treatment for gender dysphoria in minors. Prior to these December 18 proposed regulations, there have been court challenges and injunctions (that are under appeal) that have temporarily blocked the administration from pursuing certain actions related to the January 2025 executive order, and more litigation is expected. But HHS's actions reflect the current administration's ongoing focus on regulating GAC.

Proposed changes to transparency rules. On December 19, the IRS, DOL, and HHS published proposed regulations (and an associated press release and fact sheet) updating the 2020 Transparency in Coverage (TiC) final rules. The new proposed rule (if finalized) aims to build off of the 2020 rule and improve the standardization, accuracy, and accessibility of the required machine-readable files. Here are the highlights of the proposed rule:

- In-network machine readable files. The regulatory agencies propose to require plans and issuers to:
    - Make available an in-network rate file for each provider network maintained or contracted by the plan or issuer, in an effort to reduce the size of this file and reduce redundancy of contracted rates. Currently, plans and issuers must include in-network provider rates for all covered items and services (other than prescription drugs) for all plans offered. The proposal is in line with the hospital price transparency requirements for pricing information across hospitals and health plans (discussed above).
    - Exclude from the in-network rate files certain data for services providers would be unlikely to perform. Currently, plans and issuers must include all contracted rates for in-network providers.
    - Include dollar amounts in the in-network rate files, except for contractual arrangements under which a plan or issuer agrees to pay an in-network provider a percentage of billed charges and is not able to assign a dollar amount to an item or service prior to a bill being generated. In those circumstances, the proposal requires plans and issuers to report a percentage number, in lieu of a dollar amount, in the form and manner as specified in guidance issued by the regulatory agencies. Currently, plans and issuers must publish all applicable rates, including, negotiated rates, underlying fee schedule rates, or derived amounts for all covered items and services in the In-network Rate File.
- Out-of-network allowed amount machine readable files. The regulatory agencies propose to require plans and issuers to make an out-of-network allowed amount machine-readable file

available for each health insurance market (i.e., individual market, large group market, small group market, and self-insured group health plans maintained by the same plan sponsor) in which the plan or issuer offers a plan or coverage. Plans and issuers are permitted to satisfy this requirement by contracting with an issuer, service provider, or other party to make available out-of-network allowed amount data that has been aggregated to include information from more than one plan, policy, or contract. Under the current requirement, these plans, policies, or contracts may be across multiple health insurance markets. The proposed rule also increases the reporting period from 90 days to 6 months and increases the lookback period of date from 180 days to 9 months. These proposals are in an effort to ensure more data is available for out-of-network analyses.

- The proposed rule would require plans and issuers to update the in-network rate and out-of-network allowed amount files quarterly, rather than monthly as currently required. Also, plans and issuers would be required to publicly disclose, through the machine-readable files, additional contextual information (change-log, utilization, taxonomy, and text) to help users better understand and utilize the required files.
- Price comparison tool. The proposed rule would require the plan or issuer-provided price comparison tool to provide the same detailed cost-sharing information whether viewed online, in print, or provided by telephone, upon request. Currently, plans and issuers are not required to offer this information via telephone. In addition, the proposed rule would update the required disclosures to include the federal protections against balance billing under the No Surprises Act.
- The guidance notes that they are still evaluating how to implement the TiC prescription drug disclosure requirements.
- For the majority of health plans, these requirements will be handled by their insurer, TPA and/or PBM. If these rules are finalized, employers will want to check with these entities to make sure that they are providing the information as required under the updated regulations.

More most-favored-nation prescription drug pricing agreements announced. Following up on the most-favored-nation (MFN) drug pricing agreements discussed last month, the current administration (on December 19) issued a Fact Sheet announcing additional MFN drug pricing agreements with Amgen, Bristol Myers Squibb, Boehringer Ingelheim, Genentech, Gilead Sciences, GSK, Merck, Novartis, and Sanofi.

DOL expands 5500 DFVC program to late Form M-1 filers. Effective December 19, the DOL modified the Delinquent Filer Voluntary Correction (DFVC) program to further facilitate and encourage voluntary compliance with ERISA's reporting requirements. The types of entities eligible for the program has been expanded to include multiple employer welfare arrangements (MEWAs) and Entities Claiming Exception (ECEs) seeking to file a late Form M-1. The DFVC program allows plan administrators to voluntarily submit overdue annual reports while paying lower civil penalties.

Updated FAQs on the ACA premium tax credit. On December 23, the IRS updated FAQs in Fact Sheet 2025-10 regarding changes made under the OBBB related to ACA premium tax credits. For example, the OBBB removed the limitation on repayment of excess advanced payment of the premium tax credit for tax years beginning in 2026. Also, the FAQs have been updated to delete FAQs related to provisions that no longer apply.