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Compliance Directions

The Year Ahead: Planning for 2026

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The major focus of 2025 was prescription drugs – whether it was reining in costs, the announcement of direct-to-consumer programs, or upcoming transparency requirements. Throw in Trump Accounts, expanded health savings accounts (HSAs), revamped electronic disclosure rules, HIPAA and MHPAEA, and you have the makings of an exciting year ahead in health and welfare. Below we look back at the last minute changes introduced in 2025, and what we can expect in 2026.

What Happened at the End of 2025

Trump Accounts

In July 2025, the One Big Beautiful Bill Act (OBBBA) was enacted that included a new form of an individual retirement account (IRA) for children under 18, called Section 530A Accounts or Trump Accounts. In early December, initial guidance was issued in Notice 2025-68 on establishing and contributing to this new savings and investment vehicle. During a pilot program, the federal government will contribute up to $1,000 per account. Under the initial guidance, there is a maximum annual contribution of $5,000 (indexed after 2027) not counting charitable or pilot program contributions. Employers will be able to contribute up to $2,500 per employee. Further, employers may utilize their cafeteria plan to permit pretax employee contributions toward the account, which will be subject to nondiscrimination testing, potentially mimicking the rules for the dependent care assistance programs (DCAPs). For more information, please see *Initial Trump Account Guidance Released – More to Follow* in this issue of Directions.

Expansion of HSAs

The OBBBA also increased the ability to contribute to health savings accounts (HSAs) by permitting free telehealth services prior to meeting the annual high deductible health plan statutory deductible, retaining eligibility to contribute to an HSA when participating in direct primary care arrangements, and allowing HSA contributions when an individual is enrolled in a bronze or catastrophic plan. On December 9, the IRS issued guidance on those provisions through Notice 2026-05. To find out more about the newest HSA rules, please see *HSA Access Expands as 2026 Dawns* in this issue of Directions.

Reduced Hepatitis B Vaccination Recommendations

The Advisory Committee on Immunization Practices (ACIP) makes vaccine recommendations that non-grandfathered group health plans are required to cover,

without cost sharing, as part of their preventive care coverage. ACIP voted in December to reduce the Hepatis B vaccination schedule for newborns. Once the reduced recommendation is officially adopted, non-grandfathered group health plans can reduce that coverage in the first plan year effective one year after the recommendation (i.e., if adopted in December 2025, a calendar year non-grandfathered plan could adopt the reduced schedule for the 2027 plan year). But be aware that groups of east and west coast states have begun to adopt their own preventive care mandates, which only fully insured plans issued or renewed in those states or plans sponsored by public entities in those states are required to follow. See *Shifting Federal Vaccine Guidelines Spark State Reactions and New Mandates*, from our November 18, 2025 Directions issue, for more information.

What's Expected in 2026

Pharmacy Benefit Manager Transparency

Both the Office of Management and Budget (OMB) and the Spring DOL Regulatory Agenda have teased an upcoming requirement for pharmacy benefit managers (PBMs) to disclose fees and rebates to ERISA health plan fiduciaries. This disclosure will likely provide more transparency surrounding PBM compensation for easier analysis of services and corresponding fees. Such a disclosure will also require ERISA fiduciaries to analyze this data when making decisions to retain the same PBM or formulary or change to a new PBM with lower fees and similar services. Gallagher will inform employers of the regulatory release when it occurs and discuss next steps for fiduciaries. See our Toolkit: ERISA Fiduciary Governance for Health and Welfare Plans for more information about ERISA fiduciary obligations and updated information on the PBM excessive fee litigation.

Direct-to-Consumer Rx Programs

The 2025 new trend extending into 2026 is making prescription drugs available directly to consumers at lower costs, without the involvement of the group health plan or prescription drug benefit. GLP-1 prescriptions were a major driver of these programs, as some GLP-1 manufacturers made their brand name GLP-1 available at a 30% discount to the typical market cost. In furtherance of this trend, PhRMA has agreed to set up its own website, as has the federal government. Neither site (americasmedicine.com and TrumpRx) will provide direct access to drugs to consumers, but each will provide navigation services to manufacturers' sites to obtain reduced-cost prescription drugs. Both sites are expected to be active in early 2026, though both are already live. The TrumpRx site will be available for public health enrollees (Medicare and Medicaid), while PhRMA's website will be available to the general public. To take advantage of

direct-to-consumer programs, plan sponsors will need to consider carving out coverage of the prescription drugs available on those sites and then integrate the direct-to-consumer prescription drug benefit through a health reimbursement arrangement (HRA) or other medical care benefit. Standalone programs (benefits for which eligibility is not limited to medical plan enrollees) are not possible unless designed as an excepted benefit HRA (EBHRA), which is limited in its annual benefit, with maximum contributions limited to $2,200 in 2026. Watch for our article later this month on how employers can take advantage of direct-to-consumer programs in a compliant fashion.

New HIPAA Security Rules

Early in 2025, HHS issued newly proposed HIPAA Security Rules, which would require covered entity (i.e., health plans, providers, and healthcare clearinghouses) to take additional steps to protect the security and integrity of protected health information (PHI) through administrative, physical, and technical safeguards. Under the current HIPAA Security Rules, those safeguards are either required, in which the covered entity must comply, or addressable, which permits a review of the reasonableness and appropriateness of addressable implementation standards to determine if and how to implement that standard. If the proposed HIPAA Security Rules are finalized as proposed, all of the safeguard implementation standards will become required. For example, encryption and decryption are currently addressable technical standards for PHI at rest (i.e., in storage), but if finalized as written, the new rules would require all plans to implement encryption for PHI at rest. Stay tuned for news about the final rules once issued. In the meanwhile, see our January 2025 Directions article on the proposed regulations, *Proposed Changes to HIPAA Security Rule to Better Protect PHI*.

New Electronic Disclosure Rules for Health Plans

The Department of Labor's (DOL) electronic disclosure rules that apply to health and welfare plans require a plan sponsor to divide its population into those who have access to the employer's electronic system and those who do not. For those with access, most required benefit disclosures can be provided electronically with proper notice and administrative practices. For those without access, consent must be obtained in a manner showing access to the information. The DOL rules often apply to non-ERISA employers as well, for example, the Women's Health and Cancer Rights Act notice can be provided by private, public, and church employers electronically when following the DOL electronic safe harbor rules. The OMB website and their spring agenda indicate that they will newly propose electronic disclosure rules for health and welfare plans. We expect the new guidance to mimic the DOL rules that apply to retirement plans disclosures, which include the ability to post certain notices on the internet.

Mental Health Parity

The Mental Health Parity and Addiction Equity Act (MHPAEA) final rules were issued in 2024 and were to become effective at the beginning of 2025 plan years. Just after 2025 began, the ERISA Industry Committee (ERIC) sued arguing that the rules were unlawful and exceeded HHS' authority. In May 2025, at the request of the federal government, the District Court of the District of Columbia granted a pause in litigation. Simultaneously, the Departments of Labor, the Treasury, and Health and Human Services (the Departments) issued a notice of non-enforcement on the 2024 rules that differ from the 2013 MHPAEA regulations during the litigation plus an additional 18 months. The Departments announced that they may rescind or reissue the regulations. Until then, plan sponsors subject to MHPAEA should continue to comply with the parity requirements, including the non-quantitative treatment limitation (NQTL) comparative analysis. See Gallagher's June 2025 Directions article, *Departments Pause Enforcement of 2024 Mental Health Parity Rules* for more information.

Transparency

This year should bring additional transparency rules. Efforts to increase transparency in the healthcare market include the prescription drug data collection (RxDC) reports, gag clause prohibition compliance attestations, ID card cost sharing information, up-to-date provider directories, a transition period for continuing care patients whose provider loses network status, and more. In addition to those requirements, plans are required to post, and update monthly, machine-readable files for in-network negotiated rules, out-of-network allowed amounts, and prescription drug data.

Currently, plan sponsors are permitted to comply with the available guidance in good faith, and HHS has never issued those updated technical guidelines for the prescription drug files. Plan sponsors are also waiting for the advanced explanations of benefit (AEOB) regulations that would require a plan to provide an AEOB upon the receipt of a provider's good faith estimate of the cost of care.

With transparency a goal of this presidential administration, we received some guidance in late December on the machine readable file requirement and self-service tool and expect more guidance on these issues in 2026. Watch out for our article in next Directions about the newest transparency guidance.

Surprise Billing Adjustments

The No Surprises Act (NSA) prohibits the practice of balance billing consumers for out-of-network emergency care, care provided at in-network facilities by out-of-network providers, and air ambulance services. Group health plans are required to engage in negotiation and arbitration for these claims in order to settle the plan's payment to the

provider. The NSA has been subject to ongoing litigation initiated by out-of-network providers, primarily pertaining to the qualifying payment amount (QPA) that plans may use in negotiation and arbitration to comply with the NSA. QPAs are the plan's median contracted rates for the same or similar service when provided by same or similar providers in the same geographic region, adjusted for inflation.

The last piece of guidance received from the Departments prolonged a non-enforcement policy on a plan's formulation of its QPAs, extending it to February 1, 2026, while government continues to defend the regulations in court. The Departments note in the guidance that they anticipate the non-enforcement policy will not extend past August 1, 2026 and they will provide additional guidance at that time, if needed. Because the Fifth Circuit's initial decision would have required plan's to calculate their own QPAs, rather than using their insurer or TPA's book of business, if the Fifth Circuit again vacates this rule permitting, plans will need additional time to indicate their own QPAs based on their currently sponsored plans.

Employer Action Steps

Plan sponsors can prepare for 2026 by:

- Staying informed on the new HSA rules and Trump Account guidance.
- Keep up with ACA and state preventive care changes that impact the next plan year.
- Prepare for what's next in prescription drug benefits, including direct-to-consumer programs and more PBM disclosures.
- Discuss MHPAEA compliance with your medical plan carriers and continue to prepare NQTL comparative analyses with their cooperation.
- Engage with upcoming changes to surprise billing, transparency, and electronic disclosures.

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.