Compliance Monthly Update: September 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.

HIPAA Security Risk Assessment (SRA) Tool updated. On September 9, HHS announced an updated version of the interactive HIPAA Security Risk Assessment (SRA) Tool. The HIPAA Security Rule requires covered entities and business associates to conduct a risk assessment that helps ensure it is compliant with HIPAA's administrative, physical, and technical safeguards. A risk assessment also helps reveal areas where protected health information (PHI) could be at risk. The SRA Tool is designed to help conduct the risk assessment as required by HIPAA and walks users through multiple choice questions. The answers to those questions show whether corrective action is necessary to comply with the HIPAA Security Rule.

Eleventh Circuit upholds health plan's exclusion of "gender-affirming" surgery. On September 9, the U.S. Court of Appeals for the Eleventh Circuit (sitting en banc) held in *Lange v. Houston County Georgia* that the exclusion of health plan coverage for "gender-affirming" surgery is not sex discrimination under Title VII.

- The case was brought by a transgender employee who had been denied coverage for surgery recommended by her physician to treat gender dysphoria.
- The court reasoned that the exclusion did not violate Title VII because the plan denied coverage of a "sex change operation" for anyone, regardless of biological sex. Further, the court held that the exclusion did not discriminate on the basis of transgender status because it was a classification based on medical use. The court explained that the procedures that make up a sex change would be covered for other purposes, such as for cancer or reconstructive surgery following a car accident, without regard to whether the employee who needed those procedures was transgender. The court concluded the exclusion is not facially discriminatory based on a protected status.
- In reaching this conclusion, the Eleventh Circuit relied heavily on the Supreme Court's recent *Skrmetti* decision where the Supreme Court held a Tennessee law did not discriminate based on sex or transgender status when it disallowed certain hormone therapy treatments for gender dysphoria in minors but permitted the same treatments for other medical conditions. While *Skrmetti* involved the Equal Protection Clause of the Fourteenth Amendment and not Title VII, the Eleventh Circuit nonetheless found that the Supreme Court's *Skrmetti* ruling controlled. That is, the Eleventh Circuit interpreted the *Skrmetti* ruling to reach both the Equal Protection Clause of the Fourteenth Amendment and Title VII.

This case again shows the unclear legal landscape on plan coverage and exclusions of "gender-affirming" care because the courts are divided on the application of Title VII and other nondiscrimination laws like ACA Section 1557. At least one other district court addressing a similar health plan exclusion for "gender-affirming" care (post-*Skrmetti*) reached a different conclusion from the Eleventh Circuit, however that case was in the context of ACA Section 1557 and not Title VII. Plan sponsors should be aware that plan exclusions of coverage for "gender-affirming" care continue to be frequent targets of litigation.

Court finds ERISA does not preempt Arkansas PBM reporting requirements under Rule 128. A district court found that Arkansas Rule 128 requiring ERISA plans to report certain prescription drug compensation related information regarding their PBMs is not preempted by ERISA.

- As background, Rule 128 requires plans and payors to report compensation for pharmacy services with the goal of maintaining adequate PBM networks in the state. If the state insurance commissioner determines that compensation is inadequate, payment of an additional cost (a "dispensing fee") may be required.
- In this case, a plan argued that the rule was preempted because it imposed requirements directly on ERISA plans that interfered with plan design and restricted the plan's ability to structure prescription drug benefits, impacting it's nationally uniform plan administration.
- The court explained that ERISA preempts state laws that either reference (e.g., apply exclusively or immediately to) or are impermissibly connected to an ERISA plan. A state law impermissibly connected to an ERISA plan is one that governs a central matter of plan administration or interferes with nationally uniform plan administration. Determining that Rule 128 did not restrict its application to ERISA plans, the court shifted its focus to whether it was impermissibly connected to ERISA plans. It first concluded that the rule's reporting requirement was merely incidental to its purpose of procuring the information necessary to ensure fair and reasonable reimbursement of pharmacy services. The court also rejected the argument that the dispensing fee dictates ERISA plan design, reasoning that the fee "may" apply (i.e., only if imposed by the insurance commissioner). The court also noted that plans were not prohibited from seeking to offset the fee by allocating its costs to Arkansas plan participants (within the scope of plan rules) across copay, coinsurance, or deductible requirements. Comparing the rule to a similar Arkansas law at issue in the Supreme Court's *Rutledge* decision, the court noted that it is a cost regulation law that does not impermissibly interfere with uniform administration of ERISA plans—that is, it relates to the cost regulation of all health benefit plans, not just ERISA plans, and is not preempted.
- This is yet another case in the continuing trend of ERISA preemption challenges to state laws regulating PBMs. And while this decision aligns closely with *Rutledge*, it is important to note that the outcome of these cases depends on specifics. And state laws directly affecting ERISA plan design are more likely to be held preempted.

Updated preventive services coverage requirements. 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. Preventive services and recommended vaccine schedules are added or updated regularly throughout the year. For group health plans subject to the mandate, the recommendation must be covered beginning with the first plan year that begins on or after one year following publication of the new or updated recommendation. However, plans may begin implementing the change sooner, particularly in situations where a new plan year begins shortly after the recommendation is published. Here are some updates on these preventive services coverage requirements:

- For plans beginning on or after January 1, 2026, several updated recommendations are set go into effect, such as breast cancer screening for women aged 40 at average risk (HRSA), intimate partner and domestic violence screening at counseling (USPSTF), and osteoporosis to prevent fractures screening (USPSTF).

- Related to COVID vaccines, also effective January 1, 2026, plans must begin covering (a) individuals older than 65 and individuals aged six months to 64 years with moderate or severe immunocompromise receive a second COVID-19 vaccine dose 6 months after their last dose and (b) individuals aged six months or older with moderate or severe immunocompromise may receive additional doses based on shared clinical decision-making.
- On September 18 and 19, 2025, ACIP revised its recommendations on the COVID vaccine and the combined measles, mumps, rubella, varicella ("MMRV") vaccine (note that varicella is commonly referred to as chickenpox). These recommendations are not finalized until adopted by the acting CDC Director.
    - ACIP voted to change the COVID vaccine recommendation so that adults 65+ get a COVID vaccine based on shared clinical decision making. And for individuals aged 6 months to 64 years old, a vaccine is recommended based on shared clinical decision making, with an added emphasis on providing risk-benefit information. ACIP also voted that individuals that decide to get the vaccine can do so without a prescription.
    - ACIP voted that instead of recommending the MMRV vaccine which is a combined shot covering measles, mumps, rubella and varicella (chickenpox) for children under four, they are now recommending MMR by itself, and a varicella/chickenpox shot by itself. ACIP voted to continue covering the combined MMRV vaccine at 100% for children ages four and older if parents prefer.
    - Remember that a finalized recommendation must be covered beginning with the first plan year that begins on or after one year following publication of the new or updated recommendation.