# Compliance Monthly Update: October 2024

*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.*

**HHS issues 2026 adjusted ACA annual limitations on cost-sharing.** On October 8, HHS issued a memo announcing the maximum annual limitations on cost-sharing for the 2026 benefit year for non-grandfathered group health plans under the ACA. The maximum annual limit on cost-sharing for 2026 will increase to $10,150 for self-only coverage and $20,300 for other than self-only coverage (the 2025 limits are $9,200 and $18,400, respectively). In general, cost-sharing includes deductibles, coinsurance, copayments, and any other required expenditure that is a qualified medical expense with respect to essential health benefits covered under the plan.

**Recent trend in litigation targeting wellness program tobacco surcharges.** There has been a series of lawsuits this past year (brought both by the DOL and by plan participants) alleging that plans with premium surcharges related to tobacco use violate the HIPAA wellness rules. These lawsuits have specifically targeted health-contingent, outcome-based wellness programs. For example, in one case, the DOL alleged the plan (a) did not provide a reasonable alternative standard by which participants who used tobacco could obtain the premium discount and (b) failed to disclose to participants the availability of a reasonable alternative standard to qualify for the premium discount. In that case, the court entered a consent judgment that required the employer to reimburse its plan participants the amounts that they paid for the surcharges and assessed a civil monetary penalty against the employer. Most of these cases are in the very early stages. It remains to be seen how these allegations will play out in litigation and whether the plaintiffs' allegations regarding these tobacco surcharge designs are correct. Regardless, to help avoid potential litigation, plan sponsors should review their wellness programs (and program materials) for compliance under the HIPAA, ADA, and GINA wellness rules (as applicable).

**Final 2024 ACA reporting forms and instructions released.** The IRS released final 2024 forms and instructions for ACA reporting under IRS Code Sections 6055 and 6056. As a reminder, Forms 1094-B and 1095-B are filed by minimum essential coverage providers (insurers and small employers with a level or self-insured plan) to report coverage information in accordance with Section 6055. Forms 1094-C and 1095-C are filed by applicable large employers (ALEs) to provide information that the IRS needs to administer employer shared responsibility penalties and eligibility for premium tax credits, as required under Section 6056. Forms are required to be filed with the IRS by February 28, 2025, or March 31, 2025 (if filing electronically). The deadline to furnish forms to individuals is March 3, 2025. As a reminder, the electronic filing threshold was decreased (starting in 2024) so that employers filing 10 or more returns must file electronically with the IRS.

- Form 1094-B
- Form 1095-B
- Form 1094-C
- Form 1095-C
- B-Series Form Instructions
- C-Series Form Instructions

**Regulatory agencies issue reminder about December 31 gag clause attestation reporting deadline.** On October 10, the DOL, HHS, and IRS issued a joint reminder to group health plans and health insurance issuers that they must annually attest to compliance with the Gag Clause Prohibition and submit Gag Clause Prohibition Compliance Attestations (GCPCAs) by December 31.

- As a reminder, group health plans and insurers are prohibited from entering into agreements with providers, provider networks, or entities offering provider network access that contain any contractual term directly or indirectly restricting the plan or insurer from disclosing specified data and information, such as cost or quality of care data (a "gag clause"). Plans and insurers are required to annually attest to their compliance by submitting the GCPCA by December 31 each year.
- After the initial attestation (that occurred in 2023), each subsequent attestation covers the period from the date of the prior attestation through the date of the subsequent attestation. For example, if a plan submitted its first GCPCA on November 30, 2023, and submits its second GCPCA on November 15, 2024, the second GCPCA's "attestation period" would be December 1, 2023, to November 15, 2024, and the "attestation year" would be 2024.
- For fully-insured plans, if the insurance carrier submits the attestation on behalf of the group health plan, the requirement is considered met. Self-insured plans can enter into a written agreement to have their TPA submit the attestation on their behalf. However, a self-insured plan sponsor remains liable for any compliance failure.
- See our GBS Gag Clause Removal & Attestations webpage for more information and guidance.
- See also the CMS GCPCA website for FAQs, submission instructions, a user manual, and the webform used for GCPCA submissions.

**IRS guidance regarding preventive care benefits for HDHP purposes and that amounts paid for condoms can be a medical expense.** On October 17, the IRS issued two notices expanding the list of items and services that qualify as preventive care under HSA-compatible HDHPs and as medical care expenses under group health plans, including health FSAs, HRAs and HSAs. Under the guidance, condoms are to be considered medical care expenses and can be covered/reimbursed by group health plans, including FSAs, HRAs and HSAs. The guidance also clarifies that HSA-eligible HDHPs can permit pre-deductible coverage of certain over-the-counter (OTC) contraceptives, continuous glucose monitors, insulin and breast cancer screening services.

- IRS Notice 2024-71 provides a safe harbor under Code section 213(d) for amounts paid for condoms. Because amounts paid for condoms are treated as expenses for medical care under Code section 213(d), the amounts are eligible to be paid/reimbursed tax-free under a health FSA, HRA, major medical plan, or HSA. There is no effective date in the notice, so presumably the safe harbor is effective beginning on October 17, 2024, the date of publication of the Notice.
- IRS Notice 2024-75 clarifies the list of benefits that an HDHP can provide on a pre-deductible basis as preventive care to include OTC oral contraceptives (including emergency contraceptives) and male condoms. This notice also clarifies that (1) all types of breast cancer screening for individuals who have not been diagnosed with breast cancer are treated as preventive care, (2) continuous glucose monitors for individuals diagnosed with diabetes are generally treated as preventive care, and (3) the new safe harbor for absence of a deductible for certain insulin products applies without regard to whether the insulin product is prescribed to treat an individual diagnosed with diabetes or prescribed for the purpose of preventing the exacerbation of diabetes or the development of a secondary condition.

**ACA preventive care proposed rule would broaden access to over-the-counter (OTC) contraceptives.** On October 21, the DOL, HHS, and IRS released proposed regulations titled "Enhancing Coverage of Preventive Services Under the Affordable Care Act" (and an associated news release and fact sheet). These proposed rules would expand access to coverage of recommended preventive services without cost sharing, with a particular focus on reducing barriers to coverage of contraceptive services, including over-the-counter (OTC) contraceptives such as condoms, spermicides, and emergency contraception. According to the news release, the proposed regulations are intended to expand access to contraceptives, particularly with the Supreme Court *Dobbs* decision (overturning *Roe v. Wade*) and to address ongoing reports of "barriers to contraceptive coverage."

- As a reminder, the ACA requires non-grandfathered group health plans and insurers to cover recommended preventive health services, including certain contraceptives, without cost-sharing. Plans and insurers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage, to the extent not specified in the applicable recommendation or guideline.
- The proposed regulations would clarify that plans and insurers using reasonable medical management techniques for any preventive service must provide an "easily accessible, transparent, and sufficiently expedient" exceptions process that allows an individual to receive coverage without cost-sharing based on the frequency, method, treatment, or setting that is deemed medically necessary by the individual's attending provider, even if the service is not generally covered by the plan.
- Currently the requirement to cover OTC contraception only applies if the individual has a prescription. Under the proposed regulations, plans and insurers would be required to cover recommended OTC contraceptives that can be lawfully obtained without a prescription and for which the applicable preventive care recommendation or guideline does not require a prescription. That is, plans would have to cover every FDA-approved contraceptive drug or drug-led combination product without cost sharing, unless the plan or insurer covers a therapeutic equivalent without cost sharing. If finalized, the proposed rules would be the first time that male contraceptives will be covered under the ACA preventive care requirements.
- The proposed regulations would also require plans and insurers to include a disclosure with the results of a search about contraceptives in a transparency in coverage (TiC) self-service tool, explaining that OTC contraceptive items are covered without a prescription and without cost-sharing, and including a phone number and link for more information about contraception coverage under the plan or policy.
- These proposed regulations would not apply to plans exempted from contraception coverage based on a religious objection. In July 2020, the US Supreme Court ruled that private employers with religious or moral objections can be exempt from the contraceptive mandate.
- The regulatory agencies decided to take an incremental approach to the preventive service OTC rules, beginning first with recommended contraceptive items, and seeking comments on whether the proposals should be extended to other (or all) recommended preventive services.
- Note that seven states—California, Colorado, Maryland, New Jersey, New Mexico, New York, and Washington—already have laws requiring state-regulated fully insured plans to cover certain OTC contraceptives without a prescription and without cost sharing.

**FAQs (Part 68) provide guidance on preventive care and the Women's Health and Cancer Rights Act (WHCRA).** On October 21, the DOL, HHS, and IRS issued FAQs Part 68 addressing coverage of pre-exposure prophylaxis (PrEP) to reduce the risk of HIV infection, issues relating to medical coding for

preventive services, and required coverage under the Women's Health and Cancer Rights Act (WHCRA). As a reminder, the ACA requires non-grandfathered group health plans and insurers to cover certain preventive services without cost-sharing, and WHCRA sets forth coverage requirements for reconstructive surgery following a mastectomy.

- The required preventive services come from recommendations issued by four entities: the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration's (HRSA's) Bright Futures Project, and the HRSA-sponsored Women's Preventive Services Initiative (WPSI). If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan may use reasonable medical management techniques to determine coverage limitations. To the extent not specified in a recommendation or guideline, a plan may rely on the relevant clinical evidence and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service. Additionally, plans must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.
- PrEP coverage. Previously, the USPSTF updated its recommendations to include additional approved formulations of PrEP and clarified the group of individuals covered by its PrEP recommendations. Coverage of PrEP, including applicable PrEP formulations and specified baseline and monitoring services, must be provided in accordance with these expanded recommendations as of the first plan or policy year beginning on or after August 31, 2024. These FAQs advise that plans and insurers must cover the approved formulations without cost-sharing and are not permitted to apply medical management techniques to direct the use of one formulation over another.
- Coding for recommended preventive items and services. According to the regulatory agencies, individuals have reported difficulty obtaining coverage without cost-sharing for recommended preventive items and services due to coding issues. The FAQs explain that plans and insurers must cover items or services coded as preventive without cost-sharing unless the plan or insurer has individualized information to establish that the item or service is not preventive. If the plan or insurer does have such individualized information, it is not required to cover the item without cost-sharing. If the plan or insurer has information that merely suggests, but does not establish, that the item or service is not preventive, the plan or insurer should communicate with the individual to obtain any additional information needed. The FAQs note that ERISA and ACA rules for claims and appeals require such communication to facilitate full and fair review and provide a reasonable claims (and appeals) procedure. The agencies indicate that plans and insurers should review their coding guidelines, claims processing systems, and other protocols to ensure proper treatment of preventive services. Examples are provided in the FAQs to illustrate the coding guidance.
- WHCRA guidance on coverage of breast reconstruction. Under WHCRA, if a group health plan covers mastectomies—the plan must provide (in a manner determined in consultation with the attending physician and the patient) coverage for all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy, including lymphedema. In the FAQs, the regulatory agencies confirm that this includes coverage for chest wall reconstruction with aesthetic flat closure, if elected by the patient in consultation with the attending physician in connection with a mastectomy.

**2025 cost of living adjustments (COLAs) released for health FSAs, etc.** On October 22, IRS Rev. Proc. 2024-40 was released (along with a news release) with annual inflation adjustments for numerous tax provisions for tax year 2025. This includes limit adjustments relating to health FSAs, DCAPs, qualified transportation fringe benefits, adoption assistance, QSEHRAs, and premium tax credits.

- Health FSAs. For plan years starting in 2025, the dollar limit on employee salary reduction contributions to health FSAs will be $3,300 (up from $3,200). If the cafeteria plan permits health FSA carryovers, the maximum amount that can be carried over to the 2026 plan year is $660 (up from $640). Note that if these IRS FSA limits are announced after open enrollment for the next year has ended, employers could include language in the annual enrollment materials for the health FSA allowing employees to elect the annual limit for the current plan year "as adjusted for any increase announced by the IRS for the next plan year before the next plan year begins." This approach would allow an automatic adjustment for employees choosing this option.
- DCAPs. The maximum amount of DCAP benefits that can be excluded from income has not been adjusted (it is a non-indexed limit). The amount will remain at $5,000/$2,500 (depending on marital status and tax filing status) for 2025 and future years unless extended or otherwise changed by Congress.
- Qualified transportation fringe benefits. For 2025, the monthly limit on the amount that may be excluded from an employee's income for qualified parking benefits will be $325 (up from $315). The combined monthly limit for transit passes and vanpooling expenses for 2025 will be $325 (up from $315).
- QSEHRAs. For 2025, the maximum amount of payments and reimbursements under a QSEHRA will be $6,350 for self-only coverage and $12,800 for family coverage (up from $6,150 and $12,450, respectively).
- Adoption assistance exclusion and adoption credit. The maximum amount that may be excluded from an employee's gross income under an employer-provided adoption assistance program for the adoption of a child will be $17,280 for 2025 (up from $15,810). In addition, the maximum adoption credit allowed to an individual for the adoption of a child will be $17,280 for 2024 (up from $16,810). Both the exclusion and the credit will begin to be phased out for individuals with modified adjusted gross incomes greater than $259,190 and will be entirely phased out for individuals with modified adjusted gross incomes of $299,190 or more.
- Excess premium tax credit penalty limits. This tax is imposed if a taxpayer's advance premium tax credit payments for health insurance purchased through an Exchange for a year exceed the allowed credit. For taxable years beginning in 2025, the following limitations on the tax for excess advance credit payments will apply:
    - For unmarried individuals (other than surviving spouses and heads of household): $375 for household income less than 200% of the federal poverty line (FPL); $975 for household income at least 200% but less than 300% of FPL; and $1,625 for household income at least 300% but less than 400% of FPL.
    - For all other taxpayers: $750 for household income less than 200% of FPL; $1,950 for household income at least 200% but less than 300% of FPL; and $3,250 for household income at least 300% but less than 400% of FPL.
- Note that the 2025 COLAs for HSAs, HDHPs, and EBHRAs were announced by the IRS on May 9 earlier this year in Rev. Proc. 2024-25 as follows:
    - HSA contribution limits. The 2025 annual HSA contribution limit is $4,300 for individuals with self-only HDHP coverage (up from $4,150 in 2024), and $8,550 for individuals with

family HDHP coverage (up from $8,300 in 2024). The catch-up contribution limit for HSA-eligible individuals 55 or older remains unchanged at $1,000.

- HDHP Minimum Deductibles. The 2025 minimum annual deductible is $1,650 for self-only HDHP coverage (up from $1,600 in 2024) and $3,300 for family HDHP coverage (up from $3,200 in 2024).
- HDHP Out-of-Pocket Maximums. The 2025 limit on out-of-pocket expenses (including items such as deductibles, copayments, and coinsurance, but not premiums) is $8,300 for self-only HDHP coverage (up from $8,050 in 2024), and $16,600 for family HDHP coverage (up from $16,100 in 2024).
- EBHRA Contribution Limit. The maximum amount that may be made newly available for plan years beginning in 2025 is $2,150 (up from $2,100 for plan years beginning in 2024).